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Helsinki, 16 May 2024

Addressee(s)
Registrants of JS_Diniobium_Pentaoxide as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
23 October 2023

Registered substance subject to this decision ("the Substance")
Substance name: Diniobium pentaoxide
EC/List number: 215-213-6

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)

Under Article 40 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by ***21 November 2025***.

Information required from all the Registrants subject to Annex IX of REACH

1. Long-term toxicity testing on terrestrial invertebrates (triggered by Annex IX, Section 9.4.1., Column 2; test method: OECD TG 222) with the analogue substance niobium metal (EC No. 231-113-5).

The reasons for the decision(s) are explained in Appendix 1.

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you in accordance with Articles 10(a) and 12(1) of REACH. The addressee(s) of the decision and their corresponding information requirements based on registered tonnage band are listed in Appendix 3.

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 requirements for testing and reporting new tests under REACH, see Appendix 4.

Appeal

This decision, when adopted under Article 51 of REACH, may be appealed to the Board of Appeal of ECHA within three months of its notification to you. Please refer to http://echa.europa.eu/regulations/appeals for further information.

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Failure to comply

If you do not comply with the information required by this decision by the deadline indicated above, ECHA will notify the enforcement authorities of your Member State.

Authorised[1] under the authority of Mike Rasenberg, Director of Hazard Assessment

Appendix 1: Reasons for the decision
Appendix 2: Procedure
Appendix 3: Addressees of the decision and their individual information requirements
Appendix 4: Conducting and reporting new tests under REACH

[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 1: Reasons for the decision

Contents

Reasons related to the information under Annex IX of REACH

1. Long-term toxicity testing on terrestrial invertebrates

1 Short-term toxicity to invertebrates is an information requirement under Annex IX to REACH (Section 9.4.1). Long-term toxicity testing must be considered (Annex IX, Section 9.4., column 2) if the substance has a high potential to adsorb to soil or is very persistent.

1.1. Information provided to fulfil the information requirement

2 Your registration dossier does not include any information on long-term toxicity to terrestrial invertebrates.

3 You have submitted a testing proposal for an EU C.33/OECD TG 222 with an analogue substance Niobium metal powder (EC 231-113-5). You justify your testing proposal by arguing that "Available data on sorption of niobium to soil, indicates that niobium has a high sorption potential to soil and all determined acute and chronic effect values for aquatic toxicity of diniobium pentaoxide are > 1 mg/L. Therefore, the Substance is assigned to soil hazard category 3. Considering the available aquatic toxicity results, showing no intrinsic acute and chronic toxicity of diniobium pentaoxide up to its water solubility, it is not expected that it shows long-term effects to soil organisms. Nevertheless, this assumption will be assessed by conducting a confirmatory soil toxicity long-term test according to OECD 222. The confirmatory long-term soil toxicity test will be performed with the analogue substance niobium".

4 ECHA has assessed your testing proposal and notes the following:

5 Under Annex IX, Section 9.4., column 2, in the absence of toxicity data to soil organisms, the equilibrium partitioning method (EPM) may be applied to assess the hazard to soil organisms. In this context, the Guidance on IRs and CSA, Section R.7.11.16. describes an integrated testing strategy (ITS) for Effects on Terrestrial Organisms. For the soil compartment there are currently no criteria for classification and PBT assessment, therefore the ITS for soil is especially focussed on generating data for the chemical safety assessment. This approach relies on the assignment of the Substance to a "soil hazard category" and on an initial screening assessment using the EPM, in order to decide the information needed for the chemical safety assessment.

6 The following information indicates that the Substance falls into the soil hazard category 3 (HC3):

- the Substance is not considered very toxic to aquatic organisms;
- the Substance is inorganic and therefore considered to be highly persistent in soil.

7 As specified in the Guidance on IRs and CSA, Table R.7.11-2, for such substance, a confirmatory long-term test on effects to terrestrial organisms from those set out under Annex X, Section 9.4 need to be conducted. The test must be conducted with the most sensitive organism group (if any) as indicated from aquatic toxicity data. Under Guidance on IRs and CSA, Section R.7.11.5.3. in the absence of a clear indication of the most sensitive organism group as indicated by the available aquatic toxicity data, an invertebrate (earthworm or collembolan) test is preferred.

8 Based on the information under Section 6.1. of your technical dossier no sensitivity difference at least by a factor of 10 between aquatic plants, aquatic invertebrates and microorganisms can be established.

9 Therefore, ECHA agrees that an appropriate long-term toxicity study on terrestrial invertebrates is needed.

1.2. Assessment of the read-across approach

10 ECHA understands that you seek to adapt this information requirement according to Annex XI, Section 1.5. to REACH.

11 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.

12 In your testing proposal, as well as in the supplemental read-across document and data matrix provided in the technical dossier (IUCLID section 13), you justify the read-across approach by stating that "the target and source substance are considered to apply to the general rules and the similarity as outlined in scenario 1 of the RAAF document (ECHA 2017)". Your hypothesis is that the source and target substance have similar or the same (eco)toxicological properties because they undergo a transformation to the common niobium species, which is the driver for the common mode of action and fate of the substances. In addition, you state that the parent substances and their impurities are not considered to have a relevant impact on the read across.

13 ECHA has assessed the information provided in your dossiers and in the analogue read across approach justification document and agrees that the Substance (niobium pentaoxide) and source substance (niobium metal) show structural similarity due to the presence of the niobium metal (Nb) in both substances. ECHA also agrees that water solubility (OECD TG 105) and transformation/dissolution (OECD TG 29) data provided for both substances show release of Nb species at environmentally relevant conditions leading to similar exposure of organisms to the common compound Nb at low concentrations (µg-level) in water. In addition, ECHA agrees that no intrinsic toxicity up to the highest concentrations tested are seen in the available aquatic toxicity tests on the source and target substance and any potential environmental toxicity is more likely attributed to the released Nb element.

14 ECHA therefore agrees that the provided information generally supports your hypothesis.

15 However, we emphasise that any final determination on the validity of your read-across adaptation will only be possible when the information on requested studies will be available in the dossier.

1.3. Test selection and study specifications

16 The proposed EU C.33/OECD TG 222 is appropriate to cover the information requirement for long-term toxicity on terrestrial invertebrates (Guidance on IRs and CSA, Section R.7.11.3.1).

1.4. Outcome

17 Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test with the analogue substance Niobium metal powder (EC 231-113-5), as specified above.

18 In the comments to the draft decision, you agree to perform the requested study.

References

The following documents may have been cited in the decision.

Guidance on information requirements and chemical safety assessment (Guidance on IRs & CSA)

Chapter R.4 Evaluation of available information; ECHA (2011).
Chapter R.6 QSARs, read-across and grouping; ECHA (2008).
Appendix to Chapter R.6 for nanoforms; ECHA (2019).
Chapter R.7a Endpoint specific guidance, Sections R.7.1 – R.7.7; ECHA (2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Chapter R.7b Endpoint specific guidance, Sections R.7.8 – R.7.9; ECHA (2017).
Appendix to Chapter R.7b for nanomaterials; ECHA (2017).
Chapter R.7c Endpoint specific guidance, Sections R.7.10 – R.7.13; ECHA (2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Appendix R.7.13-2 Environmental risk assessment for metals and metal compounds; ECHA (2008).
Chapter R.11 PBT/vPvB assessment; ECHA (2017).
Chapter R.16 Environmental exposure assessment; ECHA (2016).

Guidance on data-sharing; ECHA (2017).
Guidance for monomers and polymers; ECHA (2023).
Guidance on intermediates; ECHA (2010).

All guidance documents are available online: https://echa.europa.eu/guidance-documents/guidance-on-reach

Read-across assessment framework (RAAF)

RAAF, 2017 Read-across assessment framework (RAAF); ECHA (2017)
RAAF UVCB, 2017 Read-across assessment framework (RAAF) – considerations on multi- constituent substances and UVCBs); ECHA (2017).

The RAAF and related documents are available online:
https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

***OECD Guidance documents* (OECD GDs)**

OECD GD 23 Guidance document on aquatic toxicity testing of difficult substances and mixtures; No. 23 in the OECD series on testing and assessment, OECD (2019).
OECD GD 29 Guidance document on transformation/dissolution of metals and metal compounds in aqueous media; No. 29 in the OECD series on testing and assessment, OECD (2002).
OECD GD 150 Revised guidance document 150 on standardised test guidelines for evaluating chemicals for endocrine disruption; No. 150 in the OECD series on testing and assessment, OECD (2018).
OECD GD 151 Guidance document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test; No. 151 in the OECD series on testing and assessment, OECD (2013).

Appendix 2: Procedure

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 1 December 2022.

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.

In your comments you agreed to the draft decision. ECHA took your comments into account and did not amend the request(s).

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 3: Addressee(s) of this decision and their corresponding information requirements

In accordance with Articles 10(a) and 12(1) of REACH, the information requirements for individual registrations are defined as follows:

- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa;

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

Appendix 4: Conducting and reporting new tests for REACH purposes

1. Requirements when conducting and reporting new tests for REACH purposes

1.1. 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[2].

(4) Under the introductory part of Annexes VII/VIII/IX/X to REACH, where a test method offers flexibility in the study design, for example in relation to the choice of dose levels or concentrations, the chosen study design must ensure that the data generated are adequate for hazard identification and risk assessment.

1.2. 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.

[2] https://echa.europa.eu/practical-guides

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[3].

2. General recommendations for conducting and reporting new tests

References to Guidance on REACH and other supporting documents can be found in Appendix 1.

[3] https://echa.europa.eu/manuals