~~Confidential~~

Helsinki, 24 November 2022

Addressees
Registrant(s) of 239-370-5_JS as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
01/05/2018

Registered substance subject to this decision ("the Substance")
Substance name: Zinc bis(dipentyldithiocarbamate)
EC number: 239-370-5

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

2. Long-term toxicity testing on aquatic invertebrates (triggered by Annex VII, Section 9.1.1., column 2; test method: EU C.20./OECD TG 211)

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

3. Long-term toxicity testing on fish (triggered by Annex VIII, Section 9.1.3., column 2; test method: EU C.47./OECD TG 210)

4. Simulation testing on ultimate degradation in surface water (triggered by Annex VIII, Section 9.2.; test method: EU C.25./OECD TG 309) at a temperature of 12°C. Non-extractable residues (NER) must be quantified and a scientific justification of the selected extraction procedures and solvents must be provided.

5. Soil simulation testing (triggered by Annex VIII, Section 9.2.; test method: EU C.23./OECD TG 307) at a temperature of 12°C. Non-extractable residues (NER) must be quantified and a scientific justification of the selected extraction procedures and solvents must be provided.

6. Sediment simulation testing (triggered by Annex VIII, Section 9.2.; test method: EU C.24./OECD TG 308) at a temperature of 12°C. Non-extractable residues (NER) must be quantified and a scientific justification of the selected extraction procedures and solvents must be provided.

7. Identification of degradation products (triggered by Annex VIII, Section 9.2; test method: EU C.25./OECD TG 309, EU C.23./OECD TG 307 or EU C.24./OECD TG 308).

8. Bioaccumulation in aquatic species (triggered by Annex I, sections 0.6.1. and 4.; Annex XIII, Section 2.1.; test method: EU C.13./OECD TG 305, aqueous exposure

The reasons for the decision(s) 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. In addition, the studies relating to biodegradation and bioaccumulation are necessary for the PBT assessment. However, to determine the testing needed to reach the conclusion on the persistency and bioaccumulation of the Substance you should consider the sequence in which these tests are performed and other conditions described in this Appendix.

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. Growth inhibition study aquatic plants

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

1.1. Information provided

You have provided a study according to OECD TG 201.

1.2. Assessment of the information provided

2 We have assessed this information and identified the following issues:

1.2.1. The provided study does not meet the information requirement

3 To fulfil the information requirement, a study must comply with OECD TG 201 and the requirements of OECD GD 23 if the substance is difficult to test (Article 13(3) of REACH). Therefore, the following specifications must be met:

Requirements applicable to difficult to test substances

a) if the test material is tested at the saturation concentration, evidence must be provided that all reasonable efforts have been taken to achieve a saturation concentration, which include:

1) an analytical method validation report demonstrating that the analytical method is appropriate,

2) the results of a preliminary experiment demonstrating that the test solution preparation method is adequate to maximize the concentration of the test material in solution, and

3) a justification for, or validation of, the separation technique is provided, as it can cause losses due to adsorption onto the filter matrix.

4 Your registration dossier provides an OECD TG 201 showing the following:

5 Reporting of the methodology and result

6 Requirements applicable to difficult to test substances

a) the water solubility of the Substance is 0.086 mg/L and you report that you achieved a 100% v/v saturated solution by preparing a test solution at nominal loading rate of 50 mg/L, which was stirred, filtered and then diluted to achieve test concentrations. On analytical method, no validation of the analytical method is provided only information that the test material concentration was determined based on elemental zinc detected through ICP-MS. On the preliminary solubility study, the analytical results are not provided. Finally, on the separation technique, you indicate that the test solution was filtered through a membrane of 0.2 µm. However no justification or validation is provided for the separation method used.

7 Based on the above,

8 Additional requirements applicable to difficult to test substances:

9 You have not demonstrated that saturation concentration was achieved due to the following:

i. As you have not provided an analytical method validation report, you have not demonstrated that the ICP-MS method is an appropriate analytical method to detect the dissolved fraction of the source substance. Therefore it is not possible to conclude if (apart of the zinc ion) analytical method is appropriate to confirm the concentration of all the constituents of the Substance.

ii. The results of the preliminary solubility study are not provided, therefore ECHA is not in a position to assess if the test solution preparation method is adequate to maximize the concentration of the test material in solution.

iii. Separation method, you have not justified nor demonstrated that the method applied in the aquatic toxicity test, allowed achieving maximum dissolved concentrations.

10 In the comments to the draft decision, you submitted all the missing information listed above, supported by document "Appendix 1". ECHA has assessed the information against the requirement in OECD TG 201. The information you have provided in your comments addresses the incompliances identified in this decision for this information requirement. However, as the information is currently not available in your registration dossier, the data gap remains. You should therefore submit this information in an updated registration dossier by the deadline set out in the decision.

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

1.3. Study design and test specifications

12 The Substance is difficult to test due to the low water solubility (0.086 mg/L) and/or adsorptive properties (Log Kow = 9.4). 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.

2. Long-term toxicity testing on aquatic invertebrates

13 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. Information provided

14 You have provided an OECD TG 202 study but no information on long-term toxicity on aquatic invertebrates for the Substance.

2.2. Assessment of the information provided

15 We have assessed this information and identified the following issue:

16 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).

17 In the provided OECD TG 105 (2012), the saturation concentration of the Substance in water was determined to be 86 µg/L.

18 Therefore, the Substance is poorly water soluble and information on long-term toxicity on aquatic invertebrates must be provided.

2.3. Study design and test specifications

19 The Substance is difficult to test due to the low water solubility (0.086 mg/L) and adsorptive properties)Log Kow of 9.4). 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.

20 In the comments to the draft decision, you agree to perform the requested study

Reasons related to the information under Annex VIII of REACH

3. Long-term toxicity testing on fish

21 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.

3.1. Information provided

22 You have provided an OECD TG 203 study but no information on long-term toxicity on fish for the Substance.

3.2. Assessment of the information provided

23 We have assessed this information and identified the following issues:

24 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).

25 As already explained under request 2, the Substance is poorly water soluble and information on long-term toxicity on fish must be provided.

3.3. Study design and test specifications

26 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.).

27 The Substance is difficult to test due to the low water solubility (0.086 mg/L) and adsorptive properties (Log Kow of 9.4). OECD TG 210 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 210. 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.

28 In the comments to the draft decision, you agree to perform the requested study

4. Simulation testing on ultimate degradation in surface water

29 Further degradation testing must be considered if the chemical safety assessment (CSA) according to Annex I indicates the need to investigate further the degradation of the substance (Annex VIII, Section 9.2., Column 2).

30 This information requirement is triggered in case the chemical safety assessment (CSA) indicates the need for further degradation investigation (Annex I, Section 4; Annex XIII,

Section 2.1), such as if the substance is a potential PBT/vPvB substance (Guidance on IRs and CSA, Section R.11.4.). This is the case if the Substance itself or any of its constituent or impurity present in concentration ≥ 0.1% (w/w) or relevant transformation/degradation product meets the following criteria:

- it is potentially persistent or very persistent (P/vP) as:
    - it is not readily biodegradable (*i.e.* <60% degradation in an OECD 301B), and
- it is potentially bioaccumulative or very bioaccumulative (B/vB) as:
    - it has a high potential to partition to lipid storage (*e.g.* log K_{ow} > 4.5);
- it meets the T criteria set in Annex XIII: NOEC or EC_{10} < 0.01 mg/L or classification as carc. 1A or 1B, muta. 1A or 1B, repro. 1A, 1B or 2, or STOT RE 1 or 2.

4.1. Information provided

31 Your registration dossier provides the following:

- The Substance is not readily biodegradable (21% degradation after 28 days in OECD TG 301B);
- The Substance has a high potential to partition to lipid storage (Log K_{ow} of > 9.4 based on eu Method A.8 (Partion Coefficient-HPLC Method) equivalent OECD TG 117 ;

32 Furthermore, the information in your dossier is currently incompliant and therefore:

- it is not possible to conclude on the bioaccumulation potential of the Substance (see Request 8. of this decision), and
- it is not possible to conclude on the toxicity of the Substance see Requests 2 and 3 of this decision).

33 Under section 2.3 of your IUCLID dossier ('PBT assessment'), you conclude that the Substance is not B/vB. In support of your conclusion you provide the following additional information: "*The typical molecular mass of the substance (C22H44N2S4Zn) is 530.27 daltons. These data indicate that the substance is relatively large (> 500 daltons), has very low water solubility (< 0.1 mg/L), and is a highly lipophilic (Log Pow > 5.6) molecule, and thus is not expected to be absorbed by fish. In addition, acute oral toxicity study in rats did not show any systemic effects up to 2000 mg/kg, the highest doses tested. Although the substance was not tolerated after 3 doses at 500 mg/kg/day or 2 doses at 1000 mg/kg/day and the rats were euthanized due to local effects on fore stomach and corresponding poor clinical conditions in the repeated dose oral range-finding toxicity study in rats, the substance did not induce any systemic effects up to 250 mg/kg/day, the highest doses tested in the combined repeated dose oral toxicity study with the reproductive/developmental toxicity screening test in rats".*

34 However, ECHA Guidance (R. 11-4) states that evidence for hindered uptake must include consideration of molecular size (Dmax >17.4 Å, Log Kow >10) combined with evidence of no uptake in mammalian toxicokinetic studies and no chronic toxicity in experimental studies. You have not provided any evidence of no uptake in mammalian toxicokinetic studies in your assessment of absorption potential. Furthermore, the doses tested in the repeated dose oral toxicity studies that you are referring to are limited due to local toxicity. In the oral range-finding study, rats were euthanised after 3 doses at 500 mg/kg/day or 2

doses at 1000 mg/kg/day, and therefore, while no systemic toxicity was reported, the study does not allow to conclude on absorption potential of the Substance when tested at higher doses.

35 Therefore, the additional information from your PBT assessment is not adequate to conclude that the Substance is not B/vB.

36 Based on the above, the available information on the Substance indicates that it is a potential PBT/vPvB substance. Further, the additional information from your PBT assessment is not adequate to conclude on the PBT/vPvB properties of the Substance.

37 In the comments to the draft decision, you explain that while the Substance is not expected to degrade rapidly under environmentally relevant conditions, it is expected to degrade over time via decomplexation. To support your explananation, you have provided the biodegradation curve of the Substance (in Appendix 2 attached to your document) and Figure 1 in which you illustrate the "Decomplexation and subsequent decomposition" of the Substance. On this basis you conclude that " *as long as the complex is intact (and therefore insoluble), it is stable and persistent; if any of the parent substance decomplexes and dissolves, the dithiocarbamate portion will rapidly form two known substances, carbon disulfide and dibutylamine, both of which are readily biodegradable and neither of which bioconcentrates"*

38 Furthermore, you add "Given experience with the substance and the available study data, it is not feasible to demonstrate empirically this proposed degradation pathway due to analytical limitations […], While it may be feasible to radiolabel the Substance by labelling the carbon of the dithiocarbamate (i.e., through labelling carbon disulfide), tracking the radiolabel in aqueous, sediment, and soil matrices is considered to be of limited utility, as mineralization (and quantitation of 14C) is expected to be negligible, parent material cannot be distinguished from degradates, and, in the absence of specific and sensitive methods or reference standards, identification of major degradates is not feasible."

39 ECHA acknowledges your arguments, however your explanations are referring to assumptions but you do not provide specific information addressing the issues identified above and/or experimental information to substantiate your assumptions. Therefore, the information provided in your comments does not change the outcome of ECHA's assessment, as set out out further above.

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

4.2. Study design and test specifications

41 Simulation degradation studies must include two types of investigations (Guidance on IRs and CSA, Section R.7.9.4.1.):

1) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and

2) a kinetic study where the degradation rate constants (and degradation half-lives) of the parent substance and of relevant transformation/degradation products are experimentally determined.

42 You must perform the test, by following the pelagic test option with natural surface water containing approximately 15 mg dw/L of suspended solids (acceptable concentration between 10 and 20 mg dw/L) (Guidance on IRs and CSA, Section R.11.4.1.1.3.).

43 The required test temperature is 12°C, which corresponds to the average environmental temperature for the EU (Guidance on IRs and CSA, Table R.16-8) and is in line with the applicable test conditions of the OECD TG 309.

5. Soil simulation testing

44 Further degradation testing must be considered if the chemical safety assessment (CSA) according to Annex I indicates the need to investigate further the degradation of the substance (Annex VIII, Section 9.2., Column 2).

45 This information requirement is triggered in case the chemical safety assessment (CSA) indicates the need for further degradation investigation (Annex I, Section 4; Annex XIII, Section 2.1), such as if the substance is a potential PBT/vPvB substance (Guidance on IRs and CSA, Section R.11.4.).

46 As already explained in Request 4, the Substance is a potential PBT/vPvB substance.

47 Further, the Substance has low water solubility (0.086 mg/L) and high partition coefficient (Log Kow 9.4), indicating high potential to adsorb to soil.

48 Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation. Based on the adsorptive properties of the Substance, soil represents a relevant environmental compartment.

In the comments to the draft decision you have provided the same information as provided for Simulation testing in surface water (Request 4). For the same reasons explained under Request 4, whilst ECHA acknowledges your arguments, the information provided in your comments does not change the outcome of ECHA's assessment, as set out further above. Therefore, the information requirement is not fulfilled.

5.1. Study design and test specifications

49 Simulation degradation studies must include two types of investigations (Guidance on IRs and CSA, Section R.7.9.4.1.):

1) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and

2) a kinetic study where the degradation rate constants (and degradation half-lives) of the parent substance and of relevant transformation/degradation products are experimentally determined.

50 In accordance with the specifications of OECD TG 307, you must perform the test using at least four soils representing a range of relevant soils (i.e. varying in their organic content, pH, clay content and microbial biomass).

51 The required test temperature is 12°C, which corresponds to the average environmental temperature for the EU (Guidance on IRs and CSA, Table R.16-8) and is in line with the applicable test conditions of the OECD TG 307.

6. Sediment simulation testing

52 Further degradation testing must be considered if the chemical safety assessment (CSA) according to Annex I indicates the need to investigate further the degradation of the substance (Annex VIII, Section 9.2., Column 2).

53 This information requirement is triggered in case the chemical safety assessment (CSA) indicates the need for further degradation investigation (Annex I, Section 4; Annex XIII, Section 2.1), such as if the substance is a potential PBT/vPvB substance (Guidance on IRs and CSA, Section R.11.4.).

54 As already explained in Request 4, the Substance is a potential PBT/vPvB substance.

55 Further, the Substance has low water solubility (0.086 mg/L) and high partition coefficient (Log Kow 9.4), indicating high potential to adsorb to sediment.

56 Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation. Based on the adsorptive properties of the Substance, sediment represents a relevant environmental compartment.

57 In the comments to the draft decision, you have provided the same information as provided for Simulation testing in surface water (Request 4). For the same reasons explained under Request 4, whilst ECHA acknowledges your arguments, the information provided in your comments does not change the outcome of ECHA's assessment, as set out further above. Therefore, the information requirement is not fulfilled.

6.1. Study design and test specifications

58 Simulation degradation studies must include two types of investigations (Guidance on IRs and CSA, Section R.7.9.4.1.):

1) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and

2) a kinetic study where the degradation rate constants (and degradation half-lives) of the parent substance and of relevant transformation/degradation products are experimentally determined.

59 In accordance with the specifications of OECD TG 308, you must perform the test using two sediments. One sediment should have a high organic carbon content (2.5-7.5%) and a fine texture, the other sediment should have a low organic carbon content (0.5-2.5%) and a coarse texture. If the Substance may also reach marine waters, at least one of the water-sediment systems should be of marine origin.

60 The required test temperature is 12°C, which corresponds to the average environmental temperature for the EU (Guidance on IRs and CSA, Table R.16-8) and is in line with the applicable test conditions of the OECD TG 308.

7. Identification of degradation products

61 Further degradation testing must be considered if the chemical safety assessment (CSA) according to Annex I indicates the need to investigate further the degradation of the substance (Annex VIII, Section 9.2., Column 2).

62 This information requirement is triggered in case the chemical safety assessment (CSA) indicates the need for further degradation investigation (Annex I, Section 4; Annex XIII, Section 2.1), such as if the substance is a potential PBT/vPvB substance (Guidance on IRs and CSA, Section R.11.4.).

63 As already explained in Request 4 , the Substance is a potential PBT/vPvB substance.

64 Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation.

In the comments to the draft decision, you specified that "*as mineralization (and quantitation of 14C) is expected to be negligible, parent material cannot be distinguished from degradates, and, in the absence of specific and sensitive methods or reference standards, identification of major degradates is not feasible*."

65 ECHA acknowledges your arguments, however your explanations are referring to assumptions but you do not provide specific information addressing the issues identified

above and/or showing that identification of the degradation products is not feasable. Therefore, the information provided in your comments does not change the outcome of ECHA's assessment, as set out further above.

66 Therefore, the information requirement is not fulfilled.

7.1. Study design and test specifications

67 Identity, stability, behaviour, and molar quantity of the degradation/transformation products relative to the Substance must be evaluated and reported, when analytically possible. In addition, degradation half-life, log K_{ow} and potential toxicity of the transformation/degradation may need to be investigated. You must obtain this information from one of the degradation studies requested in Requests 4, 5 or 6.

68 To determine the degradation rate of the Substance, the requested study according to OECD TG 309 (Request 4) must be conducted at 12°C and at a test concentration < 100 µg/L. However, to overcome potential analytical limitations with the identification and quantification of major transformation/degradation products, you may consider running a parallel test at higher temperature (but within the frame provided by the test guideline, e.g. 20°C) and at higher application rate (i.e. > 100 µg/L).

69 To determine the degradation rate of the Substance, the requested studies according to OECD TG 308/307 (Requests 5 and 6) must be conducted at 12°C and at a test material application rates reflecting realistic assumptions. However, to overcome potential analytical limitations with the identification and quantification of major transformation/degradation products, you may consider running a parallel test at higher temperature (but within the frame provided by the test guideline) and at higher application rate (e.g. 10 times).

8. Bioaccumulation in aquatic species

70 Bioaccumulation in aquatic species is required for the purpose of PBT/vPvB assessment (Annex I, Sections 0.6.1 and 4 to REACH).

71 This information requirement is triggered in case the chemical safety assessment (CSA) indicates the need for further investigation on bioaccumulation in aquatic species (Annex I, Section 4; Annex XIII, Section 2.1), such as if the substance is a potential PBT/vPvB substance (Guidance on IRs and CSA, Section R.11.4.).

72 As already explained in Request 4 , the Substance is a potential PBT/vPvB substance.

73 Therefore, the chemical safety assessment (CSA) indicates the need for further investigation on bioaccumulation in aquatic species.

74 In the comments to the draft decision, you agree to perform the requested study

8.1. Study design and test specification

75 Bioaccumulation in fish: aqueous and dietary exposure (Method EU C.13 / OECD TG 305) is the preferred test to investigate bioaccumulation (Guidance on IRs and CSA, Section R.7.10.3.1.). Exposure via the aqueous route (OECD TG 305-I) must be conducted unless it can be demonstrated that:

- a stable and fully dissolved concentration of the test material in water cannot be maintained within ± 20% of the mean measured value, and/or
- the highest achievable concentration is less than an order of magnitude above the limit of quantification (LoQ) of a sensitive analytical method.

76 This test set-up is preferred as it allows for a direct comparison with the B and vB criteria of Annex XIII of REACH.

77 You may only conduct the study using the dietary exposure route (OECD 305-III) if you justify and document that testing through aquatic exposure is not technically possible as indicated above. You must then estimate the corresponding BCF value from the dietary test data according to Annex 8 of the OECD 305 TG and OECD Guidance Document on Aspects of OECD TG 305 on Fish Bioaccumulation (ENV/JM/MONO(2017)16).

78 In the comments to the draft decision, you indicate that based on the test guideline, testing very poorly water soluble substances using the aquatic exposure test design may not be technically feasible. In addition, you refer to your own experience with the acute aquatic toxicity testing of this type of substances. On this basis, you consider that the dietary exposure test design is more suitable than the aqueous exposure test for the Substance due to its low solubility in water and challenges with preparing and maintaining stable, measurable, fully dissolved aqueous concentrations. However, as indicated above if you decide to conduct the study using the dietary exposure route (OECD 305-III) you need to demonstrate that :

- a stable and fully dissolved concentration of the test material in water cannot be maintained within ± 20% of the mean measured value, and/or
- the highest achievable concentration is less than an order of magnitude above the limit of quantification (LoQ) of a sensitive analytical method.

79 As you have not provided any justification demonstrating the conditions listed above, you did not justify that testing through aquatic exposure is not technically possible.

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 16 June 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 request(s) or the deadline.

Deadline to submit the requested information in this decision

From the comments to the draft decision, ECHA understands that in relation to requests 2 and 3 of this decision, namely Long-term toxicity testing on aquatic invertebrates and Long-term toxicity testing on fish, you request an extension of the deadline set in the decision. You indicate that "*when requesting timings for this type of study to be conducted at qualified European Union (EU) and U.S. testing laboratories, start dates were quoted out to Q4 2023.* [redacted] *understands that this delay is due to the current high demand for this study type. Hence,* [redacted] *requests that ECHA take laboratory capacity into consideration when issuing a deadline for updating the dossier and Chemical Safety Report (CSR) with the requested information"*. You claim that the extension is needed for the possible delays because of limited capacity in the Contract Research Organizations (CRO).

ECHA acknowledges the explanation you have provided about CRO capacity, however you have not provided any documentary evidence to substantiate your request based on the limited capacity in the CRO.

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.

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.

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]

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].

1.2. Test material

(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 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.

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

2. General recommendations for conducting and reporting new tests

2.1. Strategy for the PBT/vPvB assessment

Under Annex XIII, the information must be based on data obtained under conditions relevant for the PBT/vPvB assessment. You must assess the PBT properties of each

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

relevant constituent of the Substance present in concentrations at or above 0.1% (w/w) and of all relevant transformation/degradation products. Alternatively, you would have to justify why you consider these not relevant for the PBT/vPvB assessment.

You are advised to consult Guidance on IRs & CSA, Sections R.7.9, R.7.10 and R.11 on PBT assessment to determine the sequence of the tests needed to reach the conclusion on PBT/vPvB. The guidance provides advice on 1) integrated testing strategies (ITS) for the P, B and T assessments and 2) the interpretation of results in concluding whether the Substance fulfils the PBT/vPvB criteria of Annex XIII.

In particular, you are advised to first conclude whether the Substance fulfils the Annex XIII criteria for P and vP, and then continue with the assessment for bioaccumulation. When determining the sequence of simulation degradation testing you are advised to consider the intrinsic properties of the Substance, its identified uses and release patterns as these could significantly influence the environmental fate of the Substance. You must revise your PBT assessment when the new information is available.