

Helsinki, 5 May 2022

Addressees

Registrants of RECONSILE EC#252-161-3 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision

08/06/2021

Registered substance subject to this decision ("the Substance")

Substance name: Triethoxy(3-thiocyanatopropyl)silane

EC number: 252-161-3

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

DECISION ON TESTING PROPOSAL(S)

Based on Article 40 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by **13 May 2024**.

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

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

1. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: EU C.20./OECD TG 211)
2. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: EU C.47./OECD TG 210)
3. Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: EU C.21./OECD TG 216)
4. Long-term toxicity testing on terrestrial invertebrates (triggered by Annex IX, Section 9.4.1., column 2; test method: EU C.33/OECD TG 222)
5. Long-term toxicity on terrestrial plants (triggered by Annex IX, Section 9.4.3., column 2; test method: EU C.31./OECD TG 208 with at least six species)

Your originally proposed test using the silanol hydrolysis product of the Substance(3-thiocyanatopropyl)silanetriol is rejected, according to Article 40(3)(d).

The reasons for the decisions 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.

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.

Authorised¹ 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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Reasons for the decision(s) related to the information under Annex IX of REACH**1. Long-term toxicity testing on aquatic invertebrates**

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

1.1. Information provided to fulfil the information requirement

2. You have submitted a testing proposal for a Daphnia magna reproduction test (test method: EU C.20/OECD TG 211).
3. Your registration dossier does not include any information on long-term toxicity on aquatic invertebrates.
4. ECHA agrees that an appropriate study on long-term toxicity on aquatic invertebrates is needed.
5. In the comments to the draft decision, you agree to perform the requested study.

1.2. Test selection and study specifications

6. The proposed Daphnia magna reproduction test (test method: EU C.20/OECD TG 211) is appropriate to cover the information requirement for long-term toxicity on aquatic invertebrates (Guidance on IRs and CSA, Section R.7.8.4.1.).
7. The Substance is difficult to test due to the short hydrolysis half-life (23 h at pH 7 based on an OECD TG 111 study). OECD TG 211 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 211. 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 solutions.

1.3. Outcome

8. Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test with the Substance, as specified above.

2. Long-term toxicity testing on fish

9. Long-term toxicity testing on fish is an information requirement under Annex IX to REACH (Section 9.1.6.).
10. Under Article 40(3)(c) of REACH, ECHA may require a registrant to carry out one or more additional tests in case of non-compliance of the testing proposal with Annexes IX, X or XI of the REACH Regulation. The information requirement on Aquatic toxicity at Annex IX covers both long-term toxicity on invertebrates (Section 9.1.5.) and on fish (Section 9.1.6.). You have submitted a testing proposal for long-term testing on aquatic

invertebrates. In case there is also a data gap for toxicity on fish, it is necessary to request this information as an additional test to further investigate aquatic toxicity.

2.1. Information provided to fulfil the information requirement

11. Your registration dossier does not include any information on long-term toxicity on fish.
12. Instead, you provided an adaptation under Annex IX, Section 9.1.6., column 2 with the following justification:
 1. You claim that the risk characterisation ratio (RCR) is lower than 1 and therefore the risk associated with the Substance is already adequately controlled.
 2. You nevertheless indicate your intention to review the RCR and re-evaluate the need for a long-term fish toxicity study after the results of the proposed OECD TG 211 study are available.
 3. On the basis of available short-term aquatic toxicity data, you claim that the most sensitive trophic level is that of the fish.
 4. You apply an assessment factor (AF) of 1000 for deriving the $PNEC_{\text{freshwater}}$ and you claim that this high AF reflects the difference between effect concentrations derived from short-term and long-term studies and provides sufficiently conservative risk characterisation conclusion for the Substance.
13. ECHA assessed this information and identified the following issue:
14. 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 fish if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).
15. Your adaptation is therefore rejected.
16. Therefore, ECHA concludes that an appropriate long-term toxicity study on fish is needed.
17. In the comments to the draft decision, you agree to perform the requested study.

2.2. Test selection and study specifications

18. The Fish, Early-Life Stage Toxicity Test (test method: OECD TG 210) is appropriate to cover the information requirement for long-term toxicity on fish (Guidance on IRs and CSA, Section R.7.8.4.1.).
19. OECD TG 210 specifies that for difficult to test substances OECD GD 23 must be followed. As already explained under Request 1, the Substance is difficult to test. Therefore, you must fulfil the requirements described in the 'Study design' under Request 1.

2.3. Outcome

20. Under Article 40(3)(c) of REACH, you are requested to carry out the additional test with the Substance, as specified above.

3. Effects on soil micro-organisms

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

3.1. Information provided to fulfil the information requirement

22. You have submitted a testing proposal for a Soil Microorganisms: Nitrogen Transformation Test (EU C.21/OECD TG 216) with the following justification:

1. You provide the results of an OECD TG 209 test which indicate that the Substance is toxic to wastewater (activated sludge) bacteria.
 2. You refer to the Guidance on IRs and CSA, Section 7.11.5.3. and claim that a study on soil microbial toxicity is necessary for the Substance that is toxic to aquatic microorganisms.
23. Your registration dossier does not include any information on effects on soil microorganisms.
24. ECHA assessed your testing proposal and notes the following:
25. Under Annex IX, Section 9.4., column 2, in the absence of toxicity data to soil organisms, the equilibrium partitioning method (EPM) may be applied to assess the hazard to soil organisms. In this context, the Guidance on IRs and CSA, Section R.7.11.16. describes an integrated testing strategy (ITS) for Effects on Terrestrial Organisms. For the soil compartment there are currently no criteria for classification and PBT assessment, therefore the ITS for soil is especially focussed on generating data for the chemical safety assessment. This approach relies on the assignment of the Substance to a "soil hazard category" and on an initial screening assessment using the EPM, in order to decide the information needed for the chemical safety assessment.
26. The following information indicates that Substance falls into the soil hazard category 3 (HC3) and microorganisms are the most sensitive group:
- The Substance is not considered very toxic to aquatic organisms.
 - In Sections 2.3 and 5.2.1. of the technical dossier, you provide the following information:
 1. You claim that the Substance hydrolyses and that the hydrolysis products are (3-thiocyanatopropyl)silanetriol and ethanol (EC 200-578-6). Further, you claim that the silanol hydrolysis product of the Substance may persist in the environment.
 2. You claim that the silanol hydrolysis product of the Substance is not expected to biodegrade to any significant extent.
27. You provide an initial screening assessment based on a $PNEC_{screen}$ estimated using the EPM. You apply an assessment factor (AF) of 10. Your screening assessment concludes that there is a risk for the soil compartment ($RCR > 1$).
28. In Section 6.1. of your technical dossier, you provide the following results derived from studies conducted with the Substance:
1. LC50 (*D. rerio*, 96h): 10-18 mg/L and NOEC: 10 mg/L from an OECD TG 203 study
 2. EC50 (*D. magna*, 24h, immobilisation): 29 mg/L and NOEC: 10 mg/L from an OECD TG 202 study
 3. EC50 (*S. subspicatus*, 96h, growth rate): 160 mg/L and NOEC: 10 mg/L from an OECD TG 201 study
 4. EC10 (3h, respiration rate and inhibition of total respiration): 4.3 mg/L and NOEC: 1.0 mg/L from an OECD TG 209 study
29. On the basis of the reported NOEC values, aquatic micro-organisms are more sensitive by a factor of 10 than aquatic invertebrates or aquatic plants.
30. Therefore, ECHA agrees that an appropriate study on effects on soil microorganisms is needed.

3.2. Test selection and study specifications

31. The proposed Soil Microorganisms: Nitrogen Transformation Test (EU C.21/OECD TG 216) is appropriate to cover the information requirement on effects on soil microorganisms (Guidance on IRs and CSA, Section R.7.11.3.1.).

3.3. Outcome

32. Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test with the Substance, as specified above.

4. Long-term toxicity testing on terrestrial invertebrates

33. Short-term toxicity to invertebrates is an information requirement under Annex IX to REACH (Section 9.4.1). Long-term toxicity testing must be considered (Annex IX, Section 9.4., column 2) if the substance has a high potential to adsorb to soil or is very persistent.

4.1. Information provided to fulfil the information requirement

34. You have submitted a testing proposal for an EU C.33/OECD TG 222 study with the following justification:
1. You indicate the Substance as the proposed test material in the "Test material information" section of your testing proposal.
 2. You claim that the Substance belongs to the soil hazard category 3.
 3. You claim that RCR is above 1 for the terrestrial compartment. You acknowledge that on this basis, long-term tests on both terrestrial invertebrates and plants should be conducted.
 4. In the "Principles of method if other than guideline" section of your testing proposal, you propose to conduct a confirmatory long-term soil toxicity test with the silanol hydrolysis product of the Substance on invertebrates. In Section 6.3. of your technical dossier, you conclude that the Substance will be completely hydrolysed to its hydrolysis products by the time it reaches the terrestrial compartment.
35. Your registration dossier does not include any information on long-term toxicity to terrestrial invertebrates.
36. ECHA assessed your testing proposal and notes the following:
37. Under Annex IX, Section 9.4., column 2, in the absence of toxicity data to soil organisms, the equilibrium partitioning method (EPM) may be applied to assess the hazard to soil organisms. In this context, the Guidance on IRs and CSA, Section R.7.11.16. describes an integrated testing strategy (ITS) for Effects on Terrestrial Organisms. For the soil compartment there are currently no criteria for classification and PBT assessment, therefore the ITS for soil is especially focused on generating data for the chemical safety assessment. This approach relies on the assignment of the Substance to a "soil hazard category" and on an initial screening assessment using the EPM, in order to decide the information needed for the chemical safety assessment.
38. As explained above under Request 3, available information indicates that Substance falls into the soil hazard category 3 (HC3). Further, on the basis of your initial screening assessment, there is a risk for the soil compartment (RCR >1).
39. As specified in the Guidance on IRs and CSA, Table R.7.11-2, in such case, long-term toxicity tests as set out under Annex X, Section 9.4. (invertebrates and plants) need to be provided.
40. Therefore, ECHA agrees that an appropriate long-term toxicity study on terrestrial invertebrates is needed.

4.2. Grouping of substances and read-across approach

41. In your testing proposal, you indicate both the Substance and the silanol hydrolysis product of the Substance as the test material. Further, you claim that the risk assessment of the Substance for the terrestrial compartment is based on the hydrolysis products of the Substance.
42. ECHA understands that you intend to fulfil the information requirement for Long-term toxicity testing on terrestrial invertebrates by way of adaptation under Annex XI, Section 1.5 ('Read-across and grouping of substances').
43. 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.
44. Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance R.6. and related documents^{2,3}.
45. You do not provide a read-across justification document in IUCLID Section 13. However, you provide additional information (Considerations of both the silanol hydrolysis product: triethoxy(3-thiocyanatopropyl)silanetriol and the non-silanol hydrolysis product: ethanol) in IUCLID Section 6.3.
46. You read-across between the structurally similar substances, triethoxy(3-thiocyanatopropyl)silanetriol (i.e., the silanol hydrolysis product of the Substance, EC and CAS number not provided) as source substance and the Substance as target substance.
47. You have provided the following reasoning for the prediction of the ecotoxicological property (toxicity to terrestrial invertebrates):
 - In IUCLID Section 6.3., on the basis of the reported hydrolysis half-life of the Substance, you claim that the Substance will be completely hydrolysed to its hydrolysis products by the time it reaches the terrestrial compartment.
48. In the comments to the draft decision, you re-iterate the same consideration, claiming that the hydrolysis product of the Substance is more relevant for the terrestrial toxicity testing than the Substance, because the Substance will be hydrolysed before the soil exposure takes place.
49. ECHA understands that you predict the properties of the Substance using a read-across hypothesis which is based on the "moderately rapid" formation of transformation products. The properties of your Substance are predicted to be quantitatively equal to those of the source substance.
50. ECHA notes the following shortcoming with regards to prediction of ecotoxicological properties.

4.2.1. Insufficient information for supporting the test material selection

51. Annex XI, Section 1.5 of the REACH Regulation states that "physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s)". For this purpose, "it is important to provide

² Read-Across Assessment Framework (RAAF). 2017 (March) ECHA, Helsinki. 60 pp. Available online: [Read-Across Assessment Framework \(https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across\)](https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across)

³ Read-across assessment framework (RAAF) - considerations on multi-constituent substances and UVCBs. 2017 (March) ECHA, Helsinki. 40 pp. Available online: <https://doi.org/10.2823/794394>

supporting information to strengthen the rationale for the read-across" (Guidance on IRs and CSA R.6, Section R.6.2.2.1.f.). The set of supporting information should allow to verify the crucial aspects of the read-across hypothesis and establish that the properties of the Substance can be predicted from the data on the source substance(s).

52. Supporting information must include bridging studies to compare properties of the Substance and source substance on the prediction.
53. As 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 substance 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 substance.
54. For the source substance, you provide the following information: In Section 7 of the CSR, you claim that a functional group associated with ecotoxicity by a specific mode of action (thiocyanate) is present both in the Substance and in the silanol hydrolysis product. The toxic effects seen in available studies are attributed to this functional group. You conclude that both the Substance and the silanol hydrolysis product could contribute equivalently to any effects observed.
55. Your registration dossier does not include any robust study summaries or descriptions of data for the source substance that would confirm that both substances cause the same type of effects.
56. Additionally, you report that hydrolysis half-life of the Substance is 23 h at pH 7 (OECD TG 111 study, 2012). On the basis of this half-life value, you claim that the terrestrial organisms will be exposed solely to the hydrolysis products of the Substance (i.e., (3-thiocyanatopropyl)silanetriol and ethanol) by the time it reaches the soil compartment. However, you do not provide further data to substantiate this claim.

4.2.2. *Conclusion on the test material selection*

57. In the absence of such information, you have not established that the Substance and the source substance are likely to have similar properties. Based on the assessment of the registration dossier, the supporting information currently available does not allow for concluding on the acceptability of the proposed read-across approach. Therefore, ECHA cannot confirm that the testing of the hydrolysis product of the Substance would generate information that fulfils the information requirement.

4.3. *Additional considerations on the test material selection*

58. In the comments to the draft decision, you claim that the Substance will not be maintained in the test system, therefore, effects potentially observed in the test will not be attributable to either the Substance or the hydrolysis product of the Substance.
59. However, ECHA notes the following:
 - The reported hydrolysis half-life of the Substance is long enough to assume that the testing of the Substance is technically feasible.
 - Further, for the Substance, you provide aquatic toxicity studies (OECD TG 203, TG 202, TG 201, TG 209) in IUCLID Section 6.1. In the conclusion of those studies, you claim the following: The Substance "is susceptible to hydrolysis and it is likely that the test organisms were primarily exposed to a mixture of the parent compound and the hydrolysis products" of the Substance. Therefore, effects seen in the aquatic toxicity studies were attributed to the mixture of the Substance and the hydrolysis products of the Substance. You propose an OECD TG 211 study

(duration: 21 days) and an OECD TG 216 study (duration: 28 days) with the Substance. In these tests, as in the proposed OECD TG 222 study (duration: 28 days), the test organisms will also likely be exposed to a mixture of the Substance and the hydrolysis products of the Substance.

60. Therefore, ECHA concludes that testing with the Substance is appropriate.
61. In the comments to the draft decision, you agree to perform the requested study and acknowledge that the test material requested by ECHA is the Substance.

4.4. Test selection and study specifications

62. The proposed EU C.33/OECD TG 222 is appropriate to cover the information requirement for long-term toxicity on terrestrial invertebrates (Guidance on IRs and CSA, Section R.7.11.3.1).

4.5. Outcome

63. Your testing proposal is rejected under Article 40(3)(d) of REACH. Under Article 40(3)(c) you are requested to carry out the test with the Substance, as specified above.

5. Long-term toxicity to terrestrial plants

64. Short-term toxicity to terrestrial plants is an information requirement under Annex IX to REACH (Section 9.4.3). Long-term toxicity testing must be considered (Annex IX, Section 9.4., column 2) if the substance has a high potential to adsorb to soil or is very persistent.
65. Under Article 40(3)(c) of REACH, ECHA may require a registrant to carry out one or more additional tests in case of non-compliance of the testing proposal with Annexes IX, X of the REACH Regulation. The information requirement for Effects on terrestrial organisms at Annex IX covers short-term toxicity to invertebrates (Section 9.4.1.), effects on soil micro-organisms (Section 9.4.2.) and short-term toxicity to plants (Section 9.4.3.). You have submitted a testing proposal for long-term toxicity to invertebrates and effects on soil micro-organisms. In case there is also a data gap for toxicity to plants, it is necessary to request this information as an additional test to further investigate the effects on terrestrial organisms.

5.1. Information provided to fulfil the information requirement

66. Your registration dossier does not include any information on long-term toxicity to terrestrial plants.
67. Instead, you have provided the following information:
1. You submitted testing proposals for long-term aquatic and terrestrial toxicity studies (OECD TG 211, TG 216, TG 222).
 2. You indicated your intention to review the risk assessment of the Substance and the need for a study on long-term toxicity to plants, after data from these studies become available.
68. In the comments to the draft decision, you present a “tiered testing strategy” in which you propose to update the aquatic PNEC_{screen} value after data from long-term aquatic toxicity (fish and invertebrate) studies have become available. You re-iterate your proposal to re-assess if the long-term toxicity test on plants is needed, taking into account the updated PEC/PNEC ratio, as well as the effects observed in the long-term toxicity test on terrestrial invertebrates.

69. ECHA understand that you seek to adapt the information requirement under Annex IX, Section 9.4, column 2.
70. ECHA assessed this information and identified the following issue:
71. Under Annex IX, Section 9.4., column 2, in the absence of toxicity data to soil organisms, the equilibrium partitioning method (EPM) may be applied to assess the hazard to soil organisms. In this context, the Guidance on IRs and CSA, Section R.7.11.16. describes an integrated testing strategy (ITS) for Effects on Terrestrial Organisms. For the soil compartment there are currently no criteria for classification and PBT assessment, therefore the ITS for soil is especially focused on generating data for the chemical safety assessment. This approach relies on the assignment of the Substance to a "soil hazard category" and on an initial screening assessment using the EPM, in order to decide the information needed for the chemical safety assessment.
72. As already explained above under Request 3, available information indicates that Substance falls into the soil hazard category 3 (HC3). Further, on the basis of your initial screening assessment using the EPM, there is a risk for the soil compartment (RCR >1).
73. As specified in the Guidance on IRs and CSA, Table R.7.11-2, in such case, long-term toxicity tests as set out under Annex X, Section 9.4. (invertebrates and plants) need to be provided.
74. Therefore, ECHA concludes that an appropriate long-term toxicity study on terrestrial plants is needed.
75. Further, ECHA acknowledges your intention to use a tiered testing strategy, and the EPM. As indicated in your comments, the refined EPM screening relies on data from studies requested in sections 1, 2 and 4 above, which are yet to be generated. Therefore, no conclusion on the compliance can currently be made. ECHA notes that the deadline set by this decision allows for sequential testing.

5.2. Test selection and study specifications

76. The proposed Terrestrial Plant Test (EU C.31./OECD TG 208, with at least six species) is appropriate to cover the information requirement for long-term toxicity on terrestrial plants.
77. The OECD TG 208 (EU C.31.) considers the need to select the number of test species according to relevant regulatory requirements, and the need for a reasonably broad selection of species to account for interspecies sensitivity distribution. For long-term toxicity testing, ECHA considers six species as the minimum to achieve a reasonably broad selection. Testing must be conducted with species from different families, as a minimum with two monocotyledonous species and four dicotyledonous species, selected according to the criteria indicated in the OECD TG 208.

5.3. Outcome

78. Under Article 40(3)(c), you are requested to conduct the additional test with the Substance, as specified above.

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

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 23 August 2021.

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

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

ECHA took into account your comments and did not amend the request(s).

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

As no amendments were proposed, ECHA took the decision according to Article 51(3) of the REACH Regulation.

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 Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa.

| Registrant Name | Registration number | Highest REACH Annex applicable to you |
|------------------------|----------------------------|--|
| ████████████████████ | ████████████████████ | ██████ |
| ████████████████████ | ████████████████████ | ██████ |

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 summaries⁴.

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.

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 dossiers⁵.

⁴ <https://echa.europa.eu/practical-guides>

⁵ <https://echa.europa.eu/manuals>