Helsinki, 28 July 2020

Addressees
Registrants of JS_Ditapento_215-238-2 listed in the last Appendix of this decision

Date of submission for the jointly submitted dossier subject of this decision
24 August 2017

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: DITANTALUM PENTAOXIDE
EC number: 215-238-2
CAS number: 1314-61-0

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)

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

1. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method OECD TG 408) 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 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 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:

- A key study by [redacted] (2012) according to EU test method A.6 and OECD TG 105 with the Substance (Batch no. [redacted]);
- A supporting study by [redacted] (2012) according to EU test method A.6 and OECD TG 105 with the Substance (Batch no. [redacted]);
- References to handbooks by Kirk (1997), O'Neyl *et al.* (2006) and Clayton (1981) which refer to the Substance as being insoluble in water.

We have assessed this information and identified the following issues:

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 both experimental studies, you specify that, although the water solubility, determined during the preliminary test, was below 10 mg/L, the flask method was used as the substance is inorganic and cannot be coated on the media utilised for the column elution method. For the study by [redacted] (2012), slow stirring at < 100 rpm was employed and you report a water solubility < 5 µg/L at 20.0°C after five days of stirring. For the study by [redacted] (2012), you report a water solubility < 1 mg/L at 30°C after 3 days stirring.

Based on the information you provided the column elution method is not applicable. 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. Although you do not explicitly claim an adaptation, the reference to the handbooks by Kirk (1997), O'Neyl *et al.* (2006) and Clayton (1981) may be interpreted as an attempt to meet the information required by way of adaptation under Annex XI, Section 1.1.1. Under this adaptation rule the data from experiments not carried out according to GLP or the test methods referred to in Article 13(3) can be considered equivalent to data generated by those test methods where a number of cumulative conditions are met, in particular:
   - The data are valid for the endpoint being investigated and the study is performed using acceptable level of quality assurance,
   - Adequate and reliable documentation of the study is provided, and
   - Adequacy for the purpose of classification and labelling and/or risk assessment.

For each of these three sources of information you state the following: "*Tantalum pentoxide was described as insoluble in water, according to a peer reviewed handbook.*

A specific value has not been provided. The method or guidelines followed have not been mentioned".

As no information is available on the identity and purity of the test substance and on the methodology used to make the measurement, the reliability of the data is not demonstrated. Furthermore, none of these secondary data sources provide a quantitative estimate of the water solubility of the Substance. Hence this information is not adequate for classification and labelling and/or risk assessment. Therefore your adaptation is rejected.

Therefore, the information requirement is not fulfiled.

In your comments on the draft decision you agreed to conduct the requested study. You also indicate that you intend to "*provide additional information on bioavailability of ditantalum pentoxide in different artificial body fluids*".

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 on the market. It also states that the specific surface area of the test material must be determined.

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.

In your dossier, you have provided a key study ([redacted], 2000) conducted according to OECD TG 201 and EU C.3. with the Substance (Batch no. [redacted]).

We have assessed this information and identified the following issue:

Tests on substances must be conducted in accordance with the OECD test guidelines or another internationally recognised international test method (Article 13(3) of REACH). For this endpoint the preferred test method is the OECD TG 201 which requires that the following conditions are met:

- a validated method for the quantification of the substance in the test solutions with reported recovery efficiency and limit of detection must be available;
- the test solutions should be analysed to verify the initial concentrations and maintenance of the exposure concentrations during the test;
- where test concentrations are unlikely to remain within 80-120 % of nominal, it is recommended to measure all test concentrations at the beginning and at the end of the test.

In your technical dossier you specify that no analytical monitoring was conducted and you provide the following justification: "*considering the low aqueous solubility of the test substance (< 1 mg/L) no specific analysis was established*".

However, the fact that the Substance may be poorly water soluble (i.e. water solubility < 1 mg/L) is not a valid reason to omit the need to verify the exposure levels during the test. Indeed poorly water soluble substance may be lost from the test medium by

e.g. precipitation and therefore nominal concentrations will not reflect the true exposure to the test substance. Hence the conditions of OECD TG 201 are not met.

In your comments on the draft decision you have not discussed the issues identified on the study by [redacted] (2000). You provide a statement which indicates that you intend to adapt this information requirement according to Annex XI, Section 1.5. However, you have not provided a read-across justification document. Therefore, ECHA is not in a position to evaluate the relevance and reliability of the proposed adaptation.

Therefore, the information requirement is not fulfiled.

Study design

The OECD TG 201 recommends to use the OECD medium to conduct testing on heavy metals. In this test medium, the molar ratio of EDTA to iron only slightly exceed unity. This prevents iron precipitation and, at the same time, chelation of heavy metal ions is minimised.

Furthermore 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.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.

In your dossier, you have provided a key study ([redacted], 2001) conducted according to OECD TG 202 and EU C.2. with the Substance (Batch no. [redacted]).

We have assessed this information and identified the following issues:

A. Tests on substances must be conducted in accordance with the OECD test guidelines or another internationally recognised international test method (Article 13(3) of REACH). For this endpoint the preferred test method is the OECD TG 202 which requires that the following conditions are met:
   - The concentration of the test substance must be measured, as a minimum, at the highest and lowest test concentration, at the beginning and end of the test

   In your technical dossier you specify that no analytical monitoring was conducted and you provide the following justification: "*considering the low aqueous solubility of the test substance (< 1 mg/L) no specific analysis was established*".

   However, the fact that the Substance may be poorly water soluble (i.e. water solubility < 1 mg/L) is not a valid reason to omit the need to verify the exposure levels during the test. Indeed poorly water soluble substance may be lost from the test medium by

e.g. precipitation and therefore nominal concentrations will not reflect the true exposure to the test substance. Hence the conditions of OECD TG 202 are not met.

B. Poorly water soluble substances require longer time to reach steady-state conditions[2]. 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.

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 Substance, we consider that the information provided is sufficient to conclude that it is poorly water soluble (i.e. water solubility below 1 mg/L).

In your comments on the draft decision you have not discussed the above assessment on the study by [redacted] (2001). You provide a statement which indicates that you intend to adapt this information requirement according to Annex XI, Section 1.5. However, you have not provided a read-across justification document. Therefore, ECHA is not in a position to evaluate the relevance and reliability of the proposed adaptation.

In addition, in your comments you acknowledge that "*poorly water-soluble substances require longer time to reach steady-state conditions*" but that you request not "*to confuse equilibration time during solubilisation and exposure periods during toxicity tests*". However, you do not provide any supporting evidence to substantiate that the duration of short-term toxicity test is sufficient to reach steady-state conditions despite the low solubility of the Substance.

Therefore, the information requirement is not fulfiled.

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.

[2] ECHA Guidance R.7b, Section R.7.8.10.3.

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.

In your dossier, you have provided:
1. a key study ([redacted], 2001) conducted according to OECD TG 203 and EU C.1. with the Substance;
2. A supporting study ([redacted], 2004) conducted according to OECD TG 203 with the Substance.

We have assessed this information and identified the following issues:

A. Tests on substances must be conducted in accordance with the OECD test guidelines or another internationally recognised international test method (Article 13(3) of REACH). For this endpoint the preferred test method is the OECD TG 203 requires that the following conditions are met:
   - There must be evidence that the concentration of the substance being tested has been satisfactorily maintained, and preferably it should be at least 80 per cent of thenominal concentration throughout the test.

   In your technical dossier, on the key study ([redacted], 2001), you specify that no analytical monitoring was conducted and you provide the following justification: "*considering the low aqueous solubility of the test substance (< 1 mg/L) no specific analysis was established*". On the supporting study ([redacted], 2004), you did not report the result of any analytical monitoring of exposure.

   The fact that the Substance may be poorly water soluble (i.e. water solubility < 1 mg/L) is not a valid reason to omit the need to verify the exposure levels during the test. Hence, in none of the reported study, adequate information is available to demonstrate that the concentration of the substance being tested has been satisfactorily maintained and the conditions of OECD TG 202 are not met.

B. Poorly water soluble substances require longer time to reach steady-state conditions[3]. 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.

   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 Substance, we consider that the information provided is sufficient to conclude that it is poorly water soluble (i.e. water solubility below 1 mg/L).

[3] ECHA Guidance R.7b, Section R.7.8.10.3.

In your comments on the draft decision you have not discussed the above assessment on the studies by [redacted] (2001) and [redacted] (2004). You provide a statement which indicates that you intend to adapt this information requirement according to Annex XI, Section 1.5. However, you have not provided a read-across justification document. Therefore, ECHA is not in a position to evaluate the relevance and reliability of the proposed adaptation.

In addition, in your comments you acknowledge that "*poorly water-soluble substances require longer time to reach steady-state conditions*" but that you request not "*to confuse equilibration time during solubilisation and exposure periods during toxicity tests*". However, you do not provide any supporting evidence to substantiate that the duration of short-term toxicity test is sufficient to reach steady-state conditions despite the low solubility of the Substance.

Therefore, the information requirement is not fulfiled.

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.

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), oral route (Annex IX, Section 8.6.2.)

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

In your dossier, you have provided:

1. a key study ([redacted], 2016) conducted according to OECD TG 422 with the analogue substance Tantalum pentachloride (EC No. 231-755-6);
2. a supporting study (Nemetschek-Gansler *et al.*, 1975) for a repeated dose toxicity study via inhalation with the Substance. The study was not conducted according to any recommended guideline.

You have also provided an adaptation according to Column 2 of Annex IX, Section 8.6.2. in your dossier. In support of your adaptation, you provided the following justification: *"the sub-chronic toxicity study (90-day), listed under standard information requirement 8.6.2, can be omitted if the substance is unreactive, insoluble and not inhalable and there is no evidence of absorption and no evidence of toxicity in a 28-day 'limit test'". The water solubility of Ta2O5 has been determined to be <0.005 mg/L at 20 °C. The substance is considered inert and highly insoluble which also restricts bioavailability. With respect to systemic toxicity, in a 28-day repeated dose toxicity study via the oral route using a more soluble tantalum compound (tantalum pentachloride, OECD 422), no toxicity was observed at the highest dose of 1.000 mg/kg/day. The substance is potentially inhalable as it is a powder, but is not expected to cause substance specific adverse effects. The standard risk management measures applicable to inhalation of poorly soluble particles (PSP) are considered sufficient. Therefore, conducting a 90d study is not considered justified".*

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

A. To be considered compliant and enable concluding whether the Substance has dangerous properties and supports the determination of the No-Observed Adverse Effect Level (NOAEL), a study has to meet the requirements of OECD TG 408.

   The study by [redacted] (2016) is a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422). It does not have an exposure duration of 90 days as required in OECD TG 408, 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 408. Therefore this study does not fulfil the information requirement.

B. To be considered compliant and enable concluding whether the Substance has dangerous properties and supports the determination of the No-Observed Adverse Effect Level (NOAEL), a study has to meet the requirements of a sub-chronic toxicity study (90-day). The following key parameters include, among others:
   - testing of at least three dose levels and a concurrent control;
   - dosing of the Substance daily for a period of 90 days until the scheduled termination of the study;

- Clinical observations, ophthalmological examination, sensory reactivity to various stimuli and functional observations of the animals, recording of body weight, hematology, clinical biochemistry, and pathology of sexual (male and female) organs, full detailed gross necropsy and subsequent histopathology of tissues.

The study Nemetschek-Gansler *et al.* (1975) you have provided has not been conducted with at least three dose levels because you indicated a single dose level (i.e. 150 mg/m3). This does not have the required exposure duration of 90 days, because you indicated an exposure duration of 10 days. Finally the key parameters studies are limited to the "histopathology of lungs, quantitative dust examinations and ray bronchographs". Therefore this study does not fulfil the information requirement.

C. 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.

On this attempt to adapt the information requirement, we note the following issues:

a) You have not provided an appropriate justification that the substance is unreactive. Tantalum oxides may be used as solid acid catalysts due to their surface acidic properties. Therefore the physico-chemical properties of the Subtance does not support that it has no inherent chemical reactivity.

In your comments on the draft decision, you state that "*ditantalum pentoxide is commonly described in standard textbook of inorganic chemistry (e.g. Hollemann/Wiberg, Ed 103, 2017, p1839) as being insoluble, stable, and chemically inert at ambient temperatures*" and that "*a possible use in chemical catalysis, as mentioned in the draft decision, is probably restricted to mixed metal catalysts or high temperature applications*".

ECHA agrees that the use of ditantalum pentoxide as a solid acid catalyst is likely limited to conditions that are not physiologically relevant. While the information you have provided in your comments is supportive that the Substance has low reactivity, we note that your dossier currently does not include an appropriate justification that the Substance is unreactive.

b) As explained under request A.1., your dossier currently does not include reliable value on the water solubility of the Substance. Therefore you did not demonstrate that it is insoluble.

In your comments on the draft decision, you specify that you "*will provide additional experimental information on the solubility of ditantalum pentoxide both in water (by means of a transformation/dissolution test) and in artificial body fluids"* to support that the Substance is insoluble.

c) 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 experimental evidence showing that the Substance is not absorbed via

any relevant route of exposure.

In Section 7.1.1., you state the following: "*as worst case estimate oral* [...] *absorption values at 1% are assumed for risk assessment purposes*". However, you did not provide any direct evidence that the Substance is not absorbed via the oral route.

In your comments on the draft decision, you explain that you will provide "*additional experimental data on the solubility of ditantalum pentoxide in artificial body fluids to further strengthen* [your] *argument that* [...] *there is no evidence of absorption via the oral route*".

However, low solubility in artificial fluids does not demonstrate that no absorption occurs. As explained in ECHA Guidance R.7a, Section R.7.5.4.3.4, there has to be evidence of the lack of absorption. Such evidence may include toxicokinetics data to prove that no systemic absorption occurs.

d) With regard to human exposure, you have not provided an exposure assessment in accordance with Section 5 of Annex I in your Chemical Safety Report. Consequently, you did not demonstrate that human exposure is limited.

In your comments on the draft decision, you explain that you intend to "*refine the exposure assessment to show there is limited human exposure*".

Therefore, based on the above and taking into account the information provided as part of your comments on the draft decision, the cumulative conditions described above are not met and your adaptation according to Annex IX, Section 8.6.2., Column 2 is rejected and the information requirement is not fulfilled.

Study design

Following the criteria provided in Annex IX, Section 8.6.2, Column 2, the oral route is the most appropriate route of administration to investigate repeated dose toxicity[4]. The sub-chronic toxicity study must be performed according to the OECD TG 408, in rats and with administration of the Substance via the oral route because although the substance is reported to occur as a dust with a significant proportion (>1% on weight basis) of particles of inhalable size (MMAD < 50 µm), your Chemical Safety Report indicate that risk management measures are in place to prevent exposure of humans via inhalation.

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

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 ([redacted], 2016) conducted according to OECD TG 422 with the analogue substance Tantalum pentachloride (EC No. 231-755-6).

Furthermore you have provided an adaptation according to Column 2 of Annex IX, Section 8.7. in your dossier. You provide the same lines of evidence as those described under request C.1. to justify that conducting further testing on pre-natal developmental toxicity is not justified.

Based on the information provided in your dossier and in your comments on the draft decision we have identified the following issues:

A. In order to be considered compliant and enable assessing if the Substance is a developmental toxicant, information provided has to meet the requirements of OECD TG 414 in one species.

   The study by [redacted] (2016) conducted according to OECD TG 422 does not provide equivalent information to a pre-natal developmental toxicity study as some of the key parameters required in 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.

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 note 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. As already explained under request C.1., the information in your dossier does not demonstrate that the Substance is not absorbed via any relevant route of exposure. Consequently, the condition set out in point 2 is not fulfilled.

      In your comments on the draft decision, you explained that, in line with the comments provided on request C.1 above, you intend to provide "*additional information on the solubility of ditantalum pentoxide in water as well as in artificial*

body fluids" to support that "*no systemic absorption via relevant routes of exposure*".

However, as already explained, low solubility in artificial fluids does not demonstrate that no absorption occurs. As explained in ECHA Guidance R.7a, Section R.7.5.4.3.4, there has to be evidence of the lack of absorption. Such evidence may include toxicokinetics data to prove that no systemic absorption occurs.

b) With regard to human exposure, you have not provided an exposure assessment in accordance with Section 5 of Annex I in your Chemical Safety Report. As a result, you did not demonstrate that there is no or no significant human exposure.

In your comments on the draft decision, you indicated that you will provide further information related to the human exposure.

Therefore, based on the above and taking into account the information provided as part of your comments on the draft decision, the cumulative conditions described above are not met and your adaptation according to Annex IX, Section 8.7., Column 2 is rejected.

Based on the above the information requirement is not fulfilled.

Study design

A PNDT study according to the test method OECD TG 414 must be performed in rat or rabbit as preferred species with oral[5] 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.

You have adapted these information requirements based on Annex IX, Section 9.1, Column 2 and you have provided the following justification: "*In accordance with Annex IX of Regulation (EC) No 1907/2006, chronic toxicity tests shall be proposed by the registrant if the chemical safety assessment indicates the need to investigate further the effects on aquatic species. According to Annex I of this regulation, the chemical safety assessment triggers further action when the substance or the preparation meets the criteria for classification as dangerous according to Regulation (EC) No 1272/2008 or is assessed to be a PBT or vPvB. The hazard assessment reveals neither a need to classify the substance as dangerous to the environment, nor that it is a PBT or vPvB substance. In accordance with Column 2 of REACH Annex IX, endpoint 9.1.6, a proposal for a long-term toxicity study in fish does not need to be provided*".

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

In order to adapt the information requirement for long-term toxicity testing to aquatic

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

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 of 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.).

As explained under request A.1., while there are remaining uncertainties regarding the relative water solubility of the various forms of the Substance, ECHA considers that 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 state that "*the chemical safety assessment has concluded that the risk to aquatic organisms is controlled, based on the finding that no hazard has been identified*". However, the CSA is based on the information which are subject to the issue described above. Therefore, your CSA is not reliable and your adaptation according to Annex IX, Section 9.1., Column 2 is rejected.

You then refer to "*a robust summary of the water solubility of the source substance TaCl5*" that you intend to include in your next dossier update. ECHA understands that as already discussed under requests A.3 and B.1 you intend to to adapt these information requirements according to Annex XI, Section 1.5. However, you have not provided a read-across justification document. Therefore, ECHA is not in a position to evaluate the relevance and reliability of the proposed adaptation.

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.

Study design

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 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 06 March 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 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'[6].

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 particle size distribution. 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.

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

Technical instructions are available in the manual "How to prepare registration and PPORD dossiers"[7].

5. List of references of the ECHA Guidance and other guidance/ reference documents[8]

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)[9]

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[10]
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.

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