~~Confidential~~

Helsinki, 09 November 2023

Addressees
Registrants of JS_Dilanthanum tricarbonate as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
29/11/2019

Registered substance subject to this decision ("the Substance")
Substance name: Dilanthanum tricarbonate
EC/List number: 209-599-5

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 ***14 August 2026***.

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. 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)

3. 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

4. Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.; test method: EU C.1./OECD TG 203)

5. Long-term toxicity testing on fish also requested below (triggered by Annex VIII, Section 9.1.3., column 2; test method: EU C.47./OECD TG 210) 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. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: EU C.20./OECD TG 211)

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

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

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0. Reasons common to several requests

0.1. Assessment of the read-across approach

1 You have adapted the following standard information requirements by using grouping and read-across approach under Annex XI, Section 1.5:

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

2 ECHA has considered the scientific and regulatory validity of your read-across approaches in general before assessing the specific standard information requirements in the following sections.

3 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.

4 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).

0.1.1. Predictions for ecotoxicological properties

5 You provide a read-across justification document in IUCLID Section 13.

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

Source substance 1 Cerium carbonate, EC No. 691-114-5.

7 You provide the following reasoning for the prediction of for the prediction of ecotoxicological and environmental fate properties: "*The similarity in chemical behaviour of Lanthanum and Cerium can be stated due to the close electro-negative value (Pauling scale) and similar ionic radius (in 6 coordination number). Consequently, the two carbonates show very similar properties: the same composition, the same crystallographic structure and a very close solubility in pure water*".

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

9 We have identified the following issues with the predictions of aquatic toxicity:

0.1.1.1. Inadequate read-across hypothesis

10 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 include an explanation why the properties of the Substance may be predicted from other substances in the group, i.e. a read-across hypothesis.

11 This hypothesis should be based on recognition of the structural similarities and differences between the substances (Guidance on IRs and CSA, Section R.6.).It should also explain why the differences in the chemical structures should not influence the ecotoxicological properties or should do so in a regular pattern, taking into account that variations in chemical structure can affect both toxicokinetics (uptake and bioavailability) and toxicodynamics (e.g. interactions with receptors and enzymes) of substances (Guidance on IRs and CSA, Section R.6.2.1.3).

12 Your read-across hypothesis is only based on structural similarities and similarities in the physico-chemical properties of the source substances and the Substance. You consider that these elements are a sufficient basis for predicting the ecotoxicological properties of the Substance.

13 You have not substantiated how physico-chemical similarity between dilanthanum tricarbonate and cerium carbonate alone would explain similarity in the predicted property and thus be sufficient to justify the ecotoxicological predictions.

14 Physico-chemical similarity alone does not necessarily lead to predictable or similar ecotoxicological properties. You have not provided a well-founded hypothesis to establish a reliable prediction for an ecotoxicological property, explaining why the structural differences do not influence toxicokinetics and toxicodynamics of the substances, and thus why the properties of the Substance may be predicted from information on the source substances.

0.1.1.2. Missing supporting information

15 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.).

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

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

18 Furthermore, 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.

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

20 Furthermore, for the source substance, you provide the studies used for the predictions in the registration dossier. Apart from these studies, 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 the target and source substances cause the same type of effects.

21 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. Furthermore, also you have not established that the Substance and the source substance are likely to have similar properties. Therefore, you have not provided sufficient supporting information to scientifically justify your read-across hypothesis.

0.1.2. Conclusion on the read-across approach

22 For the reasons above, you have not established that relevant properties of the Substance can be predicted from data on the source substance(s).

23 In your comments to the draft decision you provide the same statement for the endpoints presented above. You specifically state for that an "*updated Read Across in accordance with ECHA 2017 would provide the necessary level of information a suitable format.* ECHA takes note of your intentions to submit an updated version of your 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.

24 Your read-across approach under Annex XI, Section 1.5. is rejected.

Reasons related to the information under Annex VII of REACH

1. Water solubility

25 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

26 Based on a water solubility experiment according to the key OECD TG 105 submitted in your dossier, the Substance is concluded to be a sparingly soluble metal compound as its solubility in water was determined to be 1.24 mg/L at 20°C (loading rate of c.a. 3.5 mg/L).

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

1.2. Information provided

28 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).

29 However, you have provided OECD TG 105 studies (2006, 2009, 2010) but no information on the transformation/dissolution in aqueous media of the Substance.

30 In your comments on the draft decision, you consider that the provided OECD 105 study "*is suitable to cover this endpoint*" and you state your intention to update your registration dossier and that "*the study robust summary will have to be enhanced for distinction between poorly soluble, soluble and sparingly soluble*".

31 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.

1.3. Study design and test specifications

32 Under Section 4.5. of your technical dossier, dossier two key studies on granulometry carried out according to OECD 110 and the Guidance document, ECB/TM/February 1996 show that the registered substance have particle size ranging between 6.6 µm and 52 µm with a mass median diameter (D_{50}) of 29.6 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. Long-term toxicity testing on aquatic invertebrates

33 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.

2.1. Triggering of the information requirement

34 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).

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

36 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.

37 In your comments to the draft decision you do not agree to perform the study. You state that "*according to the OECD 105 provided, the water soluble is more than 1 mg/l.*"

38 However, as already stated under request 1 information on transformation/dissolution in aqueous media are not provided in your dossier or your comments on the draft decision. Therefore the information currently available in your dossier does not demonstrate that the substance is not poorly water soluble.

2.2. Information provided

39 You have provided an OECD TG 202 study and information on long-term toxicity on aquatic invertebrates for the Substance.

2.3. Assessment of the information provided

40 The examination of the information provided, as well as the selection of the requested test and the test design are addressed under Request 6.

3. Growth inhibition study aquatic plants

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

3.1. Information provided

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

i. an OECD TG 201 study (2007) with the analogue substance Cerium carbonate, EC 208-655-6.

3.2. Assessment of the information provided

3.2.1. Read-across adaptation rejected

43 As explained in Section 0.1., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5 is rejected.

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

3.3. Study design and test specifications

45 The Substance is difficult to test due to the 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

4. Short-term toxicity testing on fish

46 Short-term toxicity testing on fish is an information requirement under Annex VIII to REACH (Section 9.1.3.).

4.1. Information provided

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

i. an OECD TG 203 study (2007) with the analogue substance Cerium carbonate, EC 208-655-6.

4.2. Assessment of the information

4.2.1. Read-across adaptation rejected

48 As explained in Section 0.1., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5 is rejected.

4.3. Study design and test specifications

49 OECD TG 203 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 3.

5. Long-term toxicity testing on fish

50 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

51 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).

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

53 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.

54 In your comments to the draft decision you do not agree to perform the study. You state that "*according to the OECD 105 provided, the water soluble is more than 1 mg/l.*"

55 However, as already stated under request 1 information on transformation/dissolution in aqueous media are not provided in your dossier or your comments on the draft decision. Therefore the information currently available in your dossier does not demonstrate that the substance is not poorly water soluble.

5.2. Information provided

56 As explained in Request 4, you have incompliant information on short-term toxicity to fish. Furthermore, you have adapted the information requirement for long-term toxicity on fish for the Substance.

5.3. Assessment of the information provided

57 The examination of the information provided on long-term toxicity on fish, as well as the selection of the requested test and the test design are addressed under section 7.

Reasons related to the information under Annex IX of REACH

6. Long-term toxicity testing on aquatic invertebrates

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

6.1. Information provided in your dossier

59 You have provided:

i. an OECD 211 study (2010) with the Substance

60 In addition, you have adapted this information requirement by using a Grouping of substances and read-across approach based on the following experimental data:

ii. an OECD 211 study (2009) with the analogue substance Cerium carbonate, EC 208-655-6

6.2. Assessment of the information provided in your dossier

6.2.1. The provided study on the Substance (study i) does not meet the information requirement

61 To fulfil the information requirement, a study must comply with the OECD TG 211 (Article 13(3) of REACH). Therefore, the following specifications must be met:

62 Validity criteria

a) the mean number of living offspring produced per surviving parent animal in the control is ≥ 60 at the end of the test.

63 Your registration dossier provides an OECD TG 211 study showing the following:

a) the mean number of living offspring produced per parent animal surviving at the end of the test was 43.

64 Based on the above, the validity criteria of OECD TG 211 are not met.

6.2.2. Read-across adaptation rejected (study ii)

65 As explained in Section 0.1., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5 is rejected.

6.3. Information provided in your comments on the draft decision

66 In your comments to the draft decision you do not agree to perform the study. However, you state that "*… both M4 and M7 media contain phosphates*" and that precipitation might influence the test results as the "*concentration of the test item would decrease parallel to the formation of Lanthanum phosphate*". You also state that "*conducting a test in the absence of phosphate may be feasible*". ECHA understands that you intend to adapt this information requirement on the basis of Annex XI, Section 2.

6.3.1. Adaptation under Annex XI, Section 2 is rejected

67 Under Annex XI, Section 2, a study may be omitted if it is technically not feasible to conduct because of the properties of the substance.

68 You claim that the study might be difficult to conduct however you do not provide evidence to demonstrate that it was technically not feasible which is a different legal criteria. ECHA notes that according to the OECD TG 211, M4 and M7 are not recommended for testing substances containing metals and the use of an alternative medium is advised (e.g. ASTM reconstituted hard fresh water).

69 Therefore, your adaptation is rejected.

70 On this basis, the information requirement is not fulfilled and you remain responsible for complying with this decision by the set deadline.

6.4. Study design and test specifications

71 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 3.

7. Long-term toxicity testing on fish

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

7.1. Information provided in your dossier

73 You have adapted this information requirement by using Column 2 of Annex IX, Section 9.1. To support the adaptation, you have provided the following information:

(i) The Chemical safety assessment according to Annex I does not indicate the need to investigate further the effects on aquatic organisms. You further provide the following statements to support this justification:

a. "*The short-term toxicity to fish shows no effects up to the highest concentration of 100 mg/L tested for the analogue substance*";
b. "*None of the available aquatic studies for three trophic levels showed any hazard effects up to the limit of water solubility of the substance*";
c. "*There is no indication that fish could be the most sensitive species between the three trophic levels*";
d. "*No toxicity through bioaccumulation is expected either*".

(ii) You refer to minimisation of vertebrate animal testing: "[…] *due to animal welfare reasons long-term testing on fish is not considered justifiable*".

7.2. Assessment of the information provided in your dossier

7.2.1. Annex IX, Section 9.1., Column 2 is not a valid basis to omit the study (i)

74 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).

75 Your adaptation is therefore rejected.

7.2.2. Your justification (ii) has no legal basis

76 A registrant may only adapt this information requirement based on the general rules set out in Annex XI.

77 Your justification to omit this information based on minimisation of testing on vertebrate animals does not refer to any legal ground for adaptation under Annex XI to REACH.

78 Therefore, you have not demonstrated that this information can be omitted.

7.3. Information provided in your comments on the draft decision

79 In your comments on the draft decision, you state that you do not agree to perform the study. However, you state that *"A test demand should be considered after receiving the water solubility/dissolution transformation data (OECD 29) data and in line with animal welfare for the most appropriate"*. ECHA understands that you may 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 indicated in your comments, this strategy relies essentially on data which is yet to be generated, therefore no conclusion on the compliance can currently be made.

81 On this basis, the information requirement is not fulfilled, and you remain responsible for complying with this decision by the set deadline.

7.4. Study design and test specifications

82 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.).

83 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 3.

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;
- the information specified in Annexes VII to X to REACH, for registration at more than 1000 tpa.

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