~~Confidential~~

Helsinki, 22 November 2021

Addressees
Registrants of JS_tellurium listed in the last Appendix of this decision

Date of submission of the dossier subject of a decision
09/03/2020

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Tellurium
EC number: 236-813-4
CAS number: 13494-80-9

Decision number: Please refer to the REACH-IT message which delivered this communication (in format TPE-D-XXXXXXXXXX-XX-XX/F)

DECISION ON TESTING PROPOSAL(S)

Based on Article 40 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by ***29 November 2022***.

The requested information must be generated using the Substance unless otherwise specified.

We note that in the dossier there is no reference to nanoparticles in the analytical report, however, it is possible for the Substance to be manufactured or imported in the European Union in nanoforms. The REACH Regulation (as amended by Regulation Commission Regulation (EU) 2018/1881) sets out explicit information requirements for nanoforms of substances. Manufacturers and importers of nanoforms must have fulfilled these specific information requirements by 1st January 2020. As the registration dossier currently submitted on the Substance does not cover any nanoform(s), the information required in the present decision relates only to information required on non-nanoforms.

A. Information required from the Registrants subject to Annex IX of REACH

1. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: EU C.20./OECD TG 211)

2. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: EU C.47./OECD TG 210)

Your originally proposed test using an analogue substance Sodium tellurate (EC No. 233-259-5) is rejected, according to Article 40(3)(d):

> Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method EU C.20./OECD TG 211)

Reasons for the request(s) are explained in the appendix entitled "Reasons to request information required under Annex IX of REACH".

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you, and in accordance with Articles 10(a) and 12(1) of REACH, the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa.

You are only required to share the costs of information that you must submit to fulfil your information requirements.

How to comply with your information requirements

To comply with your information requirements you must submit the information requested by this decision in an updated registration dossier by the deadline indicated above. You must also update the chemical safety report, where relevant, including any changes to classification and labelling, based on the newly generated information.

You must follow the general testing and reporting requirements provided under the Appendix entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes". For references used in this decision, please consult the Appendix entitled "List of references".

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, has to be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under: http://echa.europa.eu/regulations/appeals.

Approved[1] under the authority of Christel Schilliger-Musset, Director of Hazard Assessment

[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.

Appendix A: Reasons to request information required under Annex IX of REACH

This decision is based on the examination of the testing proposals you submitted.

1. Long-term toxicity testing on aquatic invertebrates

Long-term toxicity testing on aquatic invertebrates is an information requirement under Annex IX to REACH (Section 9.1.5.).

1.1. Information provided to fulfil the information requirement

You have submitted a testing proposal for a Daphnia magna reproduction test (test method: EU C.20/OECD TG 211) to be performed with the analogue substance Sodium tellurate (EC No. 233-259-5).

Your registration dossier does not include any information on long-term toxicity on aquatic invertebrates.

ECHA agrees that an appropriate study on long-term toxicity on aquatic invertebrates is needed.

1.2. Grouping of substances and read-across approach

In your testing proposal you proposed testing with an analogue substance. We understand that you seek to adapt this information requirements by applying a read-across approach in accordance with Annex XI, Section 1.5.

Annex XI, Section 1.5. specifies two conditions which must be fulfilled whenever a read-across approach is used. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group.

Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance R.6. and related documents[2,3].

You have provided a read-across justification document in IUCLID Section 6.1.4 and in Section 13.

You propose to predict the properties of the Substance from the structurally similar substance Sodium tellurate (EC No. 233-259-5).

You have provided the following reasoning for the prediction of ecotoxicological properties:

- "[…] *Since the physico-chemical behaviour of elemental Tellurium and Tellurium dioxide is the same with regard to their metabolic fate (reduction to the Telluride cation), there seems to be good evidence that tellurium from different moieties will behave very similar with regard to systemic toxicity."*

[2] Read-Across Assessment Framework (RAAF). 2017 (March) ECHA, Helsinki. 60 pp. Available online: Read-Across Assessment Framework (https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across)

[3] Read-across assessment framework (RAAF) - considerations on multi-constituent substances and UVCBs. 2017 (March) ECHA, Helsinki. 40 pp. Available online: https://doi.org/10.2823/794394

- "[…] *Elemental tellurium and tellurium dioxide are relatively poorly water soluble. Underlying the basic assumption that effects caused by the bioavailable metal fraction and the same toxicokinetic behaviour, ecotoxicity data from higher soluble tellurium compound were considered appropriate for the ecotoxicity assessment of tellurium. Sodium tellurate (Na2TeO4; CAS: 10101-83-4) is known to be readily soluble in water, it is therefore considered as an adequate testing material for OECD 211 and for read-across to tellurium metal and tellurium dioxide."*
- *"This read-across is based on the hypothesis that source and target substances do possess similar toxicological properties because elemental Tellurium is in vivo obviously reduced to Telluride [Te2-] which is further metabolized to the Mono- and dimethyl telluride (which are excreted to various degrees (also depended on route of exposure) in exhaled air, sweat, feces and urine) and also to the Trimethyl telluronium cation which is excreted in urine."*

ECHA understands that you predict the properties of the Substance using a read-across hypothesis which assumes that different compounds have the same type of effects. The properties of your Substance are predicted to be quantitatively equal to those of the source substance.

ECHA notes the following shortcoming with regards to the predictions of ecotoxicological properties:

Missing supporting information

Annex XI, Section 1.5 of the REACH Regulation states that "*physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s)*". For this purpose, "it is important to provide supporting information to strengthen the rationale for the read-across" (ECHA Guidance R.6.2.2.1.f). The set of supporting information should allow to verify the crucial aspects of the read-across hypothesis and establish that the properties of the Substance can be predicted from the data on the source substance(s).

As indicated above, your read-across hypothesis is based on the assumption that the structurally similar substances cause the same type of effect(s). In this context, relevant, reliable and adequate information allowing to compare the properties of the Substance and of the source substance(s) is necessary to confirm that the substances cause the same type of effects.

In your read-across justification document, you do not address the impact of differences in metal speciation between the target and source substance on the prediction of ecotoxicological properties. Your read across justification is focused on the *in vivo* metabolism of the target and source substance in mammals. However, you do not provide supporting information to justify this approach for the assessment of toxicity towards aquatic invertebrates.

However, metal speciation can significantly impact bioavailability and (eco)toxicity. The Substance is Te(0) while the selected source substance is Te(VI). You have not provided any supporting information to demonstrate that the difference in valency between the target and source substance does not impact the prediction. Further, we note that you have not provided any aquatic toxicity data for the Substance or the source substance. As a result, you failed to provide relevant, reliable and adequate information in support of your read-across hypothesis.

As explained above, you have not established that relevant properties of the Substance can be predicted from data on the analogue substance. Therefore, your adaptation does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5. and your grouping and read-across approach is rejected.

In your comments to the draft decision, you acknowledge the uncertainties identified by ECHA regarding the speciation of the test substance and acknowledge, based on recent findings, that a soluble tetravalent tellurium compound would be more appropriate as a source substance for the ecotoxicological assessment of the Substance than the hexavalent source substance proposed in the testing proposal.

1.3. Test selection and study specifications

The Daphnia magna reproduction test (test method: EU C.20/OECD TG 211) is appropriate to cover the information requirement for long-term toxicity on aquatic invertebrates (ECHA Guidance R.7.8.4.1.).

The Substance may be difficult to test due to the relatively low water solubility (1.7 mg/L based on OECD 105). OECD TG 211 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified and documented. Due to the properties of Substance, it may be difficult to achieve and maintain the desired exposure concentrations. Therefore, you must monitor the test concentration(s) of the Substance throughout the exposure duration and report the results. If it is not possible to demonstrate the stability of exposure concentrations (i.e. measured concentration(s) not within 80-120% of the nominal concentration(s)), you must express the effect concentration based on measured values as described in OECD TG 211. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solutions.

1.4. Outcome

Your testing proposal on the analogue substance Sodium tellurate (EC No. 233-259-5) is rejected under Article 40(3) (d) of REACH. Under Article 40(3)(c) you are requested to carry out the additional test with the Substance, as specified above.

In your comments to the draft decision, you agree to conduct the study and propose the following testing strategy:

- "[…] *Determination of the relevant Te-speciation that is expected in T/Dp medium of Tellurium metal;*
- *Selection of the appropriate soluble Te-salt (Na2TeO3) that will generate a speciation profile which is representative for the speciation profile in the T/Dp medium of Tellurium metal;*
- *Conduct the requested long-term Daphnia reproduction test with the selected Te-salt;*
- *Prepare an Environmental Read-Across Framework Assessment (RAAF) Report, which justifies the applied environmental read-across between the selected source substance and the target substance;*
- *Assess the classification for long-term toxicity of Tellurium metal to invertebrates by comparing the results of the long-term Daphnia reproduction test with the available T/Dp data."*

Based on the information above, ECHA understands that you now intend to conduct the study with a soluble tetravalent tellurium compound, potentially Sodium tellurite (Na_2TeO_3).

ECHA acknowledges that the proposed testing strategy has some merit but also notes that in the absence of reliable and adequate supporting information to demonstrate similar speciation behaviours of the target and selected source substance, ECHA cannot assess the validity of the proposed approach.

2. Long term toxicity testing on fish

Long-term toxicity testing on fish is an information requirement under Annex IX to REACH (Section 9.1.6.).

Under Article 40(3)(c) of REACH, ECHA may require a registrant to carry out one or more additional tests in case of non-compliance of the testing proposal with Annexes IX, X or XI of the REACH Regulation. The information requirement on Aquatic toxicity at Annex IX covers both long-term toxicity on invertebrates (Section 9.1.5.) and on fish (Section 9.1.6.). However, you have provided a testing proposal for long-term testing on aquatic invertebrates only. In case of data gap for long-term toxicity testing on fish, it is necessary to request this information as an additional test to ensure compliance with the endpoint.

2.1. Information provided to fulfil the information requirement

Your registration dossier does not include any information on long-term toxicity on fish. Instead, you have provided a justification to omit the study which you consider to be based on Annex IX, Section 9.1., Column 2. In support of your adaptation, you provided the following justification: "*According to column 2 of REACH Annex IX long-term toxicity testing should be proposed by the registrant if the chemical safety assessment (CSA) indicates the need to investigate further the effects on aquatic organism. Due to the insolubility of tellurium and the low acute aquatic toxicity of tellurium compounds to fish, chronic aquatic toxicity to fish is not expected and testing is not justified. For invertebrates as the most sensitive species to tellurium compounds a testing proposal for chronic ecotoxicity is included*."

We have assessed this information and identified the following issue:

> Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term toxicity to fish under Column 1. It must be understood as a trigger for providing further information on long-term toxicity to fish if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).
>
> Your adaptation is therefore rejected.

Therefore, the information requirement is not fulfilled.

2.2. Test selection and study specifications

The Fish, Early-Life Stage Toxicity Test (test method: OECD TG 210) is appropriate to cover the information requirement for long-term toxicity on fish (ECHA Guidance R.7.8.4.1.).

OECD TG 210 specifies that for difficult to test substances OECD GD 23 must be followed. As already explained under Appendix A.1, the Substance may be difficult to test. Therefore, you must fulfil the requirements described in 'Study design' under Appendix A.1.

2.3. Outcome

Under Article 40(3)(c) of REACH, you are requested to carry out the additional test with the

Substance, as specified above.

In your comments to the draft decision, you agree to conduct the Fish, Early-Life Stage Toxicity Test (test method: OECD TG 210) and propose to follow a similar approach as for long-term invertebrates.

For the reason explained above in Appendix A.1, ECHA cannot assess the validity of the proposed approach.

Appendix B: Requirements to fulfil when conducting and reporting new tests for REACH purposes

A. Test methods, GLP requirements and reporting

1. Under Article 13(3) of REACH, all new data generated as a result of this decision must be conducted according to the test methods laid down in a European Commission Regulation or to international test methods recognised by the Commission or ECHA as being appropriate.

2. Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses must be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.

3. Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries[4].

B. Test material

Before generating new data, you must agree within the joint submission on the chemical composition of the material to be tested (Test material) which must be relevant for all the registrants of the Substance.

1. Selection of the Test material(s)

   The Test material used to generate the new data must be selected taking into account the following:
   - the variation in compositions reported by all members of the joint submission,
   - the boundary composition(s) of the Substance,
   - the impact of each constituent/ impurity on the test results for the endpoint to be assessed. For example, if a constituent/ impurity of the Substance is known to have an impact on (eco)toxicity, the selected Test material must contain that constituent/ impurity.

2. Information on the Test material needed in the updated dossier
   - You must report the composition of the Test material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
   - The reported composition must include all constituents of each Test material and their concentration values and other parameters relevant for the property to be tested in this case the particle size of the test material.

This information is needed to assess whether the Test material is relevant for the Substance and whether it is suitable for use by all members of the joint submission.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[5].

[4] https://echa.europa.eu/practical-guides
[5] https://echa.europa.eu/manuals

Appendix C: Procedure

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 9 March 2020.

ECHA followed the procedure detailed in Articles 50 and 51 of REACH.

ECHA notified you of the draft decision and invited you to provide comments.

ECHA took into account your comments and did not amend the requests.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

As no amendments were proposed, ECHA adopted the decision under Article 51(3) of REACH.

Appendix D: List of references - ECHA Guidance[6] and other supporting documents

Evaluation of available information
Guidance on information requirements and chemical safety assessment, Chapter R.4 (version 1.1., December 2011), referred to as ECHA Guidance R.4 where relevant.

QSARs, read-across and grouping
Guidance on information requirements and chemical safety assessment, Chapter R.6 (version 1.0, May 2008), referred to as ECHA Guidance R.6 where relevant.

Read-across assessment framework (RAAF, March 2017)[7]

RAAF - considerations on multi-constituent substances and UVCBs (RAAF UVCB, March 2017)[8]

Physical-chemical properties
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Toxicology
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

Environmental toxicology and fate
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017), referred to as ECHA Guidance R.7b in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

PBT assessment
Guidance on information requirements and chemical safety assessment, Chapter R.11 (version 3.0, June 2017), referred to as ECHA Guidance R.11 in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.16 (version 3.0, February 2016), referred to as ECHA Guidance R.16 in this decision.

Data sharing
Guidance on data-sharing (version 3.1, January 2017), referred to as ECHA Guidance on data sharing in this decision.

OECD Guidance documents[9]

[6] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[7] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[8] https://echa.europa.eu/documents/10162/13630/raaf_uvcb_report_en.pdf/3f79684d-07a5-e439-16c3-d2c8da96a316
[9] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

Guidance Document on aqueous–phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

Guidance document on transformation/dissolution of metals and metal compounds in aqueous media – No 29, referred to as OECD GD 29.

Guidance Document on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption – No 150, referred to as OECD GD 150.

Guidance Document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test – No 151, referred to as OECD GD 151.

Appendix E: Addressees of this decision and the corresponding information requirements applicable to them

You must provide the information requested in this decision for all REACH Annexes applicable to you.

Registrant Name	Registration number	Highest REACH Annex applicable to you
[redacted]	[redacted]	[redacted]

Where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.