EUROPEAN CHEMICALS AGENCY

Helsinki, 28 July 2020

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

Date of submission for the jointly submitted dossier subject of this decision
02 March 2018

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Diniobium pentaoxide
EC number: 215-213-6
CAS number: 1313-96-8

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

2. 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

Each addressee of this decision is bound by the requests for information corresponding to the REACH Annexes applicable to their own registered tonnage of the Substance at the time of evaluation of the jointly submitted dossier.

To identify your legal obligations, please refer to the following:

- you have to comply with the requirements of Annex VII of REACH, if you have registered a substance at 1-10 tonnes per annum (tpa), or as a transported isolated intermediate in quantity above 1000 tpa;
- you have to comply with the requirements of Annexes VII and VIII of REACH, if you have registered a substance at 10-100 tpa;
- you have to comply with the requirements of Annexes VII, VIII and IX of REACH, if you have registered a substance at 100-1000 tpa.

Registrants are only required to share the costs of information that they must submit to fulfil the information requirements for their registration.

When a study is required under several Annexes of REACH, the reasons are provided in the corresponding appendices of this decision. The registrants concerned must make every effort to reach an agreement as to who is to carry out the study on behalf of the other registrants in accordance with Article 53 of REACH.

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:

- *"under normal use and handling conditions, inhalation exposure and thus availability for respiratory absorption of the substance in the form of dusts is not significant";*
- *"the substance is exclusively used at the industrial site, which assumes adequate protection measures for handling".*

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 contained by technical means, it is demonstrated and documented that:
- 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 your read-across adaptations (Annex XI, Section 1.5.)

While you did not claim an adaptation according to Annex XI, Section 1.5., you use information on "*dissolved zinc*" as a "*worst-case scenario*" to predict the ecotoxicological properties of the Substance for the following endpoints:

- Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.)
- Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)
- Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.)
- Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)
- Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.)

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[2] and related documents[3,4].

[2] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals. 2008 (May) ECHA, Helsinki. 134. pp. Available online: https://echa.europa.eu/documents/10162/13632/information_requirements_r6_en.pdf/77f49f81-b76d-40ab-8513-4f3a533b6ac9

[3] 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)

[4] 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

For the endpoints listed above, you refer to data on "*dissolved zinc*". You did not provide any documentation of this read-across adaptation either in Section 13 of your technical dossier or in your CSR so condition (iii) as listed above is not met.

We also note that condition (i) requiring structural similarity between substances is not met as "dissolved zinc" and the Substance are not structurally similar.

Consequently, your adaptations fail to comply with the general rules of adaptation as set out in Annex XI, Section 1.5 and are therefore rejected.

In your comments on the draft decision, you acknowledge that information provided for dissolved zinc does not adequately support that aquatic toxicity is unlikely to occur. You intend to predict the properties of the Substance from information obtained from Niobium pentachloride (EC no. 233-059-8 / CAS no. 10026-12-7) for the following endpoints:

- Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.)
- Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)
- Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.)

You provide the following reasoning for the prediction of ecotoxicological properties:

- As specified in the executive summary of the MISA 2 workshop (ECHA, 7 February 2019), you explain that the direct aquatic ecotoxicity testing of metals and sparingly soluble metal salts (SSMCs) is in principle not recommended. You state that Niobium pentachloride is well soluble in water and therefore constitute a valid alternative to the testing of the Substance.
- You indicate that following dissolution of Niobium pentachloride, dissolved Niobium species undergo rapid hydrolysis. You refer to a study conducted according to a Transformation/Dissolution protocol similar to the screening test of OECD GD 29 to show that the dissolution of the source leads to higher concentrations in dissolved Niobium compared to the Substance.
- You consider that the effects observed in some short-term toxicity study on Niobium pentachloride are not relevant for the Substance as they were observed at concentrations over the upper dissolution limit of the Substance.

ECHA understands that you intend to predict the ecotoxicological properties of the Substance using a read-across hypothesis which is based on the similar structure and on the formation of the same dissolved Niobium forms. The properties of your Substance are predicted based on a worst-case approach.

In principle, ECHA agrees that the aquatic ecotoxicity testing of a soluble form is to be preferred to the direct testing of metals or of sparingly soluble metal forms. We consider that the testing of Niobium pentachloride may provide relevant information to cover the information requirements for the Substance. However, concerning the predictions of ecotoxicological properties based on the data on Niobium pentachloride described in your comments on the draft decision, ECHA notes the following shortcomings:

1) 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, Section 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).Supporting information must include information to confirm your claimed worst-case prediction.

As indicated above, your read-across hypothesis is based on the transformation of the Substance and of the source substance to the same dissolved Niobium forms. In this context, reliable information characterising the rate and extent of the solubilisation of the Substance and of the source substance(s) is necessary to support your predictions. Therefore adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3) must be provided. For metals of sparingly soluble metal compounds, the Transformation/Dissolution study in aqueous media (Annex 10 of UN-GHS and OECD GD 29) is the recommended method (ECHA Guidance R7.a, Section R.7.1.1.1). This method requires that the following conditions are met:

- The test material must be representative of the Substance and must correspond to the smallest representative particle size on the market;
- The screening study is performed by adding the test substance in the aqueous medium at a single loading of 100 mg/L;
- The screening test must cover a pH range from 5.5 up to 8.5. The full test must be carried out at a pH that maximizes the concentration of the dissolved metal ions in solution.

You have provided the following studies on the solubilisation of the Substance and of the source substance in water:

(i) a GLP compliant Transformation/Dissolution study according to OECD GD 29 with the Substance ([redacted], 2010) already included in your technical dossier,
(ii) a reference, in your comments on the draft decision, to a study conducted according to a Transformation/Dissolution protocol similar to the screening test of OECD GD 29 and performed with Niobium pentachloride.

With regard to study (ii), you state that the preliminary study was conducted at a loading rate of 11.5 to 14 g/L. You have not specified at which pH maximum solubilisation was achieved. We conclude that the test was conducted at extremely high loading rates with no justification and that you have not demonstrated that it was conducted at a pH that maximizes the concentration of the dissolved metal ions in solution

With regard to study (i), the highest pH tested was 8 and therefore this study did not cover the mandotory pH range from 5.5 up to 8.5. As higher dissolution was observed with increasing pH, higher dissolution may be expected at pH 8.5. In addition, as already explained under issue B. of request A.1, you have not demonstrated that the test material used to conduct this study is adequate to cover all forms of the Substance included in your registration.

In your comment, you acknowledge the test material (e.g. particle size, degree of hydration) used to conduct the Transformation/Dissolution study may have an impact on the evaluation of the properties of the Substance. You state that you "*will take into account the test materials used in the physico-chemical studies as well as their properties (e.g. particle size, degree of hydration) for the evaluation. If necessary, the additional tests (e.g. granulometry and T/D tests) on different crystalline forms will be performed in order to enable assessment of ecotoxicological properties of the substance*". Nevertheless you consider that this information support that "*Diniobium pentaoxide is expected to release in any case less Niobium species in water compared to Niobium pentachloride regardless the crystalline forms, due to the nature of target and source substances (metal oxide vs. salt)*". However, you have not provided adequate and reliable information to support this claim.

2) Reliability of the source studies

According to Annex XI, Section 1.5., if the grouping concept is applied then in all cases the results to be read across must have adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3).

In your comments on the draft decision, you refer to acute toxicity studies conducted on the source substance Niobium pentachloride, including a short-term toxicity study on aquatic invertebrates according to OECD TG 202, a growth inhibition study on aquatic plants according to OECD TG 201 and a short-term toxicity testing on fish according to OECD TG 203. You have not provided a robust study summary for any of these studies.

In the absence of adequate reporting of the methodology and results obtained in these studies ECHA is not in a position to evaluate the adequacy and reliability of this information. In particular it is not possible to verify the identity of the test material used (including purity and presence of impurities), if an adequate experimental set-up was used (e.g. adequacy of the test medium, pH of the test medium during the test period, spacing factor between test concentrations, adequacy of the selected test organisms) and in general if the validity criteria of the corresponding test guidelines were fulfilled.

3) Adequacy of the source studies

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 acute tests as specified in Annex VII, Section 9.1.1., Column2).

With regard to the studies on the source substance, you explain that some effects were observed at very high loading rates for aquatic invertebrates and algae. However you report that EC/LC/IC50 concentrations were above the highest loading rate. While the highest loading rate in these studies were ≥ 100 mg/L, you report that measured concentration in dissolved Niobium were in the 1-10 µg/L range.

We note that measured concentrations in dissolved Niobium species were well below 1 mg/L. This information indicate that upon dissolution Niobium pentachloride is transformed into poorly water soluble tantalum species. Poorly water soluble substances require longer time to reach steady-state conditions and therefore, the long-term test is required. You have not submitted long term studies and based on the limited information reported by you, the selected studies do not provide adequate information on aquatic toxicity to aquatic invertebrates and to fish for the source substance.

Conclusion:

Based on what was explained above, the information included in your comments on the source substance does not provide a reliable basis to predict the properties of the Substance. In the absence adequate and reliable information on the solubiliation of the source substance and of the Substance, you have not established that the source substance constitutes a worst-case for the prediction of the properties under consideration of the Substance. Therefore you have not provided sufficient supporting information to strengthen the rationale for the read-across.

Consequently, the proposed adaptations fail to comply with the general rules of adaptation as set out in Annex XI, Section 1.5 and are therefore 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. 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 a study conducted according to OECD GD 29 (transformation/dissolution of metals and metal compounds in aqueous media), the water solubility of the Substance was determined to be < 0.5 µg/L;
- the water solubility estimate of 0.5 µg/L is below the $PNEC_{aquatic,\ freshwater}$ for dissolved Zinc (i.e. 7.8 µg/L). You state that Zinc is known to be very toxic to the aquatic environment and is labelled as aquatic acute (and chronic) toxicity 1 according to regulation 1272/2008/EEC. You consider that it can be seen as a "*worst-case scenario*" for the Substance. You conclude that any adverse effect below the water solubility of the Substance can be excluded and testing – whether short-term or long-term – can be omitted.

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

A. 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. You report that, at a loading of 100 mg/L, the test sample used to conduct the study has a water solubility of 0.36 µg/L at pH 8 after 7 days of stirring. Therefore, 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.

B. While a registrant is at liberty to give a broad definition of the substance which it intends to register, the hazards posed by all possible forms of the substance covered by the substance definition must be addressed by the toxicological and ecotoxicological information provided in the registration dossier[5].

[5] Decision of the Board fo Appeal of ECHA of 2 March 2017 in case A-011-2014, *Huntsman P&A UK Limited*, paragraph 49.

In section 1.2. of your technical dossier, you provide a broad definition of the Substance. You indicate that the Substance includes three crystalline forms (i.e. monoclinic, orthorhombic and amorphous) some having different grades as shown by different loss-on-ignition (LOI) values (i.e. degree of hydration). However, you have provided the results of a transformation/dissolution study according to OECD GD 29 and a granulometry according to OECD TG 110 on a single crystalline form of the substance.

For the Substance, the crystalline structure, the hydration level and granulometry are relevant properties to enable assessment of the ecotoxicological properties of the Substance as they impact dissolution of metal oxides (e.g. Blesa, 2018[6]). You did not provide a justification that the information used to support your adaptation is adequate to cover all forms of the Substance included in your registration. Therefore, your adaptation according to Annex VII, Section 9.1.2., Column 2 is rejected.

C. While you did not claim an adaptation according to Annex XI, Section 1.5., you use information on *"dissolved zinc"* as a *"worst-case scenario"* to predict the ecotoxicological properties of the Substance. As explained in section ii) of the Appendix on general considerations, your adaptation is rejected.

In your comments on the draft decision you explain that you intend to cover this information through an adaptation according to Annex XI, Section 1.5 using information on the source substance Niobium pentachloride (EC no. 233-059-8 / CAS no. 10026-12-7). However, for the reasons explained under the Appendix on general considerations, your adaptation 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 Substance, this includes the particle size, the crystal structure and the degree of hydration. For the aquatic toxicity studies, you must justify that the selected test material properties (e.g. particle size, degree of hydration) 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.

2. The long-term toxicity testing on aquatic invertebrates also requested at C.3. 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 VII, Section 9.1.1., Column 2.

In support of your adaptation, you provided the following justification:

- in a study conducted according to OECD GD 29 (transformation/dissolution of metals and metal compounds in aqueous media), the water solubility of the Substance was determined to be < 0.5 µg/L;

[6] Blesa M.A., 2018. Chemical dssolution of metals. CRC Press, 484 pp.

- the water solubility estimate of 0.5 µg/L is below the $PNEC_{aquatic, freshwater}$ for dissolved Zinc (i.e. 7.8 µg/L). You state that Zinc is known to be very toxic to the aquatic environment and is labelled as aquatic acute (and chronic) toxicity 1 according to regulation 1272/2008/EEC. You consider that it can be seen as a "worst-case scenario" for the Substance. You conclude that any adverse effect below the water solubility of the Substance can be excluded and testing – whether short-term or long-term – can be omitted.

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:
   - 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 aquatic invertebrates is available.

   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. 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. While you did not claim an adaptation according to Annex XI, Section 1.5., you use information on "dissolved zinc" as a "worst-case scenario" to predict the ecotoxicological properties of the Substance. As explained in section ii) of the Appendix on general considerations your adaptation is rejected.

In your comments on the draft decision, you refer to a publication by [redacted] (2005) which reports the results of toxicity tests on *Hyalella azteca* following 7 days of exposure. You considerthat this study "*confirm*[s] *the low toxicity of Niobium species and reveal that no effects are expected by Diniobium pentaoxide towards aquatic invertebrates*".

We have assessed the information provided in your comments on the draft decision and we identified the following issue:

As already explained under issue A. above, the Substance is poorly water soluble and therefore information on long-term toxicity to aquatic invertebrates must be provided. Tests on substances must be conducted in accordance with the OECD test guidelines or other internationally recognised test method (Article 13(3) of REACH). Among others, the OECD TG 211 requires that the following conditions are met:
- the exposure duration is 21 days,
- the key parameter investigated is the reproduction output of parent animals.

In the study by [redacted] (2005), the exposure duration was 7 days and the parameter monitored was mortality.

Hence this study does not provide an adequate coverage of the key parameters foreseen to be investigated in an OECD TG 211 study and is therefore not relevant to cover this information requirement.

In your comments on the draft decision you also explain that you intend to cover this information through an adaptation according to Annex XI, Section 1.5 using information on

the source substance Niobium pentachloride (EC no. 233-059-8 / CAS no. 10026-12-7). However, for the reasons explained under the Appendix on general considerations, your adaptation is rejected.

Therefore, the information requirement is not fulfilled.

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.4. 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 a study conducted according to OECD GD 29 (transformation/dissolution of metals and metal compounds in aqueous media), the water solubility of the Substance was determined to be < 0.5 µg/L;
- the water solubility estimate of 0.5 µg/L is below the $PNEC_{aquatic,\ freshwater}$ for dissolved Zinc (i.e. 7.8 µg/L). You state that Zinc is known to be very toxic to the aquatic environment and is labelled as aquatic acute (and chronic) toxicity 1 according to regulation 1272/2008/EEC. You consider that it can be seen as a "worst-case scenario" for the Substance. You conclude that any adverse effect below the water solubility of the Substance can be excluded and testing – whether short-term or long-term – can be omitted.

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

A. 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.1. 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 VII, Section 9.1.3., Column 2 is rejected.

B. Then, while you did not claim an adaptation according to Annex XI, Section 1.5., you use information on "dissolved zinc" as a "worst-case scenario" to predict the ecotoxicological properties of the Substance. As explained in section ii) of the Appendix on general considerations your adaptation is rejected.

In your comments on the draft decision you explain that you intend to cover this information requirement through an adaptation according to Annex XI, Section 1.5 using information on the source substance Niobium pentachloride (EC no. 233-059-8 / CAS no. 10026-12-7). However, for the reasons explained under the Appendix on general considerations, your adaptation is rejected.

Therefore, the information requirement is not fulfilled.

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 already 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:

- *"The toxicity to microorganisms in water does not need to be determined* [as] *the substance is insoluble (< 0.5 µg/L)"*;
- *"For a substance being considered as insoluble, it can be assumed that it will be adsorbed and removed within the STP process"*.

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 emission to a sewage treatment plant are expected. Hence your adaptation according to Annex VIII, Section 9.1.4., Column 2 is rejected.

In your comments on the draft decision you state that *"a toxicity study towards aquatic microorganisms according to the OECD guideline 209 is available with the substance Diniobium pentaoxide (CAS 1313-96-8), which shows no effects towards aquatic microorganisms and will be used to update the dossier"*. You have not provided the robust study summary. Therefore, ECHA is not able to assess the relevance and reliability of this new study taking into account the elements described above.

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 Substance, this includes the particle size, the crystal structure and the degree of hydration. For the aquatic toxicity studies, you must justify that the selected test material properties (e.g. particle size, degree of hydration) 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 provided a key study by [redacted] (2010) according to OECD TG 422 (oral route) with the Substance.

You have also provided an adaptation according to Column 2 of Annex IX, Section 8.6.2. and Annex XI, Section 1.2. in your dossier. In support of your adaptations, you state that "*the physiochemical properties of the substance demonstrate no hazardous potential*". You consider that "*low bioavailability in humans is anticipated for the substance after any route of exposure*" as:

- "*the substance has a very low water* [...]*, being suggestive of very low absorption from the gastrointestinal tract subsequent to oral ingestion*" and "*data on the subacute (28-day) oral toxicity* ([...] *according to OECD 422)* [...] *did not indicate any adverse systemic effects and any adverse* [up to the] *limit dose* [i.e. 1000 mg/kg bw]*"*;
- *"Although the substance contains particles of inhalable size (> 90% with diameter of 69.4 µm), it is not considered to be absorbed in significant amounts, as it does not reach the thoracic or alveolar region due to their particle size higher than 50 and 10 µm, respectively";*
- *"Although the molecular weight of the substance is suggestive of dermal uptake, the physical state in combination with the very low water solubility of the substance is suggestive of very low absorption through the skin";*

Finally, you consider that there is limited human exposure as:

- *"under normal use and handling conditions, inhalation exposure and thus availability for respiratory absorption of the substance in the form of dusts is not significant";*
- *"the substance is exclusively used at the industrial site, which assumes adequate protection measures for handling".*

You conclude that "*in accordance with Annex XI, Section 1.2 of Regulation (EC) 1907/2006 further testing on vertebrate animals for that property shall be omitted and further testing not involving vertebrate animals may be omitted".*

We have assessed the information you provided in your dossier according to the requirements set out in Annex XI, Section 1.2. and Annex IX, Section 8.6.2., Column 2. We have identified the following issues:

A. Annex XI, Section 1.2 states that there may be sufficient weight of evidence from several independent sources of information leading to assumption/conclusion that a substance has or has not a particular dangerous (hazardous) property, while information from a single source alone is insufficient to support this notion.
In order to allow concluding on the properties of the Substance with regard to this endpoint based on a weight of evidence, the justification must include an adequate and reliable coverage of the key parameters foreseen to be investigated in subchronic toxicity study (90-day).

You have submitted a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422). However, this study does not have an exposure duration of 90 days as required for a sub-chronic toxicity study because the exposure duration of the screening test is approximately 54 days (for females) and 28 days (for males). Furthermore the organ weight and histopathological investigations in OECD TG 422 are only conducted using 5 animals per sex per group and not 10 per sex per group as in OECD TG 413.

Therefore, the weight-of-evidence justification you provided does not provide reliable coverage of the key parameters foreseen to be investigated in subchronic toxicity study (90 days). Consequently, your weight-of-evidence adaptation is not supported by adequate information to evaluate the properties of Substance for this endpoint and your adaptation is rejected.

B. Annex IX, Section 8.6.2., Column 2 specifies that a sub-chronic toxicity study (90 days) does not need to be conducted if all the following conditions are met:
   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.

On this attempt to adapt the information requirement we have identified the following issues:

a) Niobium oxides may be used as solid acid catalysts due to their surface acidic properties. Therefore the physico-chemical properties of the Substance do not support that it has no inherent chemical reactivity. Consequently, the condition set out in point 1 above is not fulfilled.

b) 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. As already explained under request A.1., you did not provide a justification that the data on granulometry included in your dossier represents the smallest representative particle size covered by your registration. However, the granulometry study you submitted, conducted according to OECD TG 110, already shows a D50 of 40.34 µm. Therefore you did not demonstrate that the Substance is not inhalable. Consequently, the condition set out in point 1 above is not fulfilled.

c) As specified in ECHA Guidance R.7a, the justification for the absence of absorption must be based on evidence that no absorption occurs. You provide statements that absorption is not significant but these statements are not supported by experimental evidence in your dossier, showing that the Substance is not absorbed by any relevant route of exposure. Therefore, the condition set out in point 2 above is not fulfilled.

d) 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. Therefore, the condition set out in point 3 above is not fulfilled.

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

Based on the above, the information requirement is not fulfilled.

In your comment on the draft decision, you specify that you agree to conduct the requested study.

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[7]. 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) 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, the crystal structure and the degree of hydration. 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 provided a key study by [redacted] (2010) according to OECD TG 422 (oral route) with the Substance.

You have also provided an adaptation according to Column 2 of Annex IX, Section 8.7. in your dossier. In support of your adaptation, you state that *"all available data show that the substance is of very low acute toxicity after oral, dermal and inhalation exposure"* and that *"data* [from a] *combined repeated dose toxicity and reproduction/developmental screening test according to OECD 422* [...] *demonstrate no adverse systemic effects after oral exposure and no effects on fertility and intrauterine development in rats up to the highest dose tested* [i.e. 1000 mg/kg bw]*"*.
You also consider that *"low bioavailability in humans is anticipated for the substance after any route of exposure"* as:

- *"the substance has a very low water* [...]*, being suggestive of very low absorption from the gastrointestinal tract subsequent to oral ingestion"*;
- *"Although the substance contains particles of inhalable size (> 90% with diameter of 69.4 µm), it is not considered to be absorbed in significant amounts, as it does not reach the thoracic or alveolar region due to their particle size higher than 50 and 10 µm, respectively"*;
- *"Although the molecular weight of the substance is suggestive of dermal uptake, the physical state in combination with the very low water solubility of the substance is*

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

suggestive of very low absorption through the skin".
You conclude that *"based on the physicochemical and toxicological properties, there is sufficient weight of evidence provided leading to the assumption/conclusion that the substance is not toxic to reproduction. Therefore, in accordance with Annex XI, Section 1.2 of Regulation (EC) 1907/2006 further testing on vertebrate animals for that property shall be omitted and further testing not involving vertebrate animals may be omitted".*

Based on the information you provided we have assessed the information in your dossier according to the requirements set out in Annex XI, Section 1.2. and Annex IX, Section 8.7., Column 2.

A. Annex XI, Section 1.2 states that there may be sufficient weight of evidence from several independent sources of information leading to assumption/conclusion that a substance has or has not a particular dangerous (hazardous) property, while information from a single source alone is insufficient to support this notion. In order to allow concluding on prenatal developmental toxicity for the Substance in a weight of evidence adaptation, the justification must cover the key parameters foreseen to be investigated in a prenatal developmental toxicity study (OECD TG 414) (i.e. effects of prenatal exposure to the Substance on the pregnant test animal and on the developing organism).

   You have submitted a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422). However, such study does not provide equivalent information to a pre-natal developmental toxicity study as some of the key parameters required by OECD TG 414 are not investigated. This includes histopathology of the thyroid gland / thyroid hormone measurements / gravid uterus weight in dams; detailed skeletal and soft tissue alterations (variations and malformations); measurement of anogenital distance in live rodent foetuses. In addition, the number of test animals is lower, leading to lower statistical power. Hence the study you submitted does not provide equivalent information to a pre-natal developmental toxicity study.

   Therefore, your weight of evidence adaptation is not supported by adequate information to evaluate the properties of Substance for this endpoint and your adaptation is rejected.

B. 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.

   On this attempt to adapt the information requirement we have 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. You provide statements

that absorption is not significant. Under section 7.1 you also provided a "bioaccessibility study" according to OECD GD 29 with artificial sweat and artificial gastric fluid as dilution medium. 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[8] administration of the Substance.

In your comment on the draft decision, you specify that you agree to conduct the requested study.

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.

You have adapted these information requirements based on Column 2 of Annex VII, Section 9.1.1. and Annex VIII, Section 9.1.3. In support of your adaptation, you provided the following justification:

- in a study conducted according to OECD GD 29 (transformation/dissolution of metals and metal compounds in aqueous media), the water solubility of the Substance was determined to be < 0.5 µg/L;
- the water solubility estimate of 0.5 µg/L is below the $PNEC_{aquatic,\ freshwater}$ for dissolved Zinc (i.e. 7.8 µg/L). You state that Zinc is known to be very toxic to the aquatic environment and is labelled as aquatic acute (and chronic) toxicity 1 according to regulation 1272/2008/EEC. You consider that it can be seen as a *"worst-case scenario"* for the Substance. You conclude that any adverse effect below the water solubility of the Substance can be excluded and testing – whether short-term or long-term – can be omitted.

The adaptation based on Column 2 of Annex VII, Section 9.1.1. or Annex VIII, Section 9.1.3 does not apply to the information requirement for long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.) and on fish (Annex IX, Section 9.1.6.). Therefore, we have assessed the information provided in your dossier with regard to the adaptation of

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

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 to aquatic invertebrates and on 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).

In addition, 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 of all the elements above.

You have provided the results of a transformation/dissolution study according to OECD GD 29. You report that, at a loading of 100 mg/L, the test sample used to conduct the study has a water solubility of 0.36 µg/L at pH 8 after 7 days of stirring. As explained under request A.1., you did not demonstrate that the water solubility estimate provided in your technical dossier is adequate to cover all forms of the Substance included in your registration. While there are remaining uncertainties regarding the relative water solubility of the various forms of the Substance, ECHA considers that the information provided is sufficient to conclude that the Substance is poorly water soluble.

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 tests are 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.

In your comments on the draft decision, you indicate that you disagree with the request to perform long-term toxicity tests with aquatic invertebrates and fish and you provide the following justification:
- No effects were observed in a short-term toxicity study on fish according to OECD TG 203 with the source substance Niobium pentachloride. Similarly, no effects were observed in a short-term toxicity to *Daphnia magna* according to OECD guideline 202 up to the limit of solubility of Niobium pentachloride (Okamoto *et al.*, 2014);
- You refer to T/D tests according to OECD guideline 29 on the Substance and the

source substance Niobium pentachloride which shows that for both subsances measured dissolved concentrations in Niobium are in the µg/L range or below;
- Based on the above, you conclude that toxicity to aquatic organisms is unlikely. You further state that dissolved Niobium species undergo rapid hydrolysis to insoluble forms and the "*physical effects to the tested organisms during a long-term test cannot be excluded*".

As a consequence, we understand that you still intend to adapt these information requirements according to Annex IX, Section 9.1., Column 2. You now intend to support your adaptation by providing information on the source substance Niobium pentachloride.

However, for the reasons explained under the General consideration section, your read-across adaptation based on Annex XI, Section 1.5 is rejected.

Based on the above, the information provided in your comments on the source substance Niobium pentachloride does not further substantiate that the risks of the Substance are adequately controlled.

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 Substance, this includes the particle size, the crystal structure and the degree of hydration. For the aquatic toxicity studies, you must justify that the selected test material properties (e.g. particle size, degree of hydration) 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 22 February 2019.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

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

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 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[9]'.

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 other parameters relevant for the property to be tested, in this case the crystal form, the particle size and the degree of hydration of the test material. 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.

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

Technical instructions are available in the manual "How to prepare registration and PPORD dossiers"[3].

5. List of references of the ECHA Guidance documents[10]

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)11

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[12]
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.

[10] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[11] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[12] 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.