Decision number: TPE-D-2114316120-72-01/F Helsinki, 17 February 2016

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

For tellurium dioxide, EC No 231-193-1 (CAS No 7446-07-3), 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 in accordance with Articles 10(a)(ix) and 12(1)(d) thereof for tellurium dioxide, EC No 231-193-1 (CAS No 7446-07-3), submitted by [redacted] (Registrant).

- Testing proposal: 90-day oral toxicity study (OECD 408).

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 100 to 1000 tonnes per year.

This decision does not take into account any updates after 2 October 2015, i.e. 30 calendar days after the end of the commenting period.

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.

ECHA received the registration dossier containing the above-mentioned testing proposal for further examination pursuant to Article 40(1) on 22 January 2015.

ECHA held a third party consultation for the testing proposal from 16 March 2015 until 30 April 2015. ECHA did not receive information from third parties.

On 27 July 2015 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 02 September 2015 ECHA received comments from the Registrant agreeing to ECHA's draft decision and further specifying the phase of the substance to be tested.

On 29 October 2015 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.

Subsequently, a proposal for amendment to the draft decision was submitted.

On 04 December 2015 ECHA notified the Registrant of the proposal for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposal for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposal for amendment received and amended the draft decision.

On 14 December 2015 ECHA referred the draft decision to the Member State Committee.

By 4 January 2016, in accordance to Article 51(5), the Registrant provided comments on the proposal for amendment. The Member State Committee took the comments on the proposal for amendment of the Registrant into account.

A unanimous agreement of the Member State Committee on the draft decision was reached on 18 January 2016 in a written procedure launched on 8 January 2016.

ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Testing required

A. Tests required pursuant to Article 40(3)

The Registrant shall carry out the following modified test pursuant to Article 40(3)(b) and 13(4) of the REACH Regulation using the indicated test method and the registered substance (pure grade, in its tetragonal phase) subject to the present decision:

> Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method: EU B.26/OECD 408) in rats

ECHA notes that the registration covers crude grades and a pure grade. The pure grade has to be used as test substance as specified in section III. Furthermore, ECHA notes that more than one phase is possible (tetragonal, orthorombic, and amorphous).

The REACH Regulation requires the Registrant to identify the sub-chronic toxicity potential of the substance irrespective of its phase or form, as they may, in principle, entail different hazards. In theory, in order to fulfil that requirement, experimental information is needed on each specific form and phase covered by the dossier of the registered substance. However, the Registrant may take the responsibility to select one or more representative phase(s) or form(s) of the substance in order to address the hazards of the different forms or phases.

If the Registrant decides not to perform the study with each form and phase concerned by the dossier, he shall demonstrate, in accordance with the specific requirements outlined in Section IV below, that the material used for testing is representative for every form and phase covered by the dossier, in order to establish the relevant hazards of each of these forms and phases. The information ultimately submitted by the Registrant shall thus demonstrate that the testing of such material does not result in an underestimation of the hazards of any phases or forms covered by the dossier of the registered substance. The Registrant should provide adequate information on the characteristics of the tested substance.

In case where more than one form or phase of the substance is tested, the Registrant shall submit a new testing proposal for each additional experimental study planned.

Note for consideration by the Registrant:

The Registrant may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring to and conforming with the appropriate rules in the respective Annex, and an adequate and reliable documentation.

Failure to comply with the request in this decision, or to fulfil otherwise the information requirement with a valid and documented adaptation, will result in a notification to the Enforcement Authorities of the Member States.

B. Deadline for submitting the required information

Pursuant to Articles 40(4) and 22(2) of the REACH Regulation, the Registrant shall submit to ECHA by **24 August 2017** an update of the registration dossier containing the information required by this decision, including, where relevant, an update of the Chemical Safety Report.

III. Statement of reasons

A. Tests required pursuant to Article 40(3)

Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.)

a) Examination of the testing proposal

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

A sub-chronic toxicity study (90 day) is a standard information requirement as laid down in Annex IX, Section 8.6.2. 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 has submitted a testing proposal for a sub-chronic toxicity study (90 day) by the oral route.

ECHA agrees that the oral route - which is the preferred one as indicated in ECHA Guidance on information requirements and chemical safety assessment (version 4.1, October 2015) Chapter R.7a, section R.7.5.4.3 - is the most appropriate route of administration. More specifically, even though the substance is reported to occur as a dust with a significant proportion (>[redacted]% on weight basis) of particles of inhalable size (MMAD < 50 µm), the exposure concentrations reported in the chemical safety report for the inhalation route are low (maximum [redacted] mg/m3).

The Registrant did not specify the species to be used for testing. According to the test method EU B.26/OECD 408 the rat is the preferred species. ECHA considers this species as being appropriate and testing should be performed with the rat.

The Registrant did specify that the test is to be conducted with the registered substance. However, he did not specify which of the grades covered in the registration is planned to be used for testing. ECHA notes that the crude grade is classified according to the impurities (e.g. lead, arsenic, selenium) present as STOT Rep Ex., 1 Acute Tox 4, Skin corr 1A, Eye damage 1, Skin sens. 1A, Repr. 1A (H360df), Carc 1A, aquatic acute 1, aquatic chronic 2. The CSR states that the impurities drive the classifications as well as the risk assessement for the crude grade. For the impurities information on repeated dose toxicity is available showing severe toxicity effects which meet the classification criteria for R48 and allow the extrapolation towards the NOAEL-90 days. Therefore ECHA considers the adaptation in Annex IX, 8.6.2. Column 2 (first/second indent) as met and further testing is not needed. For the pure grade a 28-day toxicity oral (gavage) study according to OECD 407 (2013) was conducted in rats. No adaptation for the Annex IX 8.6.2 requirement is proposed by the Registrant. Consequently there is a data gap and it is necessary to provide information for the requirement using the pure grade of the registered substance as test substance.

In his comments the Registrant responded to the uncertainty ECHA has expressed on the phase of the pure substance covered by the registration. It was confirmed that he intends to use the pure substance in its tetragonal (alpha-TeO2) phase for testing, since other forms are not relevant for the market of pure tellurium dioxide. ECHA notes that it needs to be specified also in the registration dossier that only the tetragonal (alpha-TeO2) phase is covered by this registration.

b) Outcome

Therefore, pursuant to Article 40(3)(b) of the REACH Regulation, the Registrant is requested to carry out the proposed/following study with the registered substance (pure grade, in its tetragonal phase) subject to the present decision: Sub-chronic toxicity study (90-day) in rats, oral route (test method: EU B.26/OECD 408).

IV. Adequate identification of the composition of the tested material

The process of examination of testing proposals set out in Article 40 of the REACH Regulation aims at ensuring that the new study 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 examination of the testing proposal. The Registrant must note, however, that this information has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

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 pure grade of the substance as actually manufactured.

Furthermore, there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the study to be assessed.

EUROPEAN CHEMICALS AGENCY

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://www.echa.europa.eu/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

Authorised[1] by Guilhem de Seze, Head of Unit, Evaluation E1

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.