EUROPEAN CHEMICALS AGENCY

Helsinki, 28 July 2020

Addressee
Registrant of JS_Niobium_Metal listed in the last Appendix of this decision

Date of submission for the dossier subject of this decision
05 April 2017

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Niobium
EC number: 231-113-5
CAS number: 7440-03-1

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

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (REACH), ECHA requests that you submit the information listed below by the deadline of ***2 November 2022***.

A. Requirements applicable to all the Registrants subject to Annex VII of REACH

1. Water solubility (Annex VII, Section 7.7.; test method: OECD series on Testing and Assessment Number 29 - Guidance Document on Transformation/Dissolution of Metals and Metal Compounds in Aqueous media) with the Substance

2. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method EU C.3./OECD TG 201) with the Substance

3. The long-term toxicity testing on aquatic invertebrates also requested at C.3. below (triggered by Annex VII, Section 9.1.1., column 2)

B. Requirements applicable to all the Registrants subject to Annex VIII of REACH

1. The long-term toxicity testing on fish also requested at C.4. below (triggered by Annex VIII, Section 9.1.3., column 2)

2. Activated sludge respiration inhibition testing (Annex VIII, Section 9.1.4.; Test method: OECD TG 209) with the Substance

C. Requirements applicable to all the Registrants subject to Annex IX of REACH

1. Sub-chronic toxicity study (90-day), inhalation route (Annex IX, Section 8.6.2.; test method OECD TG 413) in rats with the Substance

2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method OECD TG 414) in a first species (rat or rabbit), oral route with the Substance

3. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test

method EU C.20./OECD TG 211) with the Substance

4. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method OECD TG 210) with the Substance

Conditions to comply with the requests

You are bound by the requests for information corresponding to the REACH Annexes applicable to your own registered tonnage of the Substance at the time of evaluation. Therefore you have to comply with the requirements of Annexes VII to IX of REACH.

When a study is required under several Annexes of REACH, the reasons are provided in the corresponding appendices of this decision.

The Appendix on general considerations addresses issues relevant for several requests while the Appendices A to C state the reasons for the requests for information to fulfil the requirements set out in the respective Annexes of REACH.

The Appendix entitled Observations and technical guidance addresses the generic approach for the selection and reporting of the test material used to perform the required studies and provides generic recommendations and references to ECHA guidance and other reference documents.

You must submit the information requested in this decision by the deadline indicated above in an updated registration dossier and also update the chemical safety report, where relevant, including any changes to classification and labelling, based on the newly generated information. The timeline has been set to allow for sequential testing where relevant.

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.

Authorised[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 on general considerations

(i) Assessment of your exposure-based adaptations (Annex XI, Section 3.)

You have provided adaptations in your dossier for the following endpoints:

- Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.)
- Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.)

To support your adaptation you state that the uses of the Substance lead to limited human exposure as:

- *"the substance is exclusively used at the industrial site, which assumes adequate protection measures for handling"*;
- *"It should be mentioned that metallic niobium can be manipulated without formation of any respirable dust"*.

Section 3.1 of Annex XI enables testing to be omitted based on the exposure scenario(s) developed in the Chemical Safety Report, if the conditions described in Section 3.2 of Annex XI are met. The adaptation of the information requirement must be supported by adequate justification and documentation which must be based on a thorough and rigorous exposure assessment in accordance with Section 5 of Annex I.

We have assessed the information in your dossier according to the requirements set out in Annex XI, Section 3.2. and we have identified the following issues:

A. Under section 3.2(a) of Annex XI, the justification must fulfil all the following conditions:
   (i) the results of the exposure assessment covering all relevant exposures throughout the life cycle of the substance demonstrate the absence of or no significant exposure in all scenarios of the manufacture and all identified uses as referred to in Annex VI section 3.5.;
   (ii) a suitable DNEL or a PNEC can be derived from results of available test data for the Substance taking full account of the increased uncertainty resulting from the omission of the information requirement, and that DNEL or PNEC is relevant and appropriate both to the information requirement to be omitted and for risk assessment purposes;
   (iii) the comparison of the derived DNEL or PNEC with the results of the exposure assessment shows that exposures are always well below the derived DNEL or PNEC.

   However, you have not provided any DNELs for the substance. Furthermore the information available in your technical dossier with regard to repeated-dose toxicity and developmental toxicity is not adequate to derive suitable DNELs for the endpoints listed above. More specifically, you only provided a Combined repeated dose and reproduction / developmental screening study (OECD TG 422) with the Substance for the above-mentioned endpoints. However, as explained further under requests C.1. and C.2, the data from this study does not permit the derivation of a DNEL for these specific hazards (i.e. 90-day repeated dose toxicity and developmental toxicity) and for risk assessment purposes. In addition, for the developmental toxicity endpoint, footnote 1 of Annex XI, Section 3.2.(a)(ii) specifies that a DNEL derived from a screening reproduction/developmental study is not appropriate to omit a pre-natal developmental toxicity study.

B. In addition, the justification provided must fulfil the conditions set out in 3.2(b) and/or

3.2(c) of Annex XI. In particular:

(i) where the substance is not incorporated in an article, strictly controlled conditions as set out in Article 18(4)(a) to (f) must apply throughout the life cycle;

(ii) where the substance is incorporated in an article in which it is permanently embedded in a matrix or otherwise rigorously:
- the substance is not released during its life cycle, and
- negligible workers or general public or environmental exposure occurs under normal or reasonably foreseeable conditions, and
- strictly controlled conditions as set out in Article 18(4)(a) to (f) must apply during all manufacturing and production stages including the waste management of the substance during these stages.

However, you did not provide any justification and evidence supporting that the conditions set out in Section 3.2(b) and/or 3.2(c) of Annex XI are fulfilled.

Therefore, your adaptation does not comply with the general rules of adaptation set out in Annex XI, Section 3.2. Your exposure-based adaptations do not apply to the Substance, resulting in an data gap for this information requirement.

(ii) Assessment of the read-across adaptations, in light of the requirements of Annex XI, Section 1.5.

You have adapted the following standard information requirements by applying read-across approaches in accordance with Annex XI, Section 1.5:

- Water solubility (Annex VII, Section 7.7.);
- Short-term repeated dose toxicity (28 day) (Annex VIII, Section 8.6.1.);
- Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.);
- Sub-chronic toxicity study (90-day), (Annex IX, Section 8.6.2.).

Annex XI, Section 1.5. specifies three conditions which must be fulfilled whenever a read-across approach is used:

(i) 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;

(ii) 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;

(iii) adequate and reliable documentation of the applied method must be provided.

Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance and related documents.

For the endpoints listed above, you used data from an analogue substance reffered to as Ferro Niobium.

For each of the source of information provided on the analogue substance, you need to provide a justification that it is relevant to predict the properties of the Substance.

However, you have not provided any documentation, in Section 13 of your IUCLID dossier nor in the CSR, to explain your read-across hypothesis and to support that it may provide a reliable basis to predict the properties of the Substance.

Hence, as your read-across adaptations are not supported by adequate documentation, they do not comply with the general rules of adaptation as set out in Annex XI, Section 1.5. Therefore, your adaptations are rejected.

Appendix A: Reasons for the requests to comply with Annex VII of REACH

Under Articles 10(a) and 12(1) of REACH, a technical dossier registered at 1 to 10 tonnes or more per year must contain, as a minimum, the information specified in Annex VII to REACH.

1. Water solubility (Annex VII, Section 7.7.)

Water solubility is a standard information requirement in Annex VII to REACH.

In your dossier, you have provided:

1. A key study by [redacted] (2009a) for a water solubility study according to OECD TG 105 with the Substance (particle size not specified; batch no. AD/4202);
2. A key study by [redacted] (2011) for a transformation/dissolution study according to OECD GD 29 with the Substance (particle size of c.a. 1 mm; batch no. AD/4331);
3. A supporting study by [redacted] (2011) for a transformation/dissolution study according to OECD GD 29 (short-term test (7 days) only) with the Substance (particle size not specified; batch no. AD/4202);
4. A key study by [redacted] (2009b) for a water solubility study according to OECD TG 105 with Ferro Niobium;
5. A key study by [redacted] (2011) for a transformation/dissolution study according to OECD GD 29 with Ferro Niobium.

We have assessed this information and identified the following issue:

A. EU test method A.6 and OECD TG 105 describe two methods (the column elution method and the flask method) for conducting a water solubility study. The test method must be selected based on a water solubility estimate obtained in a preliminary study. For substances with preliminary water solubility below 10 mg/L the column elution method must be used.

   For study 1, you specify that "*due to the expected insolubility of the test item (niobium metal) in water no preliminary test was performed*". You have used the shake flask method and you report a water solubility estimate of < 0.5 µg/L at 20°C and pH 6.

   Based on the properties of the Substance, the column elution method is likely not applicable as it might not be technically feasible to load the Substance on the column matrix. In addition, the reported results of these studies fall outside of the applicability domain of the flask method. Therefore, none of the methods described EU test method A.6 and OECD TG 105 are applicable to the Substance.

B. OECD GD 29 specifies that as the surface area of the particles in the test sample has an important influence on the rate and extent of transformation/dissolution, powders are tested at the smallest representative particle size as placed on the market. Massives are tested at a particle size representative of normal handling and use or, in the absence of this information, a default diameter value of 1 mm must be used.

   In section 4.5. of the jointly submitted dossier, the lead registrant adapted the information requirement on particle size distribution as the substance is marketed and used in the form of massive ingots only. You opted-out for this information requirement and provided an experimental study by [redacted] (2017) conducted according to ISO 13320 (laser scattering/diffraction). You report a D50 of 24.89 µm. Therefore we understand that you intend to cover a powder form in your registration.

However, study 2 and 3 are not adequate to fulfil the information requirement as the test substance had a particle size of "c.a. 1 mm" in study 2 and no information on particle size is available on study 3.

C. While you did not claim an adaptation according to Annex XI, Section 1.5., you have also provided information of Ferro niobium for this endpoint. As explained in section ii) of the Appendix on general considerations, your adaptation is rejected.

Therefore, the information requirement is not fulfiled.

The Substance is a sparingly soluble inorganic metal compound, and therefore as specified in ECHA Guidance R.7a, Section R.7.1.7.3., water solubility must be determined according to the OECD GD 29 on Transformation/Dissolution of metals and metal compounds in aqueous media. OECD GD 29 specifies that the test must be conducted using a test material having the smallest representative particle size. It also states that the specific surface area of the test material must be determined. We note that you report under Section 4.5. of your technical dossier a granulometry according to ISO 13320 which shows that the substance you registered may have a D50 as low as 24.89 µm.

2. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)

Growth inhibition study aquatic plants is a standard information requirement in Annex VII to REACH.

You have adapted this information requirement based on Annex VII, Section 9.1.2., Column 2.

In support of your adaptation, you provided the following justification: "*In accordance with column 2 of Annex VII and VIII of Regulation (EC) No 1907/2006, short-term studies for the aquatic ecotoxicity do not need to be conducted if there are mitigating factors indicating that aquatic toxicity is unlikely to occur, for instance if the substance is highly insoluble in water*".

Based on the information provided in your dossier we have identified the following issue:

Annex VII, Section 9.1.2., Column 2 indicates that information on water solubility may be used to support that aquatic toxicity is unlikely to occur if it shows that the substance is highly insoluble. There is no scientific basis to define a cut off limit value for solubility below which no toxicity could occur (ECHA Guidance R.7b, Section R.7.8.5.). For sparingly soluble metals, measured data on the dissolved fraction are always required for getting reliable toxicity test data (ECHA Guidance R.7b, Section R.7.8.4.1.). In this context it must be considered whether or not the solubility of the Substance permits to conduct a study at concentrations below the solubility limit of the Substance. The technique used to prepare test solutions must aim to achieve the maximum dissolved concentrations (ECHA Guidance R.7b, Table R.7.8-3).

You have provided the results of a transformation/dissolution study according to OECD GD 29. The test was conducted a sample with a particle size of c.a. 1 mm which likely underestimate the water solubility of the substance as registered by you (i.e. a powder with a D50 of 24.89 µm. Nevertheless, you report that, at a loading of 100 mg/L, the test sample used to conduct the study has a water solubility of 0.104 µg/L at pH 8 after 7 days of stirring. Therefore, while the Substance is regarded as poorly water soluble, the dissolved fraction reaches concentrations that are high enough to be

quantifiable. This indicates that, the Substance can be tested at concentrations below its solubility limit and that exposure concentrations can be monitored.

Therefore, your adaptation according to Annex VII, Section 9.1.2., Column 2 is rejected and the information requirement is not fulfilled.

While selecting the test material you must take into account the impact of parameters relevant for the property to be tested. For the aquatic toxicity studies, you must justify that the selected test material properties (e.g. particle size) constitute a reasonable worst case to cover all the registrants of the Substance. Therefore the selected test material should correspond to the most soluble form of the substance taking into account the range of properties of the substance as registered under REACH.

3. The long-term toxicity testing on aquatic invertebrates also requested at C.1. below (triggered by Annex VII, Section 9.1.1., column 2)

"Short-term toxicity testing on aquatic invertebrates" is a standard information requirement in Annex VII to REACH. However, pursuant to Annex VII, section 9.1.1., Column 2, for poorly soluble substances the long-term aquatic toxicity study on aquatic invertebrates (Annex IX, Section 9.1.5.) must be considered.

You have adapted this information requirement based on Annex VIII, Section 9.1.1., Column 2. In support of your adaptation, you provided the following justification: "*In accordance with column 2 of Annex VII and VIII of Regulation (EC) No 1907/2006, short-term studies for the aquatic ecotoxicity do not need to be conducted if there are mitigating factors indicating that aquatic toxicity is unlikely to occur, for instance if the substance is highly insoluble in water*".

You have also provided a supporting study ([redacted] 2005) of the toxicity of the Substance on *Hyalella Azteca*. The study was not conducted according to any recommended guideline. You have not provided a key study for this endpoint.

Based on the information provided in your dossier we have identified the following issues:

A. Annex VII, Section 9.1.1., Column 2 specifies that this information requirement may be adapted if:
   1. there are mitigating factors indicating that aquatic toxicity is unlikely to occur (e.g. the substance is highly insoluble) or;
   2. a long-term toxicity study on aquatic invertebrates is available.

   As already explained under request A.2. above, the data provided in your dossier does not adequately support that aquatic toxicity is unlikely to occur. As explained under request C.3., you did not provide long-term toxicity study on aquatic invertebrates. Therefore, your adaptation according to Annex VII, Section 9.1.1., Column 2 is rejected.

B. To be considered compliant and therefore to enable concluding whether the Substance has dangerous properties and to support the determination of Predicted No-Effect Concentrations (PNECs) for relevant environmental compartments, a long-term toxicity study to aquatic invertebrates has to meet the requirements of EU Method C.20. / OECD TG 211. The key parameters of these test guidelines include:
   - adequate exposure duration (i.e. 21 days);
   - the study of sub-lethal endpoints (i.e. reproduction efficiency).

The study by [redacted] (2005) reports the results of toxicity tests on *Hyalella azteca* for sixty-three metals at two levels of water hardness (18 and 124 mg $CaCO_3$/L) following 7 days of exposure. In soft water, the 7d-LC50 was determined at 26 µg/L (based on measured values) for Niobium, which is among the lowest 7d-LC50 determined in this study. You consider this study non reliable as the method is not standardized and that insufficient documentation is reported to evaluate the test performance. You state that there was a large variability in the age of test organisms at test initiation (1-11 days) and you consider that the reliability of the reported effect values is low. You conclude that this study should only be used as an indicator for the toxicity range of several metal species.

While no reference to any guideline is reported, we note that the study design if very similar to the short-term test of ASTM E 1706-05. The endpoint monitored is mortality. As specified in ECHA Guidance R.7b., Section R.7.8.9.1. this type of test is considered valid to provide information on toxicity to sediment organisms. Furthermore, considering the short exposure time (7 days), the study must be regarded as a short-term test. Accordingly this study does not provide equivalent information to long-term toxicity study to aquatic invertebrates.

Therefore, the information requirement is not fulfilled.

As explained under request A.1., the information you provided on water solubility does not fulfil the information requirement. While there are remaining uncertainties regarding the relative water solubility of the various forms of the Substance, we consider that the information provided is sufficient to conclude that the Substance is poorly water soluble (i.e. water solubility below 1 mg/L).

Poorly water soluble substances require longer time to reach steady-state conditions. Hence, the short-term tests may not give a true measure of toxicity for this type of substances. Therefore, a long-term test must be conducted.

Consequently, a long-term aquatic toxicity study on aquatic invertebrates triggered by Annex VII, section 9.1.1., Column 2 must be performed. This test is already required under request C.3. in accordance with Annex IX, Section 9.1.5.

Appendix B: Reasons for the requests to comply with Annex VIII of REACH

Under Articles 10(a) and 12(1) of REACH, a technical dossier registered at 10 to 100 tonnes or more per year must contain, as a minimum, the information specified in Annexes VII and VIII to REACH.

1. The long-term toxicity testing on fish also requested at C.2. below (triggered by Annex VIII, Section 9.1.3., column 2)

"Short-term toxicity testing on fish" is a standard information requirement in Annex VIII to REACH. However, pursuant to Annex VIII, section 9.1.3., column 2, for poorly soluble substances the long-term aquatic toxicity study on fish (Annex IX, Section 9.1.6.) must be considered.

You have adapted this information requirement based on Annex VIII, Section 9.1.3., Column 2. In support of your adaptation, you provided the following justification: "*In accordance with column 2 of Annex VII and VIII of Regulation (EC) No 1907/2006, short-term studies for the aquatic ecotoxicity do not need to be conducted if there are mitigating factors indicating that aquatic toxicity is unlikely to occur, for instance if the substance is highly insoluble in water*".

Based on the information provided in your dossier we have identified the following issue:

Annex VIII, Section 9.1.3., Column 2 specifies that this information requirement may be adapted if:

- there are mitigating factors indicating that aquatic toxicity is unlikely to occur (e.g. the substance is highly insoluble) or;
- a long-term toxicity study on fish is available.

As already explained under request A.2. above, the data provided in your dossier does not adequately support that aquatic toxicity is unlikely to occur. As explained under request C.4., you did not provide long-term toxicity study on fish. Therefore, your adaptation according to Annex VIII, Section 9.1.3., Column 2 is rejected.

As explained under request A.1., the information you provided on water solubility does not fulfil the information requirement. While there are remaining uncertainties regarding the relative water solubility of the various forms of the Substance, we consider that the information provided is sufficient to conclude that the Substance is poorly water soluble (i.e. water solubility below 1 mg/L).

Poorly water soluble substances require longer time to reach steady-state conditions. Hence, the short-term tests may not give a true measure of toxicity for this type of substances. Therefore, a long-term test must be conducted.

Consequently, a long-term aquatic toxicity study on fish triggered by Annex VIII, section 9.1.3., column 2 must be performed. This test is also required under request C.4. in accordance with Annex IX, Section 9.1.6.

2. Activated sludge respiration inhibition testing (Annex VIII, Section 9.1.4.).

Activated sludge respiration inhibition testing is a standard information requirement in Annex VIII to REACH.

You have adapted this information requirement based on Annex VIII, Section 9.1.4., Column 2. In support of your adaptation, you provided the following justification: "*According to the Regulation (EC) No 1907/2006 (REACH) Annex VIII 9.1.4 column 2, the toxicity to microorganisms in water does not need to be determined if the substance is highly insoluble in water. Tests on water solubility of niobium have shown that the substance is highly insoluble 0.8 µg/L). If released into the STP, the insoluble niobium will be mostly removed in the primary settling tank and thus will not reach the activated sludge*".

Based on the information provided in your dossier we have identified the following issue:

Annex VIII, Section 9.1.4., Column 2 specifies that this information requirement may be adapted if:

- there are mitigating factors indicating that aquatic toxicity is unlikely to occur (e.g. the substance is highly insoluble) or;
- there is no emission to a sewage treatment plant.

As already explained under request A.1. above, the data provided in your dossier does not adequately support that aquatic toxicity is unlikely to occur. Furthermore, your dossier does not demonstrate that no emissions to a sewage treatment plant are expected. Hence your adaptation according to Annex VIII, Section 9.1.4., Column 2 is rejected.

Therefore, the information requirement is not fulfilled.

While selecting the test material you must take into account the impact of parameters relevant for the property to be tested. For the aquatic toxicity studies, you must justify that the selected test material properties (e.g. particle size) constitute a reasonable worst case to cover all the registrants of the Substance. Therefore the selected test material should correspond to the most soluble form of the substance taking into account the range of properties of the substance as registered under REACH.

Appendix C: Reasons for the requests to comply with Annex IX of REACH

Under Articles 10(a) and 12(1) of REACH, a technical dossier registered at 100 to 1000 tonnes or more per year must contain, as a minimum, the information specified in Annexes VII to IX to REACH.

1. **Sub-chronic toxicity study (90-day), inhalation route (Annex IX, Section 8.6.2.)**

A Sub-chronic toxicity study (90 day) is a standard information requirement in Annex IX to REACH.

You have not provided a sub-chronic toxicity study in your dossier. Instead, you have provided an adaptation according to Column 2 of Annex IX, Section 8.6.2. in your dossier. In support of your adaptation your state the following:

- *"Niobium is corrosion resistant and can be dissolved only under extreme and certainly non-physiological conditions* [...] *i. e. niobium is inert"*;
- *"Niobium has very low water solubility* [therefore] *very low solubility a very low absorption from the gastrointestinal tract subsequent to oral ingestion is likely. This assumption is supported by a bioaccessibility study* [...]. *Niobium is practically insoluble in biological media and consequently not bioavailable"*;
- *"No evidence of absorption and no evidence of toxicity were observed in two OECD Guideline 422 studies* [...] *at the limit dose of 1000 mg/kg bw/d with the special preparation of niobium, i. e. ferro niobium (*[redacted] *2010) and the read-across substance diniobium pentoxide (*[redacted] 2010)";
- *"It should be mentioned that metallic niobium can be manipulated without formation of any respirable dust"*;
- *"The substance is exclusively used at the industrial site, which assumes adequate protection measures for handling, exposure to humans in general is considered to be limited"*.

Annex IX, Section 8.6.2., Column 2 specifies that a sub-chronic toxicty study (90 days) does not need to be conducted if:

1. the substance is unreactive, insoluble and not inhalable, and
2. there is no evidence of absorption, and
3. there is no evidence in a 28-day 'limit test', particularly if such a pattern is coupled with limited human exposure.

Based on the information provided in your dossier we have identified the following issues:

a) As specified in ECHA Guidance R.7c, particles with aerodynamic diameters below 100 µm have the potential to be inhaled. Particles with aerodynamic diameters below 50 µm may reach the thoracic region and those below 15 µm the alveolar region of the respiratory tract. In your dossier, you have provided a granulometry study according to ISO 13320 with the Substance. The D50 was determined at 24.89 µm. Therefore you did not demonstrate that the Substance is not inhalable. Consequently, the condition set out in point 1 above is not fulfilled.

b) As specified in ECHA Guidance R.7a, the justification for the absence of absorption must be based on evidence that no absorption occurs. You provided a bioaccessibility study in articifial gastric fluid and in artificial sweat. The test material is described as *"metallic small pieces with a diameter/width < 1 mm and a length of approx. < 1mm*

to 2.5 mm". Therefore this study does not provide adequate information to cover the Substance as registered by you because lower solubilisation is expected as the particle size of the sample was significantly bigger than the information reported in your dossier. Furthermore low solubility in artificial fluid does not demonstrate that no absorption occur. Therefore, you did not demonstrate that the Substance is not absorbed by any relevant route of exposure. Consequently, the condition set out in point 2 above is not fulfilled.

c) With regard to human exposure, as explained in section i) of the Appendix on general considerations, the information from your dossier does not fulfil the criteria of Annex XI, Section 3.2. Therefore you did not demonstrate that human exposure is limited. Consequently, the condition set out in point 3 above is not fulfilled.

Therefore, your adaptation according to Annex IX, Section 8.6.2., Column 2 is rejected.

Based on the above the information requirement is not fulfilled.

Following the criteria provided in Annex IX, Section 8.6.2, Column 2, the inhalation route is the most appropriate route of administration to investigate repeated dose toxicity[2]. The sub-chronic toxicity study must be performed according to the OECD TG 413, in rats and with administration of the Substance by inhalation because:

- the Substance is present as fine particles with a significant proportion of particles of inhalable size;
- the use pattern of the Substance includes industrial spraying (PROC 7) in the scope of the registration and therefore human exposure to the Substance by the inhalation route is likely.

While selecting the test material you must take into account the impact of parameters relevant for the property to be tested. For the Substance, this includes the particle size. For the requested repeated dose toxicity study (inhalation route), you must justify that the test material has a particle size distribution small enough to cover all the registrants of the Substance.

2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.) in a first species

A Pre-natal developmental toxicity study in one species is a standard information requirement in Annex IX to REACH.

You have not provided a sub-chronic toxicity study in your dossier. Instead, you have provided an adaptation according to Column 2 of Annex IX, Section 8.7. in your dossier. In support of your adaptation your state the following:

- "*Niobium is corrosion resistant and can be dissolved only under extreme and certainly non-physiological conditions* [...] *i. e. niobium is inert*";
- "*Niobium has very low water solubility* [therefore] *very low solubility a very low absorption from the gastrointestinal tract subsequent to oral ingestion is likely. This assumption is supported by a bioaccessibility study* [...]. *Niobium is practically insoluble in biological media and consequently not bioavailable*";
- "*No evidence of absorption and no evidence of toxicity were observed in two OECD Guideline 422 studies* [...] *at the limit dose of 1000 mg/kg bw/d with the special*

[2] ECHA Guidance R.7a, Section R.7.5.6.3.4.

preparation of niobium, i. e. ferro niobium ([redacted] 2010) and the read-across substance diniobium pentoxide ([redacted] 2010)";
- *"It should be mentioned that metallic niobium can be manipulated without formation of any respirable dust";*
- *"The substance is exclusively used at the industrial site, which assumes adequate protection measures for handling, exposure to humans in general is considered to be limited".*

Based on the information provided in your dossier we have identified the following issues:

Annex IX, Section 8.7., Column 2 specifies that reproductive toxicity studies listed under this section do not need to be conducted if the following cumulative conditions are met:

1. the substance is of low toxicological activity (no evidence of toxicity seen in any of the tests available), and
2. it can be proven from toxicokinetics data that no systemic absorption occurs via relevant routes of exposure (e.g. plasma/blood concentrations below detection limit using a sensitive method and absence of the substance in urine, bile or exhaled air), and
3. there is no or no significant exposure.

With regard to the criteria listed above, we identified the following issues:

a) As specified in ECHA Guidance R.7a, the justification for the absence of absorption must be based on evidence that no absorption occurs. However, you did not provide any toxicokinetics data to prove that no systemic absorption occurs via any relevant routes of exposure. Therefore, the condition set out in point 2 above is not fulfilled.

b) With regard to human exposure, as explained in section i) of the Appendix on general considerations, the information from your dossier does not fulfil the criteria of Annex XI, Section 3.2. Consequently, you did not demonstrate that there is no or no significant human exposure.

Therefore, your adaptation according to Annex IX, Section 8.7., Column 2 is rejected.

Based on the above the information requirement is not fulfilled.

A PNDT study according to the test method OECD TG 414 must be performed in rat or rabbit as preferred species with oral[3] administration of the Substance.

3. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)

and

4. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.)

Long-term toxicity testing on aquatic invertebrates and on fish are standard information requirements in Annex IX to REACH.

[3] ECHA Guidance R.7a, Section R.7.6.2.3.2.

You have adapted this information requirement and you provided the following justification: "*For niobium metal the highest water solubility detected is 0.8 µg/L. Furthermore, Transformation-Dissolution tests performed with niobium in its massive or granular form (FeNb) revealed likewise low solubility's. In addition, these test showed that no metal transformation took place within 28 days. Thus, it can be concluded, that niobium remains stable and thus biologically inert during this time. In consequence, equally to acute aquatic toxicity tests, chronic aquatic toxicity tests are of no use for the assessment of niobium*".

We have assessed the information provided in your dossier with regard to the adaptation of the information requirement based on Annex IX, Section 9.1, Column 2 and we have identified the following issue:

In order to adapt the information requirement for long-term toxicity testing to aquatic invertebrates and to fish based on Annex IX, Section 9.1, Column 2, the Chemical Safety Assessment needs to demonstrate that risks towards the aquatic compartment arising from the use of the Substance are controlled (as per Annex I, section 0.1). The Chemical Safety Assessment needs to assess and document that risks arising from the Substance are controlled and demonstrate that there is no need to conduct further testing (Annex I, Section 0.1; Annex IX, Section 9.1, Column 2).

In particular, you need to take into account the following elements in your justification:

- all relevant hazard information from your registration dossier,
- the outcome of the exposure assessment in relation to the uses of the Substance,
- the outcome of the PBT/vPvB assessment including information on relevant constituents present in concentration at or above 0.1% (w/w).

For poorly water soluble substances (e.g. water solubility below 1 mg/L or below the detection limit of the analytical method of the test substance) long-term toxicity study on aquatic invertebrates and on fish) must be considered instead of an acute test (Column 2 of Annex VII, Section 9.1.1. and Annex VIII, Section 9.1.3.).

However, you have not provided any justification that the risks arising from the Substance are controlled, taking account all of the elements above.

As already explained under request A.1. and A.2., the Substance is poorly water soluble and can be tested at concentrations below its solubility limit.

Poorly water soluble substances require longer time to reach steady-state conditions. Hence, the short-term tests may not give a true measure of toxicity for this type of substances and the long-term test is required. Hence, in the absence of long-term testing on aquatic organisms your dossier does not include any relevant hazard information. Furthermore, you did not conduct an exposure assessment in relation to the uses of the Substance.

Therefore, your adaptation according to Annex IX, Section 9.1., Column 2 is rejected.

Based on the above, the information requirements on long-term toxicity testing on aquatic invertebrates and on fish set out in Annex IX Section 9.1.5 and 9.1.6.1, respectively, are not fulfilled.

While selecting the test material you must take into account the impact of parameters relevant

for the property to be tested. For the aquatic toxicity studies, you must justify that the selected test material properties (e.g. particle size) constitute a reasonable worst case to cover all the registrants of the Substance. Therefore the selected test material should correspond to the most soluble form of the substance taking into account the range of properties of the substance as registered under REACH.

Appendix D: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of registration dossiers after the date on which you were notified the draft decision according to Article 50(1) of REACH.

The compliance check was initiated on 02 April 2019.

ECHA notified you of the draft decision and invited you to provide comments within 30 days of the notification.

ECHA did not receive any comments within the 30-day notification period.

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 E: Observations and technical guidance

1. This compliance check decision does not prevent ECHA from initiating further compliance checks at a later stage on the registrations present.

2. Failure to comply with the requests in this decision, or to otherwise fulfil the information requirements with a valid and documented adaptation, will result in a notification to the enforcement authorities of the Member States.

3. Test guidelines, GLP requirements and reporting

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

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

   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: 'How to report robust study summaries'[4].

4. Test material

   Selection of the test material(s)

   The registrants of the Substance are responsible for agreeing on the composition of the test material to be selected for carrying out the tests required by the present decision. The test material selected must be relevant for all the registrants of the Substance, i.e. it takes into account the variation in compositions reported by all members of the joint submission. The composition of the test material(s) must fall within the boundary composition(s) of the Substance.

   While selecting the test material you must take into account 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.

   Technical reporting of the test material

   The composition of the selected test material must be reported in the respective endpoint study record, under the Test material section. The composition must include all constituents of the test material and their concentration values and, in this case particle size. Without such detailed reporting, ECHA may not be able to confirm that the test material is relevant for the Substance and to all the registrants of the Substance.

   Technical instructions are available in the manual "How to prepare registration and PPORD dossiers"[5].

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

5. List of references of the ECHA Guidance and other guidance/ reference documents[6]

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 in this decision.

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 in this decision.

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

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.

OECD Guidance documents[8]
Guidance Document on aqueous-phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD23.
Guidance Document on Mammalian Reproductive Toxicity Testing and Assessment – No 43, referred to as OECD GD43.

[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] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

Appendix F: List of the registrants to which the decision is addressed and the corresponding information requirements applicable to them

Registrant Name	Registration number	(Highest) Data requirements to be fufilled
[redacted]	[redacted]	[redacted]

Note: where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas the decision is sent to the actual registrant.