ECHA
EUROPEAN CHEMICALS AGENCY

Helsinki, 21 January 2019

Addressee: [redacted]

Decision number: CCH-D-2114457488-34-01/F
Substance name: dierbium trioxide
EC number: 235-045-7
CAS number: 12061-16-4
Registration number: [redacted]
Submission number [redacted]
Submission date: 30/04/2013
Registered tonnage band: 100-1000

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (the REACH Regulation), ECHA requests you to submit information on:

1. **Description of the analytical methods (Annex VI, Section 2.3.7.) on the registered substance;**

2. **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 registered substance;**

3. **Sub-chronic toxicity study (90-day), inhalation route (Annex IX, Section 8.6.2.; test method: OECD TG 413) in rats using nose-only exposure and including bronchoalveolar lavage (BAL) analysis with the registered substance;**

4. **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 registered substance;**

5. **Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: Daphnia magna reproduction test, EU C.20./OECD TG 211) with test material representative of the registered substance as specified in Appendix 1, section 5;**

6. **Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method: Fish, early-life stage (FELS) toxicity test, OECD TG 210) with test material representative of the registered substance as specified in Appendix 1, section 6;**

7. **Adsorption/desorption screening (Annex VIII, Section 9.3.1.; test method: Adsorption/desorption using an appropriate test method, with the registered substance;**

8. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.; test method: Bioaccumulation in fish: aqueous and dietary exposure, OECD TG 305, aqueous exposure with the registered substance;

You may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI to the REACH Regulation. To ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring and conforming to the appropriate rules in the respective annex, and adequate and reliable documentation.

You have to submit the requested information in an updated registration dossier by ***28 July 2021***. You also have to update the chemical safety report, where relevant. The timeline has been set to allow for sequential testing.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2 and advice and further observations are provided in Appendix 3.

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] by **Claudio Carlon**, Head of Unit, Evaluation **C3**

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

Appendix 1: Reasons

1. Description of the analytical methods (Annex VI, Section 2.3.7.)

In accordance with Article 10(a)(ii) of the REACH Regulation, the technical dossier must contain information on the identity of the substance as specified in Annex VI, Section 2 to the REACH Regulation. In accordance with Annex VI, Section 2 the information provided has to be sufficient to enable the identification of the registered substance.

According to Annex VI, section 2.3.7 of the REACH Regulation, a registration dossier shall report a description of the analytical methods or the appropriate bibliographic references for the identification of the substance and where appropriate for the identification of impurities and additives. The reporting shall be given in sufficient detail so that the methods may be reproduced.

You have provided results of particle size distribution analysis and an X-ray diffraction (XRD) diffractogram for the identification of the main constituent in section 1.4 of your registration dossier.

However, neither a description of the XRD analysis nor a quantitative analysis of the substance is provided in the dossier. Therefore the compositional information reported in section 1.2 of your dossier cannot be verified.
Consequently there is an information gap and it is necessary to provide information for this endpoint.

In your comments you agreed to provide such information including details on impurities present at a concentration > 1% as per ECHA Guidance for identification and naming of substances under REACH and CLP.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: a description of the quantitative analytical method(s) used to quantify the main constituent, namely dierbium trioxide. The description shall also include analytical method(s) used to identify and quantify the impurities reported as "Trace impurities" in section 1.2. In addition you shall provide a description of the XRD analysis including experimental parameters (source, voltage, current).

The description of the method(s) shall be given in such detail that the method(s) may be reproduced and shall include details of the experimental protocol, any calculations made and the results obtained. The information shall be sufficient to enable the compositional information reported in section 1.2 of your dossier to be verified

The information shall be attached to section 1.4 of your dossier.

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

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

"Water solubility" is a standard information requirement as laid down in Annex VII, Section 7.7 of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You provided under the endpoint information, flagged as a key study, data on [redacted] (14th edition, 2006), which is based on the Merck Index handbook. However, there is no information on the materials and methods in this peer-reviewed handbook nor under the IUCLID endpoint information fields. In the endpoint study summary, you report that the test material has a water solubility of 0.0000128 g-mol/L (equating to 4.9 mg/L) at 29 °C and as such can be described as slightly soluble.

You also provided a Supporting study (reliability indicated as not assignable) for Dierbium trioxide (CAS RN: 12061-16-4). In this study summary, information on physico-chemical properties of the test material were presented as a short abstract as part of a company Material Safety Data Sheet. The test material was reported to be insoluble in water.

However, ECHA considers that the information cannot be adequately assessed in the absence of documentation or information on the materials and methods applied. Furthermore, ECHA notes that the information on the water solubility in above study summaries is inconclusive. This is aggregated by the fact that there seems to be an additional discrepancy between the water solubility value reported in the key study under the water solubility endpoint and the concentration of the saturated solution (0.00060 up to 0.00076 mg/L), used in the aquatic toxicity tests on Algae and Fish.

Therefore, the water solubility information provided cannot be assessed as relevant and applicable and a new test has to be performed to obtain reliable and adequate results on the registered substance in order to clarify if the substance is soluble or insoluble.

As this substance is a metal/ inorganic, an alternative adequate test method shall be chosen as per the Guidance on information requirements and chemical safety assessment (version 6.0, July 2017), Chapter R7a, Section R.7.1.7.: OECD series on Testing and Assessment Number 29 - Guidance Document on Transformation/Dissolution of Metals and Metal Compounds in Aqueous media.

In your comments on the draft decision you highlighted the following:
" [...]it is not unexpected to obtain saturation concentrations during ecotoxicological tests that are different from the water solubility values. Indeed, during aquatic toxicity studies, the aqueous media used generally contained inorganic ligands that are known to impact the dissolution of rare earth compounds under the conditions of the tests. In the case of dierbium trioxide, three species were tested using three different media, which can explain the observed differences in saturation concentrations.
Nevertheless, we agree that further data to clarify this endpoint is required and hence we agree to ECHA's request to perform a new study according to test method: OECD GD 29 Transformation/Dissolution of Metals and Metal compounds in aqueous media."

ECHA understands that different saturation concentrations may be observed depending of the composition of test media and the occurrence of inorganic (or organic) ligands. However, ECHA notes that strong variations were also observed between the water solubility studies, which cannot be explained by variation in media composition. ECHA has considered your comments and concludes that there remains a need to generate reliable data on the dissolution and transformation of the substance in an aquatic medium.

With regards to the study design ECHA notes the following. As explained in OECD GD 29 the study needs to be conducted at a pH that maximises the concentration of dissolved metal ions in solution (pH range 6.5 to 8.5 in 7 day test, pH range 5.5. to 8.5 in the 28 d test). Furthermore, to allow comparison of the study results with the effect data obtained from requests 5. and 6. the smallest marketed form should be used. Lastly, the use of three loading rates is recommended to obtain a fuller understanding of metal ion formation. Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Water solubility (test method: OECD GD 29 Transformation/Dissolution of Metals and Metal compounds in aqueous media).

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

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to IX to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

A "sub-chronic toxicity study (90 day)" is a standard information requirement as laid down in Annex IX, Section 8.6.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have not provided any study record of a sub-chronic toxicity study (90 day) in the dossier that would meet the information requirement of Annex IX, Section 8.6.2.
You have sought to adapt this information requirement according to Annex XI, Section 1, by providing the following justification for the adaptation: *"In accordance with section 1 of REACH Annex XI, the repeat dose toxicity study via the inhalation route (required in section 8.6.1 of Annex VIII) does not need to be conducted if the study does not appear to be scientifically necessary. An oral study conducted to OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test) already sufficiently addresses the repeat dose toxicity data requirements".*

To support your adaptation you have provided a key study for a combined repeated dose and reproduction / developmental screening study, rat, oral route (OECD TG 422; GLP) with the registered substance, rel. 1 (2013).

ECHA notes that the information provided in your dossier, namely your adaptation and the supporting evidence, does not meet any of the (i) specific rules for adaptation of Annex IX, Section 8.6.2., column 2 nor (ii) any of the general rules for adaptation of Annex XI, Section 1. This is because:

(i) the exposure duration of an OECD TG 422 study is less than 90 days and the number of animals examined per dose group for histopathology and clinical chemistry is significantly lower than in the 90 day sub-chronic toxicity study (OECD TG 408). Therefore, the sensitivity of such study is much lower than that of a repeated dose toxicity (90-day) study. Hence the information requirement for a 90-day study, according to Annex IX of REACH is not fulfilled;

(ii) you have not substantiated the argument that the 'study does not appear to be scientifically necessary'. Specifically, you have not provided any arguments or data, justifying why the specific provisions of Annex XI, Section 1 (i.e. 'Use of existing data', 'Weight of evidence', (Q)SAR, '*in vitro* methods' or 'Grouping of

substances and read-across approach') could be applied for this substance. Furthermore, you have failed to provide adequate and reliable documentation that is required to fulfil any of the provisions for adaptation in Annex XI, Section 1.

Therefore, your adaptation of the information requirement is rejected.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement.

Consequently there is an information gap and it is necessary to provide information for this endpoint.

ECHA has evaluated the most appropriate route of administration for the study. The information provided in the technical dossier and the chemical safety report on properties of the registered substance and its uses indicate that human exposure to the registered substance by the inhalation route is likely. More specifically, the substance is reported to occur as a powder with the collated D50 range of particle sizes for dierbium trioxide between 2 and 10 µm. The substance is respirable and reported as slightly soluble (0.0000128 g-mol/L (equating to 4.9 mg/L) at 29°C). Consequently, there is a potential for accumulation of the substance in the lungs. Moreover, it contains the metal component dierbium that might potentially be hazardous to the lungs. Thus, ECHA considers that the inhalation route is the most appropriate route of administration.

ECHA recommends you to use the most recent version of the OECD TG 413 (25 June 2018) where the lung burden and the bronchoalveolar lavage fluid (BALF) measurements are mandatory. These measurements are described in paragraph 50 of the recent versions of OECD TG 413 (25 June 2018).

In case you use the OECD TG 413 from 2009, ECHA notes that bronchoalveolar lavage (BAL) analysis is an optional analysis under this version of the TG. However, paragraph 39 sets out that "When there is evidence that the lower respiratory tract (i.e., the alveoli) is the primary site of deposition and retention, then bronchoalveolar lavage (BAL) may be the technique of choice...". Since there is evidence that the lower respiratory tract is a site of deposition and retention of the registered substance because the substance is slightly soluble in water and respirable, ECHA considers that you must undertake BAL analysis. Hence, you should perform the BAL analysis as specified in paragraph 39 of OECD TG 413.

Having regard of all the above, the test shall be performed by the inhalation route using the test method OECD TG 413, and you shall perform bronchoalveolar lavage (BAL) as specified in OECD TG 413.

In your comments on the draft decision, you agreed with this request.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Sub-chronic inhalation toxicity: 90-day study (test method: OECD TG 413) in rats. The test shall include bronchoalveolar lavage (BAL) analysis.

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

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to IX to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

A "pre-natal developmental toxicity study" (test method OECD TG 414) for a first species is a standard information requirement as laid down in Annex IX, Section 8.7.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have not provided any study record of a pre-natal developmental toxicity study in the dossier that would meet the information requirement of Annex IX, Section 8.7.2.
In the technical dossier you have provided a study record for a OECD Guideline 422, Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test) from 2013 with Dierbium trioxide / 12061-16-4 / 235-045-7 in rat. However, this study does not provide the information required by Annex IX, Section 8.7.2., because it does not cover key parameters of a pre-natal developmental toxicity study like examinations of foetuses for skeletal and visceral alterations. Therefore, your adaptation of the information requirement is rejected.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to the test method OECD TG 414, the rat is the preferred rodent species and the rabbit the preferred non-rodent species. On the basis of this default assumption ECHA considers testing should be performed with rats or rabbits as a first species.

ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 6.0, July 2017) Chapter R.7a, Section R.7.6.2.3.2. Since the substance to be tested is a solid, ECHA concludes that testing should be performed by the oral route.

In your comments to the draft decision, you agreed to this request.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Pre-natal developmental toxicity study (test method: OECD TG 414) in a first species (rat or rabbit) by the oral route.

ECOTOXICOLOGICAL INFORMATION

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to IX to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

Your registration dossier contains for the endpoints on Adsorption/Desorption screening and Bioaccumulation in aquatic organisms adaptation arguments in form of a grouping and read-across approach according to Annex XI, 1.5. of the REACH Regulation. ECHA has assessed

first the scientific and regulatory validity of your Grouping and read-across approach in general before the individual endpoints (sections 7. and 8. below).

Grouping of substances and read-across approach

You have sought to adapt this information requirement for adsorption/Desorption screening study (Annex VIII, Section 9.3.1.) and Bioaccumulation in aquatic organisms (Annex IX, Section 9.3.2) by applying a weight of evidence and a read-across approach in accordance with Annex XI, Section 1.2 and Section 1.5. of the REACH Regulation.

According to Annex XI, Section 1.5., two conditions shall be necessarily fulfilled. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group (read-across approach). ECHA considers that the generation of information by such alternative means should offer equivalence to prescribed tests or test methods.

Based on the above, a read-across hypothesis needs to be provided. This hypothesis establishes why a prediction for a toxicological or ecotoxicological property is reliable and should be based on recognition of the structural similarities and differences between the source and registered substances[2]. This hypothesis explains why the differences in the chemical structures should not influence the toxicological/ ecotoxicological properties or should do so in a regular pattern. The read-across approach must be justified scientifically and documented thoroughly, also taking into account the differences in the chemical structures. There may be several lines of supporting evidence used to justify the read-across hypothesis, with the aim of strengthening the case.

Due to the different nature of each endpoint and consequent difference in scientific considerations (e.g. key parameters, biological targets), a read-across must be specific to the endpoint or property under consideration. Key physicochemical properties may determine the fate of a compound, its partitioning into a specific phase or compartment and largely influence the availability of compounds to organisms, e.g. in bioaccumulation and toxicity tests. Thus, physicochemical properties and fate of the substance influence the human health and environmental properties of a substance and should be considered in read-across assessments. However, the information on physicochemical properties and fate of the substance are only a part of the read-across hypothesis, and it is necessary to provide additional justification which is specific to the endpoint or property under consideration.

The ECHA Read-across assessment framework foresees that there are two options which may form the basis of the read-across hypothesis[3]- (1) (Bio)transformation to common compound(s)- the read-across hypothesis is that different substances give rise to (the same) common compounds to which the organism is exposed and (2) Different compounds have the same type of effect(s)- the read-across hypothesis is that the organism is exposed to different compounds which have similar (eco)toxicological properties and fate as a result of structural similarity (and not as a result of exposure to common compounds).

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[2] Please see for further information ECHA *Guidance on information requirements and chemical safety assessment* (version 1, May 2008), Chapter R.6: QSARs and grouping of chemicals.
[3] Please see ECHA's Read-Across Assessment Framework (https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across).

Finally, Annex XI, Section 1.5. lists several additional requirements, which deal with the quality of the studies which are to be read-across.

You consider to achieve compliance with the REACH information requirements for the registered substance Dierbium Trioxide (EC no 235-045-7) using data of structurally similar substance Lanthanum oxide (CAS 1312-81-8 / EC no 215-200-5) and Dicerium tricarbonate (CAS 537-01-9, EC no 208-655-6) for the adsorption/desorption screening endpoint, and for the Bioaccumulation endpoint, data on Lanthanum trinitrate (CAS 10099-59-9 / EC no 233-238-0), Gadolinium trinitrate (CAS 10168-81-7 / EC no 233-437-2) and Yttrium trinitrate (CAS 10361-93-0, EC no 233-802-6) (hereafter the 'source substances').

For adsorption/desorption you provided two study records based on a read-across from Lanthanum oxide (CAS 1312-81-8 / EC no 215-200-5), study from [redacted] 2008 (OECD TG 106, reliability 2); and dicerium tricarbonate (CAS 537-01-9, EC no 208-655-6) study summary from [redacted] 2008 (OECD TG 106, reliability 2).

For these studies you provided the following results :
Lanthanum oxide: Mean Koc value = 5480283 and Mean Koc, desorption value = 358213
Cerium carbonate: Mean Koc value = 3940404 and Mean Koc, desorption value = 7556699

But you did not specify nor justify the read-across for this endpoint where you only mentioned as justification in the summary:
"The following adsorption/desorption distribution coefficients were obtained ***for the analogous test materials Lanthanum oxide and cerium carbonate*** *at the soil-to-solution ratio of 1/50: - Mean Koc value: 5480283, 3940404, respectively. As a representative value, the lower mean value was used as the key value."*

And similarly, for the bioaccumulation endpoint you mentioned :
" [...] the substance can be predicted not to be bioaccumulative ***based on analogy with the heavy REE yttrium nitrate****."*

For Bioaccumulation endpoint, you provided a supporting study record based on a publication from Qiang et al. 1994 (OECD TG 305, non GLP), with BCF at equilibrium calculcated results for the source substances afore mentioned :

- Lanthanum: Muscles: BCF = 3.2, Skeleton: BCF = 6.1, Gill: BCF = 18, Internal organs: BCF = 91.
- Gadolinium: Muscles: BCF = 3.5, Skeleton: BCF = 5, Gill: BCF = 14, Internal organs: BCF = 105.
- Yttrium: Muscles: BCF = 1.3, Skeleton: BCF = 3.8, Gill: BCF = 8, Internal organs: BCF = 54.

However, there is no documentation for the read-across. Therefore, your dossier is lacking a basis for predicting relevant environmental properties and fate of the registered substance from data for the source substances.

In the absence of this information, ECHA cannot verify that the properties of the registered substance can be predicted from the data on the source substances.

Hence, you have not established that relevant properties of the registered substance can be predicted from data on the analogue substance. Since your adaptation does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5., it is rejected and it is

necessary to perform testing on the registered substance as further discussed in the relevant requests below.

ECHA notes that in your comments on the Draft Decision you agreed with the rejection of the read-across approach for adsorption/Desorption screening study (Annex VIII, Section 9.3.1.) and Bioaccumulation in aquatic organisms (Annex IX, Section 9.3.2).

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

"Long-term toxicity testing on aquatic invertebrates" is a standard information requirement as laid down in Annex IX, Section 9.1.5. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex IX, Section 9.1.5., column 2. You provided the following justification for the adaptation:
"As the CSA concludes that the substance is of no immediate concern to the environment. The available data are adequate for classification and labelling purposes and PBT assessment is not applicable for inorganic substances so no further testing is required."

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.1.5., column 2 because of the following reasons :

- In the range finding study of your acute aquatic toxicity test to Daphnia, solubility at saturation was measured up to 0.27 mg/L and immobilisation was observed at 0.24 mg/L (10 % v/v) and at 0.27 mg/L (100% v/v). These values consequently represent your EC50 and EC100, respectively. However, you did not derive any EC50 value based on the results obtained in the acute toxicity test to Daphnia and you concluded that NOEC ≥ 100% v/v and EC50 > 100% v/v.
- The water solubility information provided in your dossier is not considered reliable: your statement under the endpoint study summary is contradictory to the concentration measured at saturation in the different test media in aquatic toxicity tests. Besides the contradiction found on the water solubility, for inorganic substances such as erbium dioxide the T/D protocol (OECD TG 29) is considered as the main reliable and relevant test method to measure water solubility and bioavailability in aquatic environment. Neither this test method nor existing test results were provided in your dossier that would fulfil both Annex VII, Section 7.7 data and Section 9.1.1 and 9.1.2 column 2 criteria for an adaptation of these standard information requirements.
- Your substance would show that it is poorly water soluble, based on the measured concentrations in the acute aquatic toxicity tests. In such case, the integrated or tier-testing strategy from short-term to long-term toxicity tests does not apply; hence long term toxicity tests shall be considered, as indicated in Column 2 of Annex VII, Section 9.1.1.
- Furthermore, there is no data on the uses and in the CSR to prove that there is no exposure or risk for aquatic environment.

It is therefore not acceptable or reliable to perform only tests to assess the acute aquatic toxicity.

Hence, ECHA does not agree with your mentioning that CSA does not indicate a need for further investigation as no exposure assessment was provided nor a valid PNECaquatic value.

Therefore, your adaptation of the information requirement cannot be accepted.

In your comments on the draft decision you stated that :
"*As mentioned by ECHA, immobilization was observed at 10 and 100% v/v saturated solution during the range-finding test. However, further discussions with the testing laboratory at the time of the range-finding test revealed that such effects could be due to contamination ([redacted] study report [redacted]). As a consequence, it was decided to disregard the observations from this range-finding test and results of the valid definitive test were preferred for concluding on acute toxicity to daphnids. In this definitive test, the experimental design conformed to a limit test with the testing of a 100% v/v saturated solution. No significant adverse effect was observed explaining why the EC50 was set superior to 100% v/v saturated solution.*"

ECHA understands that you considered the definitive test for the acute toxicity test on Daphnia valid while you have issues with the validity of the range-finding test. ECHA considers that the acute toxicity test results for Daphnia are not sufficient and cannot be used to adapt the long-term toxicity test on aquatic invertebrates, due to the claimed low solubility of the registered substance in testing media and low relevance of the water solubility measurement as explained under issue 2 above.

You highlighted that "*for poorly water soluble rare earth compounds it is very difficult to obtain reproducible saturation concentrations/water solubility values between different tests performed in various media*" and that conducting long-term studies on the registered substance would lead to the same problems as those identified in the short-term daphnia study "*i.e. saturation concentrations different from water solubility values*". You consider that testing the substance itself would not produce meaningful data for classification and labelling and risk assessment due to difficulties related to dissolution of the test substance.

You indicated that according to ECHA Guidance on the Application of the CLP Criteria (Version 5.0, July 2017) the preferred approach for classification is to compare acute and/or chronic Ecotoxicological Reference Values (ERVs) with concentrations of dissolved metal ions observed during a transformation/dissolution study.

You therefore indicated that to complete the hazard assessment and to determine the classification of the registered substance you will conduct an OECD 29 Transformation/Dissolution of Metals and Metal compounds in aqueous media study and compare the obtained concentration(s) of soluble metal ions in this study with ERVs on soluble erbium salts. You had considered this approach already prior to conducting the acute aquatic ecotoxicity studies on the registered substance, however, as "*no relevant ecotoxicity data was available on soluble erbium compounds that could be used to derive either acute and/or chronic ERVs*" you considered it as not viable. You have tried to obtain ERVs for erbium compounds from the ECHA website and literature, however you acknowledge that such data may not be available.

ECHA agrees that ecotoxicity of most poorly soluble metal compounds is best assessed using data on the soluble metal ion, and that the approach described by you is appropriate

for classification purposes as given in ECHA Guidance on the Application of the CLP Criteria (Version 5.0, July 2017). ECHA agrees that generating data according to the OECD TG 29 is a prerequisite for the approach described by you as agreed in issue 2 by you. However, ECHA notes that transformation/dissolution data may be used to fulfil the standard information requirement of Annex VII, section 7.7., but on its own it cannot fulfil the present information requirement of long-term toxicity testing on aquatic invertebrates.

Therefore, you need to provide the requested aquatic toxicity data generated with a test material representative of the registered substance, ie. with the soluble ion(s). If no data on long-term toxicity to aquatic invertebrates is available on soluble erbium ion(s), such data need to be generated. If new ecotoxicity testing is initiated any advice provided in the specific guideline, here OECD TG 211, for testing of metals should be followed. The study should be performed at a pH that maximizes the concentration of dissolved metal ions in solution, however within the pH range given in the OECD TG 211. Analytical monitoring of the exposure concentrations is required to demonstrate the concentration of the metal ion tested. You also need to provide a scientifically valid read-across justification (according to Annex XI, section 1.5.) on how the data you intend to use to fulfil the present information requirement relates to the whole substance including, for instance the counter-ion and any impurities. To fulfil the requirements of Annex XI, section 1.5., the information provided needs to be useful for both hazard and risk assessment and for classification and labelling.

For classification purposes, you can use the approach described in ECHA Guidance on the Application of the CLP Criteria (Version 5.0, July 2017). Bearing in mind the requirement to cover the whole registered substance as given above, for hazard and risk assessment, you need to follow the approach given for PNEC derivation and risk characterisation in ECHA Guidance on Information requirements and chemical safety assessment, Chapter R.10 (May 2008) and required by Annex I, section 3.3 of the REACH Regulation. Any substance specific considerations you may use in your hazard and risk assessment need to be fully justified and the approach chosen needs to cover the whole substance as registered.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit information generated with a test material representative of the registered substance subject to the present decision: Daphnia magna reproduction test (test method: EU C.20./OECD TG 211).

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

"Long-term toxicity testing on fish" is a standard information requirement as laid down in Annex IX, Section 9.1.6. of the REACH Regulation. Adequate information on Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1.), or Fish, short-term toxicity test on embryo and sac-fry stages (Annex IX, 9.1.6.2.), or Fish, juvenile growth test (Annex IX, 9.1.6.3.) needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex IX, Section 9.1.6, Column 2, providing the same justification that you used for the long-term toxicity to invertebrates endpoint. For the reasons why ECHA does not accept your adaptation, you are therefore referred to ECHA's statement of reason under point 5 above.

Furthermore, ECHA notes that your adaptation does not meet either the specific rules for adaptation of Annex IX, Section 9.1.6., column 2 because of the following additional reasons:

- The results obtained for the acute toxicity tests on Fish and on Algae are done for a substance measured at 0.0006 mg/L hence no effects could be seen for Fish or Algae.
- The measured water solubility provided in your dossier is therefore in contradiction with the above concentration measured at saturation in the different test media in aquatic toxicity tests.
- These reasons come in addition to the ones already outlined under the respective request no. 5.

It is therefore not acceptable nor reliable to perform only tests to assess the acute aquatic toxicity.

Hence, ECHA does not agree with your mentioning that CSA does not indicate a need for further investigation as no exposure assessment was provided nor a valid PNECaquatic value.

Therefore, for all the reasons mentioned here and in ECHA's statement of reasons under point 5 above, your adaptation of the information requirement cannot be accepted.

In your comments on the draft decision you repeated the arguments provided under issue 5 on the difficulty to perform aquatic testing the registered substance. You further highlighted that the current requets is for a vertebrate test. Your comments on this request were similar to those under section 5 above. You further highlighted that the current request involves testing vertebrate animals. ECHA accordingly refers to ECHA's reply in section 5 above. Furthermore, as for the acute toxicity test to Daphnia, the acute fish test results and relevance are considered insufficient to determine if the substance is toxic to aquatic organisms and if there is any difference in sensitivity between the different aquatic species, as further discussed in the notes for your consideration.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) fish early-life stage (FELS) toxicity test (test method OECD TG 210), fish short-term toxicity test on embryo and sac-fry stages (test method EU C.15. / OECD TG 212) and fish juvenile growth test (test method EU C.14. / OECD TG 215) are the preferred tests to cover the standard information requirement of Annex IX, Section 9.1.6.

However, the FELS toxicity test according to OECD TG 210 is more sensitive than the fish, short-term toxicity test on embryo and sac-fry stages (test method EU C.15 / OECD TG 212), or the fish, juvenile growth test (test method EU C.14. / OECD TG 215), as it covers several life stages of the fish from the newly fertilized egg, through hatch to early stages of growth (see ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), *Chapter R7b, Figure R.7.8-4).*

Moreover, the FELS toxicity test is preferable for examining the potential toxic effects of substances which are expected to cause effects over a longer exposure period, or which require a longer exposure period of time to reach steady state (ECHA *Guidance Chapter R7b,* version 4.0, June 2017).

The study should be performed at a pH that maximizes the concentration of dissolved metal ions in solution, however within the pH range given in the OECD TG 210.
Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit information generated with a test material representative of the registered substance subject to the present decision: Fish, early-life stage (FELS) toxicity test (test method: OECD TG 210).

Notes for your consideration for requests 5 and 6

Once results of the tests on long-term toxicity to aquatic invertebrates and to fish are available, you shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation.

ECHA notes that there are no reliable short-term studies available on aquatic invertebrates or on fish for the registered substance. Therefore the Integrated testing strategy (ITS) outlined in ECHA Guidance on information requirements and chemical safety assessment (version 4.0, June 2017), Chapter R7b (Section R.7.8.5 including Figure R.7.8-4), is not applicable in this case and the long-term studies on both invertebrates and fish are requested to be conducted.

Furthermore, due to the low solubility of the substance in water, you could consult OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6/REV1 (6 July 2018) and ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), Chapter R7b, Table R.7.8-3 summarising aquatic toxicity testing of difficult substances which could also be considered for metallic and inorganic substances, for choosing the design of the requested ecotoxicity tests and for calculation and expression of the result of the tests.

7. Adsorption/Desorption screening (Annex VIII, Section 9.3.1.)

"Adsorption/desorption screening" is a standard information requirement as laid down in Annex VIII, Section 9.3.1. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

For this endpoint you provided two study records in the form of a weight of evidence approach based on a read-across from the following analogue substances: Lanthanum oxide (CAS 1312-81-8 / EC no 215-200-5), and dicerium tricarbonate (CAS 537-01-9, EC no 208-655-6) study summaries from [redacted] 2008 (OECD TG 106, reliability 2). ECHA thus understands that you seek to adapt the standard information requirement according to Annex XI, Section 1.2. and Section 1.5.

For these studies, you have used the lowest mean value as a representative value and therefore key value under the Weight of evidence approach.

However, as explained above in Appendix 1, under Grouping and read-across approach for ecotoxicological information section of this decision, your adaptation of the information requirement according to Annex XI, Section 1.5, cannot be accepted.

Furthermore ECHA notes that you have sought to adapt this information requirement according to Annex XI, Section 1.2., weight of evidence. Hence, ECHA has evaluated your adaptation with respect to this provision.

You have likewise not provided a justification for the weight of evidence adaptation else than the reference to Annex XI, section 1.2 in the study summary chosen weight of evidence in the adequacy of study field.

An adaptation pursuant to Annex XI, Section 1.2. requires sufficient weight of evidence from several independent sources of information leading to the assumption/conclusion that a substance has or has not a particular dangerous property with respect to the information requirement in question including an adequate and reliable documentation while the information from each single source alone is regarded insufficient to support this notion.

Your weight of evidence adaptation would need to address the specific dangerous (hazardous) properties of the registered substance with respect to adsorption/desorption screening studies (Annex VIII, section 9.3.1.) and as per Article 13(3).
However, as explained above, you failed to submit any justification on the read-across approach, as well as on the reliability of the provided two studies on the source substances as a valid adaptation of Annex XI, section 1.2.

Consequently, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex XI, Section 1.5. and section 1.2, because no adequate and reliable information and documentation on the adaptation is available in the registration dossier.

Therefore, your adaptation of the information requirement cannot be accepted.

In your comments on the draft decision you agreed on the inadequacy of the information provided based on cross-elemental read-across. You propose to cover this endpoint with a WoE approach using available (literature) data on the partitioning of erbium between water and suspended particulate matter, sediment and soil particles. You stated that you will assess the references already available and any other information still to be gathered for reliability and relevance (taking into account the recommendations on the use of such data for covering this endpoint as specified in the metal-specific guidance of ECHA, Appendix R.7.13-2) to decide if these can adequately cover this endpoint.

ECHA acknowledges your commitment to proceed with a new WoE approach. ECHA notes that as specified above any WoE approach submitted need to fulfill the criteria of Annex XI, Section 1.2 of the REACH Regulation. However, currently the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently, there is an information gap and it is necessary to provide information for this endpoint.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Adsorption- Desorption using a Batch Equilibrium Method (OECD TG 106).

Guidance for determining appropriate test methods for the adsorption/desorption screening is available in the ECHA Guidance on information requirements and chemical safety assessment (version 6.0, July 2017), Chapter R.7a, Section R.7.1.15.3 and further on Guidance R7.-13-2 provides advice on the TG and how to derive Kd for data poor metals.

8. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.)

"Bioaccumulation in aquatic species, preferably fish" is a standard information requirement as laid down in Annex IX, Section 9.3.2.of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex XI, Section 1.1. You provided the following justification for the adaptation:
"In accordance with section 1 of REACH Annex XI (testing does not appear scientifically necessary), the bioaccumulation study (required in section 9.3.2.) does not need to be conducted as the substance can be predicted not to be bioaccumulative based on analogy with the heavy REE yttrium nitrate. The available data is adequate for classification and labelling purposes and PBT assessment is not required for inorganic substances so no further testing is required."

You have also sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing a supporting study record based on a publication from Qiang et al. 1994 (OECD TG 305, non GLP), on the following analogue substances : Lanthanum trinitrate (CAS 10099-59-9 / EC no 233-238-0), Gadolinium trinitrate (CAS 10168-81-7 / EC no 233-437-2) and Yttrium trinitrate (CAS 10361-93-0, EC no 233-802-6).

However, as explained above in Appendix 1, under Grouping and read-across approach for ecotoxicological information section of this decision, your adaptation of the information requirement cannot be accepted for this endpoint either.

Furthermore, ECHA notes that your adaptation does not meet the general rule for adaptation of Annex XI: Section 1.1.2 and 1.5. because of the following deficiencies:

- The study is a not conducted according to GLP criteria;
- There is an insufficient reporting in the robust study summary with no raw data and no information on the validity criteria;
- The study report is based on a scientific publication, which did not follow the test guideline methods requirements, e.g.: no depuration period, no specific indication on the concentrations tested.

In light of the deficiencies listed in the study afore mentioned, ECHA cannot verify whether (i) the study design is adequate and reliable for the purpose of the prediction, or (ii) the results are adequate for the purpose of classification and labelling and/or risk assessment contrary to your adaptation justification as per annex XI, section 1.1.2.

Therefore, your adaptation of the information requirement cannot be accepted.

In your comments you agreed on the rejection of the proposed cross-elemental read-across. You explained that you intend to provide in the dossier update a new WoE approach for bioaccumulation based on bioaccumulation data on erbium obtained from literature. You intend to assess the data for relevance and reliability.

ECHA acknowledges your commitment to proceed with a new WoE approach. ECHA notes that as specified earlier in this decision any WoE approach submitted need to fulfill the criteria of Annex XI, Section 1.2 of the REACH Regulation.

As explained above, the information currently provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7c* (version 3.0, June 2017) bioaccumulation in fish: aqueous and dietary exposure (test method EU C.13. / OECD TG 305) is the preferred test to cover the standard information requirement of Annex IX, Section 9.3.2. Whenever technically feasible the aqueous route of exposure shall be followed .

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision
Bioaccumulation in fish: aqueous exposure bioconcentration fish test (test method: OECD TG 305-I)

Deadline to submit the requested Information

In the draft decision communicated to you the time indicated to provide the requested information was 24 months from the date of adoption of the decision. In your comments on the draft decision, you requested an extension of the timeline to 36 months. You sought to justify this request by the explanation that : *"for the ecotoxicity and e-fate endpoints a stepwise approach is preferred whereby initially the TD study would be undertaken first, followed by ecotoxicity studies and lastly adsorption/desorption and/ or bioaccumulation studies (in case the literature data is not adequate). Although, as noted above, we intend to cover the adsorption / desorption and bioaccumulation endpoints by use of literature data if it is judged necessary to undertake these studies we would like to point out that the test concentrations for such studies need to be selected carefully in order to obtain meaningful results. The results of the chronic ecotoxicity studies would be referenced in order to make this judgement. In view of this stepwise approach we feel that it may take nearer to 36 months to complete the full testing Programme."*

ECHA notes the request to extend the timeline for testing from 24 to 36 months due to a tiered testing strategy and the difficulties of testing the substance in the aquatic test media. ECHA notes this difficulty and acknowledges that such substance could be considered as a difficult to test substance.

However, ECHA notes that you did not provide documentary evidence from a selected test laboratory indicating the scheduling timelines for the studies in question of the laboratory facility in order to justify fully why an extension to the stated deadline is required.

Nevertheless, due to the difficulties acknowledged above, ECHA has partially granted the request and set the deadline to 30 months.

Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

The compliance check was initiated on 2 May 2017.

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.

ECHA took into account your comments and amended the deadline.

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

ECHA received proposals for amendment and modified the draft decision.

ECHA invited you to comment on the proposed amendments.

ECHA referred the draft decision to the Member State Committee.

You did not provide any comments on the proposed amendment(s).

The Member State Committee reached a unanimous agreement on the draft decision in its MSC-62 written procedure and ECHA took the decision according to Article 51(6) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

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

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 your Member State.

3. In relation to the information required by the present decision, the sample of the substance used for the new tests must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is suitable to fulfil the information requirement for the range of substance compositions manufactured or imported by the joint registrants.

   It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition. In addition, it is important to ensure that the particular sample of the substance tested in the new tests is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured or imported by each registrant.

   If the registration of the substance by any registrant covers different grades, the sample used for the new tests must be suitable to assess these grades. Finally there must be adequate information on substance identity for the sample tested and the grades registered to enable the relevance of the tests to be assessed.