ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-2114299687-24-01/F Helsinki, 6 May 2015

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

For strontium chromate, CAS No 7789-06-2 (EC No 232-142-6), 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 proposal submitted as part of the registration dossier in accordance with Articles 10(a)(ix) and 12(1)(e) thereof for strontium chromate, CAS No 7789-06-2 (EC No 232-142-6), by [redacted] (Registrant).

- Testing proposal: Long-term toxicity 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).

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 registration at a later stage.

On 25 November 2010, pursuant to Article 40(1) of the REACH Regulation, ECHA initiated the examination of the testing proposal 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 31 May 2011 until 15 July 2011. ECHA did not receive information from third parties.

On 15 November 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 17 December 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 for amendment of the draft decision within 30 days of the receipt of the notification.

As no proposal for amendment was submitted, 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 method and the read-across substance strontium nitrate (CAS No. 10042-76-9):

Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1.; 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 **13 May 2016** an update of the registration dossier containing the information required by this decision.

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.

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

The Registrant provided the following justification for conducting the proposed test:

"No reliable chronic data point for strontium 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."

For metals such as the strontium chromate it is generally assumed that toxicity is controlled by the dissolved metal ion. The chemical safety assessment (CSA) provided by the Registrant is based on elemental strontium and chromate concentrations and read-across to strontium and chromate substances.

The substance being registered for a quantity above 1000 tonnes or more per year, the dossier must comply with that standard information requirement on long-term toxicity testing on fish, Annex IX, 9.1.6 of the REACH Regulation. However, ECHA notes that data on that endpoint is not available in the registration dossier.

In order to consider the contribution of strontium ion to the overall substance ecotoxicity, and more specifically in order to cover the endpoint long-term toxicity testing on fish, Annex

IX, 9.1.6 of the REACH Regulation, 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 chromate (CAS No. 7789-06-2).

ECHA considers that the justification given by the Registrant for conducting the study with the soluble salt of strontium has addressed the requirements of Annex XI, section 1.5, subsections 1 and 2 and the ECHA Guidance for hazard identification and the application of the criteria of the CLP Criteria to metals (2012). Specifically, adequate and reliable documentation of the applied read-across approach has been provided.

ECHA understands that the Registrant's proposal to read-across from the source substance strontium nitrate to the target substance strontium chromate is based on the following rationale. The registrant apparently wants to assess the hazard of strontium chromate as it would have been investigated by means of the test in question, on the basis of:

- Available information on the effects of chromate in comparable test systems and
- The outcome of the proposed test.

The Registrant thereby apparently assumes that any toxic effect observed in the proposed test is only caused by strontium ions. ECHA finds this assumption acceptable. Moreover, the Registrant apparently assumes that strontium ions and chromate ions would not influence each others' toxicity and that their effects are additive. ECHA cannot judge whether the latter assumption is valid at this moment, without having the results of the proposed test available. ECHA reserves the right to come back at the outcome of the proposed read-across and potentially challenge the assumptions of the additive effects once the results of the proposed test have become available.

ECHA notes that the current conclusion reached on the read-across approach is valid only in relation to the substance to be tested as provided by the Registrant in the dossier.

In addition, in order to consider the contribution of chromate ion to the overall substance ecotoxicity, the Registrant proposes to read-across from a GLP OECD 210 study with chromium hydroxide sulphate (CAS No. 1308-38-9). The registered substance contains Chromium VI, whilst the analogue consists of Chromium III. The Registrant claims that in the environment Chromium VI will be reduced to Chromium III. However, the Registrant does not discuss the kinetics (half-life) of this reduction, and consequently the proposal to use Chromium III instead of Chromium VI in this read-across is not justified.

For chromates there are several comprehensive EU risk assessments and the Risk Assessments Reports (RARs) are available on European chemical Substances Information System (ESIS). The RARs provide several data points for aquatic toxicity for both Chromium VI and Chromium III, with the majority information on potassium dichromate in which the oxidation state is Chromium VI as in the registered substance. The number of data sources covering aquatic organisms including fish is sufficiently high to allow the derivation of a PNEC for Chromium VI, consequently no further testing on fish is needed and a read-across can be performed.

ECHA emphasises that it is the Registrant's responsibility to amend and substantiate the read-across justification for chromium VI according to Annex XI, section 1.5 and to use all relevant available data for that purpose in relation to both constituents of the substance subject to the present decision.

Following the update of the dossier based on the present decision, ECHA will decide whether the documentation provided is sufficient to satisfactorily fulfil 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.

Therefore, pursuant to Article 40(3)(a)of the REACH Regulation, the Registrant is required to carry out the proposed test according to OECD Guideline 210 (fish, early-life stage toxicity test) on the read-across substance strontium nitrate (CAS No. 10042-76-9).

Finally, ECHA notes that it is not justified to use Chromium III instead of Chromium VI in this read-across as there seems to be sufficient and publicly available data sources to allow the derivation of a PNEC for Chromium VI. Therefore, the Registrant is requested to derive PNEC for Chromium VI from the available information, and to use this PNEC in the CSA of the registered substance

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.

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 study meets 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 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 suitable in regard of the substance compositions that are given by the joint registrants. It is the responsibility of all joint registrants of the same substance to agree to the test 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 study 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 study must be suitable to assess these grades.

Finally there must be adequate information on substance identity for the sample tested and the grade registered to enable the relevance of the study to be assessed.

V. 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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