~~Confidential~~

Helsinki, 09 November 2023

Addressees
Registrants of JS_Lanthanum trifluoride as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
13/05/2013

Registered substance subject to this decision ("the Substance")
Substance name: Lanthanum fluoride
EC/List number: 237-252-8

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

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadline of ***15 February 2027***.

Requested information must be generated using the Substance unless otherwise specified.

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

1. Water solubility (Annex VII, Section 7.7.; test method: OECD GD 29)

2. Skin sensitisation (Annex VII, Section 8.3.): i. in vitro/in chemico skin sensitisation information on molecular interactions with skin proteins (OECD TG 442C), inflammatory response in keratinocytes (OECD TG 442D) and activation of dendritic cells (EU B.71/OECD TG 442E)(Annex VII, Section 8.3.1.); and ii. Only if the in vitro/in chemico test methods specified under point i.) are not applicable for the Substance or the results obtained are not adequate for classification and risk assessment, in vivo skin sensitisation (Annex VII, Section 8.3.2.; test method: EU B.42./OECD TG 429)

3. Long-term toxicity testing on aquatic invertebrates also requested below (triggered by Annex VII, Section 9.1.1., column 2; test method: EU C.20./OECD TG 211) only if the results of Request 1 show the Substance is poorly water soluble (i.e. water solubility < 1 mg/L)

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

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

5. Long-term toxicity testing on fish also requested below (triggered by Annex VIII, Section 9.1.3., column 2) only if the results of Request 1 show the Substance is poorly water soluble (i.e. water solubility < 1 mg/L)

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

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

7. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: OECD TG 414) by oral route, in one species (rat or rabbit)

8. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: EU C.20./OECD TG 211)

9. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: EU C.47./OECD TG 210)

10. Short-term toxicity to terrestrial invertebrates (Annex IX, Section 9.4.1.; test method: EU C.8./OECD TG 207)

11. Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: EU C.21./OECD TG 216)

12. Short-term toxicity on terrestrial plants (Annex IX, Section 9.4.3; test method: EU C.31./OECD TG 208, with at least three species)

The reasons for the requests are explained in Appendix 1.

Information required depends on your tonnage band

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

In the requests above, the same study has been requested under different Annexes. This is because some information requirements may be triggered at lower tonnage band(s). In such cases, only the reasons why the information requirement is triggered are provided for the lower tonnage band(s). For the highest tonnage band, the reasons why the standard information requirement is not met and the specification of the study design are provided. Only one study is to be conducted; all registrants concerned must make every effort to reach an agreement as to who is to carry out the study on behalf of the others under Article 53 of REACH.

You are only required to share the costs of information that you must submit to fulfil your information requirements.

How to comply with your information requirements

To comply with your information requirements, you must submit the information requested by this decision in an updated registration dossier by the deadline indicated above. You must also **update the chemical safety report, where** relevant, including any changes to classification and labelling, based on the newly generated information.

You must follow the general requirements for testing and reporting new tests under REACH, see Appendix 4.

Appeal

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

Failure to comply

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

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

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

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

Appendix 1: Reasons for the decision

Contents

Reasons related to the information under Annex VII of REACH

1. Water solubility

1 Water solubility is an information requirement under Annex VII to REACH (Section 7.7). However, information on transformation/dissolution in aqueous media shall be provided when the substance is a metal or sparingly soluble metal compound (Section 7.7., Column 2).

1.1. Triggering of the information required

2 Based on a water solubility experiment according to the OECD TG 105 study submitted in your dossier, the Substance is concluded to be a sparingly soluble metal compound as its solubility in water was determined to be 0.69 mg/L at 20°C in pure water (loading rate of c.a. 100 mg/L)and to range from 1.7 µg/L to 3.4 mg/L in buffer solutions of pH 4 to 8.7 (loading rate of c.a. 100 mg/L).

3 Therefore, water solubility is required in accordance with Section 7.7., Column 2.

1.2. Information provided

4 Guidance on IRs and CSA, Section R.7.1.7.3. specifies that, for metal or sparingly soluble metal compound, water solubility must be determined according to the OECD GD 29 (Transformation/Dissolution of metals and metal compounds in aqueous media).

5 However, you have provided OECD TG 105 studies (2013) but no information on the transformation/dissolution in aqueous media of the Substance.

6 In the absence of information on transformation/dissolution in aqueous media, the information requirement set out in Section 7.7., Column 2 is not fulfilled.

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

1.3. Study design and test specifications

8 Under Section 4.5. of your technical dossier a key non TG study on granulometry (Laser scattering / diffract)) shows that the registered substance have particle size ranging between 5.3 µm and 349.2 µm with a mass median diameter (D_{50}) of 52.41 µm. For powders (particle size < 1mm) the test must be conducted using a test material having the smallest representative particle size on the market. OECD TG GD 29 on Transformation/Dissolution of metals and metal compounds in aqueous media specifies that the specific surface area of the test material must be determined.

2. Skin sensitisation

9 Skin sensitisation is an information requirement under Annex VII, Section 8.3. Under Section 8.3., Column 1, the registrants must submit information allowing (1) a conclusion whether the substance is a skin sensitiser and (2) whether it can be presumed to have the potential to produce significant sensitisation in humans (Cat. 1A).

2.1. Information provided

10 You have provided an OECD 429 (2012) with the Substance

2.2. Assessment of the information provided

2.2.1. Assessment whether the Substance causes skin sensitisation

2.2.1.1. The provided study does not meet the specification of the applicable test guideline

11 To fulfil the information requirement, and to enable concluding whether the Substance causes skin sensitisation, a study must comply with the EU Method B.6/OECD TG 406 / EU Method B.42/OECD TG 429 (Article 13(3) of REACH). Therefore, the following specifications must be met:

a) the highest concentration is the highest technically possible concentration that maximises exposure while avoiding systemic toxicity and/or excessive local skin irritation

12 The study (i) is described as a Local Lymph Node Assay. However, the following specifications are not according to the requirements of OECD TG 429:

a) no dose level selection rationale was provided for selecting the highest dose; (25 % w/w in propylene glycol)

13 Therefore the study does not fulfil the key parameter(s) set in the EU method B.42/OECD TG 429 and does not allow to make a conclusion whether the Substance causes skin sensitisation.

14 In the comments to the draft decision you disagree with the request and you provided the following arguments: "*The registrant has subsequently reviewed the study report and concludes that the deficiencies noted by ECHA in the draft decision are not with the methodology of the study itself, which is judged to be scientifically sound, but rather on the reporting of this in the registration dossier. The registrant therefore proposes to address the identified deficiencies by means of updating and improving the quality of the robust study summary of the existing data*".

15 ECHA takes note or your intentions to submit a dossier update and to improve the robust study summary. As the information in your comments is not sufficient for ECHA to make an assessment, no conclusion on the compliance can currently be made.

16 You remain responsible for complying with this decision by the set deadline.

2.2.2. No assessment of potency

17 To be considered compliant and enable a conclusion in cases where the substance is considered to cause skin sensitisation, the information provided must also allow a conclusion whether it can be presumed to have the potential to produce significant sensitisation in humans (Cat. 1A).

18 As the currently available data does not allow to conclude whether the Substance causes skin sensitisation (see section 2.2.1. above), this condition cannot be assessed.

19 On this basis, the information requirement is not fulfilled.

2.3. Specification of the study design

20 To fulfil the information requirement for the Substance, information on molecular interaction with skin proteins and inflammatory response in keratinocytes and activation of dendritic cells (OECD TG 442C and OECD TG 442D and EU B.71/OECD TG 442E) must be

provided. Furthermore an appropriate risk assessment is required if a classification of the Substance as a skin sensitiser (Cat 1A or 1B) is warranted.

21 In case no conclusion on the skin sensitisation potency can be made for the Substance based on the existing data or newly generated in vitro/in chemico data, in vivo skin sensitisation study must be performed and the murine local lymph node assay (EU Method B.42/OECD TG 429) is considered as the appropriate study for the potency estimation.

3. Long-term toxicity testing on aquatic invertebrates

22 Short-term toxicity testing on aquatic invertebrates is an information requirement under Column 1 of Annex VII to REACH (Section 9.1.1.). However, long-term toxicity testing on aquatic invertebrates must be considered (Section 9.1.1., Column 2) if the substance is poorly water soluble.

3.1. Triggering of the information requirement

23 Poorly water soluble substances require longer time to reach steady-state conditions. As a result, the short-term tests does not give a true measure of toxicity for this type of substances and the long-term test is required. A substance is regarded as poorly water soluble if, for instance, it has a water solubility below 1 mg/L or below the detection limit of the analytical method of the test material (Guidance on IRs and CSA, Section R.7.8.5).

24 For the reasons explained under Request 1, the information requirement on water solubility is not fulfilled.

25 If the results of the information requested under Request 1 show that the Substance is poorly water soluble (i.e. water solubility under relevant conditions < 1 mg/L), information on long-term toxicity on aquatic invertebrates will need to be provided.

3.2. Information provided

26 You have adapted this information requirement by using a Grouping of substances and read-across approach based on an OECD 202 (2007) with the analogue substance Lanthanum Oxide, EC 215-200-5.

27 However, you provided no information on long-term toxicity on aquatic invertebrates for the Substance.

3.3. Assessment of the information provided

28 The examination of the information provided, as well as the selection of the requested test and the test design are addressed under Request 8.

4. Growth inhibition study aquatic plants

29 Growth inhibition study on aquatic plants is an information requirement under Annex VII to REACH (Section 9.1.2.).

4.1. Information provided

30 You have adapted this information requirement by using a Grouping of substances and read-across approach based on experimental data from the following substance:

(i) a OECD 201 (2007) with the analogue substance Cerium carbonate, EC 208-655-6

4.2. Assessment of the information provided

31 Annex XI, Section 1.5. specifies two conditions which must be fulfilled whenever a read-across approach is used. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group.

32 Additional information on what is necessary when justifying a read-across approach can be found in the Guidance on IRs and CSA, Chapter R.6. and related documents (RAAF, 2017; RAAF UVCB, 2017).

33 You do not provide any form of read-across justification for the prediction of this information requirement.

34 You predict the properties of the Substance from information obtained from the following source substance:

Cerium carbonate, EC 208-655-6

35 ECHA assumes that your read-across hypothesis is based on the production of common soluble ionic metal species. You predict the properties of your Substance to be quantitatively equal to those of the source substance.

36 We have identified the following issues with the prediction of growth inhibition on algae:

4.2.1. Absence of read-across documentation

37 Annex XI, Section 1.5 requires that whenever read-across is used adequate and reliable documentationof the applied method must be provided. Such documentation must include an explanation why the properties of the Substance may be predicted from information on the source substance.

38 You have provided robust study summary for study conducted with another substance than the Substance in order to comply with the REACH information requirements. However, you have not provided documentation as to why this information is relevant for the Substance and thus why the properties of the Substance may be predicted from information on the source substance.

39 In the absence of such documentation, the properties of the Substance cannot be reliably predicted from the data on the source substance.

4.2.2. Missing supporting information

40 Annex XI, Section 1.5 requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must provide supporting information to scientifically justify the read-across explanation for prediction of properties. The set of supporting information should strengthen the rationale for the read-across in allowing to verify the crucial aspects of the read-across hypothesis and establishing that the properties of the Substance can be predicted from the data on the source substance(s) (Guidance on IRs and CSA R.6, Section R.6.2.2.1.f.).

41 Supporting information must include transformation/dissolution information on the formation of the common ionic metal species and bridging studies to compare properties of the Substance and source substances.

42 As indicated above, your read-across hypothesis is based on the production of similar soluble ionic metal species from the Substance and the source substances. In this context, information characterising the rate and extent of the transformation/dissolution of the Substance and of the source substances is necessary to confirm the production of the proposed ionic metal species and to assess the impact of the exposure to the parent compounds.

43 Furthermore, as also indicated above, your read-across hypothesis is based on the assumption that the structurally similar substances cause the same type of effect(s). In this context, relevant, reliable and adequate information allowing to compare the properties of the Substance and of the source substances is necessary to confirm that both substances cause the same type of effects. Such information can be obtained, for example, from bridging studies of comparable design and duration for the Substance and of the source substances.

44 However, you have not provided any experimental information, about the transformation/dissolution of the Substance nor the source substance to support your claims regarding formation of a similar compounds.

45 Furthermore, for the source substance, you provide the study used in the prediction in the registration dossier. Apart from that study, your read-across justification or the registration dossier does not include any robust study summaries or descriptions of data for the Substance that would confirm that both substances cause the same type of effects.

46 In the absence of this information, you have not provided supporting evidence establishing the extent that the proposed similar soluble ionic metal species is formed as assumed in your read-across hypothesis. Therefore, you have not provided sufficient supporting information to scientifically justify your read-across hypothesis. Consequently, you have not established that the Substance and the source substances are likely to have similar properties.

47 As explained above, you have not established that relevant properties of the Substance can be predicted from data on the source substances. Therefore, your read-across approach under Annex XI, Section 1.5. is rejected and the information requirement is not fulfilled.

48 In the comments to the draft decision, you do not agree to perform the requested study. However, you state that *"a document, summarising and discussing all available data on the growth inhibition of rare earths to aquatic plants"* will be added to the dossier. On this basis ECHA undestands that, you intend to adapt this information requirement by means of another grouping and read-across approach according to Annex XI, Section 1.5, of the REACH Regulation.

49 ECHA takes note or your intentions to submit a read-across approach for this information requirement. As the information in your comments is not sufficient for ECHA to make an assessment, no conclusion on the compliance can currently be made.

50 You remain responsible for complying with this decision by the set deadline.

4.3. Study design and test specifications

51 The Substance is difficult to test due to its low water solubility. OECD TG 201 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified and documented. Due to the properties of Substance, it may be

difficult to achieve and maintain the desired exposure concentrations. Therefore, you must monitor the test concentration(s) of the Substance throughout the exposure duration and report the results. If it is not possible to demonstrate the stability of exposure concentrations (i.e. measured concentration(s) not within 80-120% of the nominal concentration(s)), you must express the effect concentration based on measured values as described in OECD TG 201. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solution.

Reasons related to the information under Annex VIII of REACH

5. Long-term toxicity testing on fish

52 Short-term toxicity testing on fish is an information requirement under Column 1 of Annex VIII to REACH (Section 9.1.3.). However, long-term toxicity testing on fish must be considered (Section 9.1.3., Column 2) if the substance is poorly water soluble.

5.1. Triggering of the information requirement

53 Poorly water-soluble substances require longer time to reach steady-state conditions. As a result, the short-term tests do not give a true measure of toxicity for this type of substances and the long-term test is required. A substance is regarded as poorly water soluble if, for instance, it has a water solubility below 1 mg/L or below the detection limit of the analytical method of the test material (Guidance on IRs and CSA, Section R.7.8.5).

54 For the reasons explained under Request 1, the information requirement on water solubility is not fulfilled.

55 If the results of the information requested under Request 1 show that the Substance is poorly water soluble (i.e. water solubility under relevant conditions < 1 mg/L), information on long-term toxicity on fish will need to be provided.

5.2. Information provided

56 You have adapted this information requirement by using a Grouping of substances and read-across approach based on experimental data from the following substance:

(i) a OECD 203 (2000) with the analogue substance Lanthanum Oxide, EC 215-200-5

57 However, you provided no information on long-term toxicity on fish for the Substance.

5.3. Assessment of the information provided

58 The examination of the information provided, as well as the selection of the requested test and the test design are addressed under section 9.

Reasons related to the information under Annex IX of REACH

6. Sub-chronic toxicity study (90-day)

59 A sub-chronic toxicity study (90 day) is an information requirement under Annex IX, Section 8.6.2.

6.1. Information provided

60 You have provided an OECD 422 (2013), GLP, with the Substance

61 You have also provided following justification: "In accordance with Section 1 of Annex XI a subchronic toxicity study, as required under Section 8.6.2 of Annex IX does not appear scientifically necessary. The existing oral OECD 422 data is considered to adequately address the repeated dose toxicity endpoint and a further 90-day study is regarded as unnecessary".

6.2. Assessment of the information provided

6.2.1. Study not adequate for the information requirement

62 To fulfil the information requirement, a study must comply with the OECD TG 408 (Article 13(3) of REACH). Therefore, the following specifications must be met:

a) dosing of the Substance daily for a minimum of 90 days;

63 In study (i), the following specifications are not according to the requirements of the OECD TG 408:

a) an exposure duration of ca 28 days for males and ca 42 days for females;

64 The information provided does not cover the key parameter required by the OECD TG 408.

65 Therefore, the information requirement is not fulfilled.

66 In the comments to the draft decision, you do not agree to perform the requested study. Instead, you indicate that you intend to adapt this information requirement by means of grouping and read-across according to Annex XI, Section 1.5, of the REACH Regulation.

67 ECHA takes note or your intentions to submit a read-across approach for this information requirement. As the information in your comments is not sufficient for ECHA to make an assessment, no conclusion on the compliance can currently be made.

68 You remain responsible for complying with this decision by the set deadline.

6.3. Specification of the study design

69 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 of the Substance; Guidance on IRs and CSA, Section R.7.5.6.3.2.

70 According to the OECD TG 408, the rat is the preferred species.

71 Therefore, the study must be performed in rats according to the OECD TG 408 with oral administration of the Substance.

7. Pre-natal developmental toxicity study in one species

72 A pre-natal developmental toxicity (PNDT) study (OECD TG 414) in one species is an information requirement under Annex IX, Section 8.7.2.

7.1. Information provided

73 You have provided an OECD 422 (2013), GLP, with the Substance

74 You have also provided the following justification: "*In accordance with Section 1 of Annex XI, the pre-natal developmental toxicity study (as required in Section 8.7.2 of Annex IX) does not appear scientifically necessary. No developmental effects were noted in an OECD 422 screening study and there is considered to be no need to further investigate this endpoint".*

7.2. Assessment of the information

7.2.1. Study not adequate for the information requirement

75 To fulfil the information requirement, a study must comply with OECD TG 414 (Article 13(3) of REACH). Therefore, the following specifications must be met:

a) at least 20 female animals with implantation sites are included for each test and control group;
b) the foetuses are examined for sex and body weight/external, skeletal and soft tissue alterations (variations and malformations)/number of resorptions and or live foetuses/ measurement of anogenital distance in live rodent foetuses.

76 The study is described as a Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test. This study has been conducted using the OECD TG 422 which is a screening tests rather than a conclusive developmental toxicity study.

77 That study does not cover the key parameters of the OECD TG 414 such as:

a) a statistical power equivalent to the OECD TG 414, as the study provided has 10 animals in each group
b) skeletal and soft tissue alterations (variations and malformations).

78 The study is therefore rejected.

79 In the comments to the draft decision, you do not agree to perform the requested study. Instead, you indicate that you intend to adapt this information requirement by means of grouping and read-across according to Annex XI, Section 1.5, of the REACH Regulation.

80 ECHA takes note or your intentions to submit a read-across approach for this information requirement. As the information in your comments is not sufficient for ECHA to make an assessment, no conclusion on the compliance can currently be made.

81 You remain responsible for complying with this decision by the set deadline.

7.3. Specification of the study design

82 A PNDT study according to the test method OECD TG 414 should be performed in rat or rabbit as preferred species.

83 The study must be performed with oral administration of the Substance (Guidance on IRs and CSA, Section R.7.6.2.3.2.).

84 Therefore, the study must be conducted in rats or rabbits with oral administration of the Substance.

8. Long-term toxicity testing on aquatic invertebrates

85 Long-term toxicity testing on aquatic invertebrates is an information requirement under Annex IX to REACH (Section 9.1.5.).

8.1. Information provided

86 You have adapted this information requirement by using Column 2 of Annex IX, Section 9.1. To support the adaptation, you have provided following justification "chemical safety assessment concludes that the substance is of no immediate concern to the environment".

8.2. Assessment of the information provided

8.2.1. Annex IX, Section 9.1., Column 2 is not a valid basis to omit the study

87 Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term toxicity to aquatic invertebrates under Column 1. It must be understood as a trigger for providing further information on aquatic invertebrates if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).

88 Your adaptation is therefore rejected.

89 In your comments on the draft decision, you state that you do not agree to perform the study. However, you state that "*reliable data*" are available for the "*water soluble compound (LaCl3)*". On this basis, ECHA undestands that you intend to adapt this information requirement by means of grouping and read-across according to Annex XI, Section 1.5, of the REACH Regulation.

90 ECHA takes note or your intentions to submit a read-across approach for this information requirement. As the information in your comments is not sufficient for ECHA to make an assessment, no conclusion on the compliance can currently be made.

91 You remain responsible for complying with this decision by the set deadline.

8.3. Study design and test specifications

92 OECD TG 211 specifies that, for difficult to test substances, OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design and test specifications' under Request 4.

9. Long-term toxicity testing on fish

93 Long-term toxicity testing on fish is an information requirement under Annex IX to REACH (Section 9.1.6.).

9.1. Information provided

94 You have adapted this information requirement by using Column 2 of Annex IX, Section 9.1. To support the adaptation, you have provided following justification "chemical safety assessment concludes that the substance is of no immediate concern to the environment".

9.2. Assessment of the information provided

9.2.1. Annex IX, Section 9.1., Column 2 is not a valid basis to omit the study

95 Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term toxicity to fish under Column 1. It must be understood as a trigger for providing further information on long-term toxicity to fish if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).

96 Your adaptation is therefore rejected.

97 In your comments on the draft decision, you state that you do not agree to perform the study. However, you state that "r*eliable data will be available for a water soluble compound on this endpoint*". On this basis, ECHA undestands that you intend to adapt this information requirement by means of grouping and read-across according to Annex XI, Section 1.5, of the REACH Regulation.

98 ECHA takes note or your intentions to submit a read-across approach for this information requirement. As the information in your comments is not sufficient for ECHA to make an assessment, no conclusion on the compliance can currently be made.

99 You remain responsible for complying with this decision by the set deadline.

9.3. Study design and test specifications

100 To fulfil the information requirement for the Substance, the Fish, Early-life Stage Toxicity Test (test method OECD TG 210) is the most appropriate (Guidance on IRs and CSA, Section R.7.8.2.).

101 OECD TG 210 specifies that, for difficult to test substances, OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design and test specifications' under Request 4.

10. Short-term toxicity to terrestrial invertebrates

102 Short-term toxicity to invertebrates is an information requirement under Annex IX to REACH (Section 9.4.1.)

10.1. Information provided

103 You have adapted this information by referring to Annex XI, Section 1. In support of your adaptation, you provided the following statement: "[the study] does not need to be conducted as the hazard assessment performed during the chemical safety assessment concludes that the substance is not classified and is of no immediate concern to the environment. 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".

10.2. Assessment of the information provided

10.2.1. Your adaptation does not meet the condition set out in Annex XI, Section 1

104 Annex XI, Section 1 describes general rules for adaptation in order to demonstrate that testing does not appear scientifically necessary. The corresponding provisions rely on the use of experimental evidence (in vitro and/or in vivo and/or in silico) to omit testing and include:

1) The use of existing data (Annex XI, Section 1.1.)
2) Weight of evidence (Annex XI, Section 1.2.)
3) Qualitative and quantitative structure-activity relationship (Annex XI, Section 1.3.)
4) In vitro methods (Annex XI, Section 1.4.)
5) Grouping of substances and read-across approach (Annex XI, Section 1.5.)

105 Your justification does not explicitly relate to any of the general rules for adaptation from Annex XI, Section 1. Furthermore, it does not rely on any experimental evidence (in vitro and/or in vivo and/or in silico). Therefore, you have not demonstrated that this information can be omitted.

106 In your comments to the draft decision, you do not agree to perform the requested study. Instead, you indicate that you intend to adapt this information requirement by means of grouping and read-across according to Annex XI, Section 1.5, of the REACH Regulation.

107 ECHA takes note or your intentions to submit a read-across approach for this information requirement. As the information in your comments is not sufficient for ECHA to make an assessment, no conclusion on the compliance can currently be made.

108 You remain responsible for complying with this decision by the set deadline.

10.3. Study design and test specifications

109 To fulfil the information requirement for the Substance the earthworm acute toxicity test (test method: EU.C.8/OECD TG 207) is the most appropriate (Guidance on IRs and CSA, Section R.7.11.3.1.).

11. Effects on soil micro-organisms

110 Effects on soil microorganisms is an information requirement under Annex IX to REACH (Section 9.4.2).

11.1. Information provided

111 You have adapted this information by referring to Annex XI, Section 1. In support of your adaptation, you provided the following statement: "[the study] does not need to be conducted as the hazard assessment performed during the chemical safety assessment concludes that the substance is not classified and is of no immediate concern to the environment. 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".

11.2. Assessment of the information provided

11.2.1. Your adaptation does not meet the condition set out in Annex XI, Section 1

112 For the reasons already explained under Section 10.2.1., your adaptation is rejected.

113 In your comments to the draft decision, you do not agree to perform the requested study. Instead, you indicate that you intend to adapt this information requirement by means of grouping and read-across according to Annex XI, Section 1.5, of the REACH Regulation.

114 ECHA takes note or your intentions to submit a read-across approach for this information requirement. As the information in your comments is not sufficient for ECHA to make an assessment, no conclusion on the compliance can currently be made.

115 You remain responsible for complying with this decision by the set deadline.

11.3. Study design and test specifications

116 To fulfil the information requirement for the Substance the Soil Microorganisms: Nitrogen Transformation Test (EU C.21/OECD TG 216) is most appropriate for assessing effects on soil microorganisms for most non-agrochemicals (Guidance on IRs and CSA, Section R.7.11.3.1.).

12. Short-term toxicity on terrestrial plants

117 Short-term toxicity plants is an information requirement under Annex IX to REACH (Section 9.4.3).

12.1. Information provided

118 You have adapted this information by referring to Annex XI, Section 1. In support of your adaptation, you provided the following statement: "[the study] does not need to be conducted as the hazard assessment performed during the chemical safety assessment concludes that the substance is not classified and is of no immediate concern to the environment. 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".

12.2. Assessment of the information provided

12.2.1. Your adaptation does not meet the condition set out in Annex XI, Section 1

For the reasons already explained under Section 10.2.1., your adaptation is rejected.

119 In your comments to the draft decision, you do not agree to perform the requested study. Instead, you indicate that you intend to adapt this information requirement by means of grouping and read-across according to Annex XI, Section 1.5, of the REACH Regulation.

120 ECHA takes note or your intentions to submit a read-across approach for this information requirement. As the information in your comments is not sufficient for ECHA to make an assessment, no conclusion on the compliance can currently be made.

121 You remain responsible for complying with this decision by the set deadline.

12.1. Study design and test specifications

122 To fulfil the information requirement for the Substance the Seedling Emergence and Seedling Growth Test (EU C.31./OECD TG 208, with at least three species) is the most appropriate (Guidance on IRs and CSA, Section R.7.11.3.1.).

References

The following documents may have been cited in the decision.

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

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

Guidance on data-sharing; ECHA (2017).

All Guidance on REACH is available online: https://echa.europa.eu/guidance-documents/guidance-on-reach

Read-across assessment framework (RAAF)

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

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

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

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

Appendix 2: Procedure

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

ECHA followed the procedure detailed in Articles 50 and 51 of REACH.

The compliance check was initiated on 07 December 2021.

ECHA notified you of the draft decision and invited you to provide comments.

ECHA took into account your comments and did not amend the requests.

The deadline of the decision is set based on standard practice for carrying out OECD TG tests. It has been exceptionally extended by 12 months from the standard deadline granted by ECHA to take into account currently longer lead times in contract research organisations.

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

As no amendments were proposed, ECHA adopted the decision under Article 51(3) of REACH.

Appendix 3: Addressees of this decision and their corresponding information requirements

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

- the information specified in Annex VII to REACH, for registration at 1-10 tonnes per year (tpa), or as a transported isolated intermediate in quantity above 1000 tpa;
- the information specified in Annexes VII and VIII to REACH, for registration at 10-100 tpa;
- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa;

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

Where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.

Appendix 4: Conducting and reporting new tests for REACH purposes

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

1.1. Test methods, GLP requirements and reporting

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

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

(3) Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries[2].

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

1.2. Test material

Before generating new data, you must agree within the joint submission on the chemical composition of the material to be tested (Test Material) which must be relevant for all the registrants of the Substance.

(1) Selection of the Test material(s)
The Test Material used to generate the new data must be selected taking into account the following:
- the variation in compositions reported by all members of the joint submission,
- the boundary composition(s) of the Substance,
- the impact of each constituent/ impurity on the test results for the endpoint to be assessed. For example, if a constituent/ impurity of the Substance is known to have an impact on (eco)toxicity, the selected Test Material must contain that constituent/ impurity.

(2) Information on the Test Material needed in the updated dossier
- You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
- The reported composition must include all constituents of each Test Material and their concentration values and other parameters relevant for the property to be tested.

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

This information is needed to assess whether the Test Material is relevant for the Substance and whether it is suitable for use by all members of the joint submission.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[3].

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