~~Confidential~~

Helsinki, 03 June 2024

Addressee
Registrant as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
12 June 2019

Registered substance subject to this decision ("the Substance")
Substance name: bis(2,4-dicumylphenyl) neopentyl diphosphite 3,9-bis[2,4-bis(1-methyl-1-phenylethyl)phenoxy]-2,4,8,10-tetraoxa-3,9-diphosphaspiro[5.5]undecane
EC/List number: 421-920-2

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 under Request 1 below by ***9 December 2025*** and all other information listed below by ***12 March 2029***.

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

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

1. 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

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

3. Simulation testing on ultimate degradation in surface water (triggered by Annex VIII, Section 9.2., Column 2; test method: EU C.25./OECD TG 309) at a temperature of 12°C.

4. Soil simulation testing (triggered by Annex VIII, Section 9.2., Column 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.

5. Sediment simulation testing (triggered by Annex VIII, Section 9.2., Column 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.

6. Identification of degradation products (triggered by Annex VIII, Section 9.2., Column 2; test method: EU C.23/OECD TG 307, EU C.24/OECD TG 308 and EU C.25/OECD TG 309).

The reasons for the request(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 are necessary for the PBT assessment. However, to determine the testing needed to reach the conclusion on the persistency 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 request(s)
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 request(s)

Reasons related to the information under Annex VII of REACH

1. Long-term toxicity testing on aquatic invertebrates

1 Short-term toxicity testing on aquatic invertebrates is an information requirement under Annex VII, Column 1, Section 9.1.1. However, under Column 2, long-term toxicity testing on aquatic invertebrates may be required by the Agency if the substance is poorly water soluble, i.e. solubility below 1 mg/L.

1.1. Triggering of the information requirement

2 In the provided water solubility study ("Directive 92/69/EEC, A.6 Column elution method") the saturation concentration of the Substance in water was below the limit of detection of the analytical method (i.e. <0.05 mg/L).

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

1.2. Information requirement not fulfilled

4 You have provided a short-term toxicity study on aquatic invertebrates but no information on long-term toxicity on aquatic invertebrates for the Substance.

5 Therefore, the information requirement is not fulfilled.

1.3. Study design

6 The Substance is difficult to test due to the low water solubility (<0.05 mg/L) and adsorptive properties (Log K_{ow} >6). The OECD TG 211 specifies that, for difficult to test substances, you must consider the approach described in the 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 the 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 solution.

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

Reasons related to the information under Annex VIII of REACH

2. Long-term toxicity testing on fish

8 Short-term toxicity testing on fish is an information requirement under Annex VIII, Column 1, Section 9.1.3. However, long-term toxicity testing on fish may be required by the Agency (Section 9.1.3., Column 2) if the substance is poorly water soluble, i.e. solubility below 1 mg/L.

2.1. Triggering of the information requirement

9 As already explained in request 1, the Substance is poorly water soluble and information on long-term toxicity on fish must be provided.

2.2. Information requirement not fulfilled

10 You have provided a short-term toxicity study on fish but no information on long-term toxicity on fish for the Substance.

11 Therefore, the information requirement is not fulfilled.

2.3. Study design

12 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.).

13 The OECD TG 210 specifies that, for difficult to test substances, the 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" under request 1.

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

3. Simulation testing on ultimate degradation in surface water

15 Under Annex VIII, Section 9.2., Column 2, further information on degradation or further testing as described in Annex IX must be generated if the chemical safety assessment (CSA) in accordance with Annex I indicates the need to investigate further the degradation of the substance.

3.1. Triggering of the information requirement

16 This information requirement is triggered in case if for example additional information on degradation as set out in Annex XIII, point 3.2.1, is required to assess PBT or vPvB properties of the substance in accordance with subsection 2.1 of that Annex. 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. <60/70% degradation in an OECD 301 B);
- 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);

17 Your registration dossier provides the following

- The Substance is not readily biodegradable (1.3 % degradation after 28 days in test according to "*Directive 92/69 EEC, C.4 Mod. Sturm Test*", equivalent to OECD TG 301 B);
- The Substance has a high potential to partition to lipid storage (log K_{ow} of >6 based on "*Directive 92/69/EEC, A.8 HPLC-method*");

18 Under section 2.3 of your IUCLID dossier and section 8 of your CSR ("PBT assessment"), you conclude that no conclusion on P/vP properties of the Substance can be reached based on available information.

19 You further conclude that the Substance is not B/vB. You base your conclusion on the following additional information:

- the Substance is not B or vB based on a predicted (BCFBAF v.3.01) BFC of 6.94 L/kg wet-wt and logBCF of 0.84;
- the Substance is unlikely to bioaccumulate because the molecular weight is 853 and logKow >6.

20 ECHA notes the following shortcomings in your conclusion on non B/vB properties of the Substance.

3.1.1. Provided BCF estimation is not reliable

21 Under Annex XI, Section 1.3., the following conditions must be fulfilled whenever a (Q)SAR approach is used:

- the prediction needs to be derived from a scientifically valid model,
- the substance must fall within the applicability domain of the model,
- results need to be adequate for the purpose of risk assessment or classification and labelling, and
- adequate and reliable documentation of the method must be provided.

22 Under Appendix C of the OECD Guidance document on the validation of (Q)SAR models (ENV/JM/MONO(2007)2) and Guidance on IRs & CSA Section R.6.1.6.3., adequate and reliable documentation must include a (Q)SAR Model Reporting Format document (QMRF) and (Q)SAR Prediction Reporting Format document (QPRF).

23 You have not provided a QMRF and a QPRF including a description of the applicability domain of the model and the relationship between the modelled substance and the defined applicability domain.

24 In absence of such information, ECHA cannot establish that the prediction can be used to predict the bioaccumulation potential of the Substance.

25 In your comments to the draft decision you indicate your intention to provide further documentation of the QSAR predictions for BCF values of the Substance in a dossier update. This information is not yet available to ECHA and it can thus not be assessed. Therefore no conclusion can be made on bioaccumulation properties of the Substance.

3.1.2. *Low bioaccumulation potential based on high molecular weight and logKow not demonstrated*

26 The Guidance on IRs & CSA Section R.7.8.5. explains that there is no scientific basis to define molecular characteristics that would render a substance unlikely to cross biological membranes. In this context, the indicators used for low likelihood of a high bioaccumulation potential (Guidance on IRs & CSA Chapter R.11, Figure R.11-4) must be considered, including:

- physico-chemical indicators of hindered uptake due to large molecular size (*e.g.* D_{max} > 17.4 Å or 1.7 nm) or high octanol-water partition coefficient (log K_{ow} > 10) or low potential for mass storage (octanol solubility (mg/L) < 0.002 x MW), and
- supporting experimental evidence of hindered uptake (no chronic toxicity for mammals and birds, no chronic ecotoxicity, no uptake in mammalian toxicokinetic studies, very low uptake after chronic exposure).

27 Your arguments on low bioaccumulation potential includes physicochemical indicators such as high molecular weight of the Substance and logKow >6. While this information may indicate hindered uptake, the physicochemical indicators for hindered uptake must be assessed in conjunction with experimental indicators such as chronic toxicity and toxicokinetic studies for mammals and birds. You have not considered the experimental indicators in your PBT assessment.

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

29 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.

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

3.2. Information requirement not fulfilled

31 Your registration dossier does not include any information on simulation testing on ultimate degradation in surface water.

32 Therefore, the information requirement is not fulfilled.

33 In your comments to the draft decision you refer to the specific adaptation possibility for this information requirement under Annex IX, Section 9.2.1.2, Column 2 due to the Substance being highly insoluble based on its water solubility < 0.05 mg/L. ECHA also understands that you intend to rely on the general adaptation possibility under Annex XI, Section 2, which allows testing to be omitted if it is technically not possible to conduct the study.

3.2.1. The provided adaptation does not meet the criteria of annex IX, Section 9.2.1.2., Column 2

34 Under Annex IX, Section 9.2.1.2., Column 2, first indent, the study can be omitted in case the Substance is highly insoluble.

35 There is no cut off value in the REACH Regulation. Since any substance may be persistent, what is most important is what can be assessed in a study, i.e., it is necessary to demonstrate that it is not reasonably possible to develop an analytical method with sufficient sensitivity to meet the test guideline requirements taking into account the specific technical limitations of the OECD TG 309 which include, in particular:

- for the determination of biodegradation kinetics, the concentrations of the test substance must be below its water solubility, and
- the limit of quantification (LOQ) should be equal to or less than 10% of the applied concentration.

36 Consequently, a substance has an insolubility too high for conducting a simulation testing on ultimate degradation in surface water in accordance with OECD TG 309 if the LOQ of a

sensitive analytical method is not at least ten times lower to the water solubility of the substance.

37 You provided the following justification in support of your claim: "*As the water solubility is below 50 µg/L and the analytical method is very challenging, in practice we think OECD 309 is not suitable to be done*".

38 In support for your adaptation, you did not provide any argument in relation to the specific technical limitations of the OECD TG 309. You did not provide any evidence e.g. based on analytical method developed and their corresponding limits of detection/quantification for the Substance that could support your claim.

39 In the provided water solubility study ("Directive 92/69/EEC, A.6 Column elution method") the saturation concentration of the Substance in water was below the limit of detection of the analytical method (i.e. <0.05 mg/L.

40 Therefore, the adaptation is rejected.

3.3. Testing technically not feasible not demonstrated

41 According to Annex XI, Section 2, a study may be omitted if it is technically not feasible to conduct because of the properties of the substance. The guidance given in the test methods referred to in Article 13(3), in this case OECD TG 309, more specifically on the technical limitations of a specific method, shall always be respected.

42 The OECD TG 309 provides in particular that this test is applicable to non-volatile or slightly volatile organic substances tested at low concentrations. As regards to water solubility, no lower limit is specified under which the study would be not feasible.

43 You claim that due to the Substance being highly insoluble, conducting OECD TG 309 might be not successful. However, you have not provided any evidence based on e.g. experimental data that supports your claim.

44 Your claim does not take into account the specific technical limitations, or lack thereof, of the applicable test method.

45 Therefore, your adaptation is rejected.

3.4. Study design

46 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.

47 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.).

48 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.

49 As specified in Guidance on IRs and CSA, Section R.7.9.4.1., the organic carbon (OC) concentration in surface water simulation tests is typically 2 to 3 orders of magnitude higher

than the test material concentration and the formation of non-extractable residues (NERs) may be significant in surface water tests. Paragraph 52 of the OECD TG 309 provides that the "total recovery (mass balance) at the end of the experiment should be between 90% and 110% for radiolabelled substances, whereas the initial recovery at the beginning of the experiment should be between 70% and 110% for non-labelled substances". NERs contribute towards the total recovery. Therefore, the quantity of the (total) NERs must be accounted for the total recovery (mass balance), when relevant, to achieve the objectives of the OECD TG 309 to derive degradation rate and half-life. The reporting of results must include a scientific justification of the used extraction procedures and solvents.

50 For the persistence assessment by default, total NERs is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NERs may be differentiated and quantified as irreversibly bound or as degraded to biogenic NERs, such fractions could be regarded as removed when calculating the degradation half-life(s) (Guidance on IRs and CSA, Section R.11.4.1.1.3.). Further recommendations may be found in the background note on options to address non-extractable residues in regulatory persistence assessment available on the ECHA website (NER - summary 2019 (europa.eu) [1]).

[1] https://echa.europa.eu/documents/10162/13632/bg_note_addressing_non-extractable_residues.pdf/e88d4fc6-a125-efb4-8278-d58b31a5d342

51 Relevant transformation/degradation products are at least those detected at ≥ 10% of the applied dose at any sampling time or those that are continuously increasing during the study even if their concentrations do not exceed 10% of the applied dose, as this may indicate persistence (OECD TG 309; Guidance on IRs and CSA, Section R.11.4.1.).

4. Soil simulation testing

52 Under Annex VIII, Section 9.2., Column 2, further information on degradation or further testing as described in Annex IX must be generated if the chemical safety assessment (CSA) in accordance with Annex I indicates the need to investigate further the degradation of the substance.

4.1. Triggering of the information requirement

53 Therefore, this information requirement is triggered in case if for example additional information on degradation as set out in Annex XIII, point 3.2.1, is required to assess PBT or vPvB properties of the substance in accordance with subsection 2.1 of that Annex.

54 As already explained in request 3, the Substance is a potential PBT/vPvB substance.

55 Further, the Substance has low water solubility (<0.05 mg/L) and high partition coefficient (log K_{ow} >6 and predicted Koc of 1e+10 L/kg), indicating high potential to adsorb to soil.

56 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.

4.2. Information requirement not fulfilled

57 Your registration dossier does not include any information on soil simulation testing.

58 Therefore, the information requirement is not fulfilled.

4.3. Study design

59 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.

60 In accordance with the specifications of the 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).

61 In accordance with the specifications of the OECD TG 307, non-extractable residues (NER) must be quantified. The reporting of results must include a scientific justification of the used extraction procedures and solvents (Guidance on IRs and CSA, Section R.7.9.4.1.). By default, total NER is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NER may be differentiated and quantified as irreversibly bound or as degraded to biogenic NER, such fractions could be regarded as removed when calculating the degradation half-life(s) (Guidance on IRs and CSA, Section R.11.4.1.1.3.). Further recommendations may be found in the background note on options to address non-extractable residues in regulatory persistence assessment available on the ECHA website.

62 Relevant transformation/degradation products are at least those detected at ≥ 10% of the applied dose at any sampling time or those that are continuously increasing during the study even if their concentrations do not exceed 10% of the applied dose, as this may indicate persistence (OECD TG 307; Guidance on IRs and CSA, Section R.11.4.1.).

63 In your comments to the draft decision you agree to conduct the study.

5. Sediment simulation testing

64 Under Annex VIII, Section 9.2., Column 2, further information on degradation or further testing as described in Annex IX must be generated if the chemical safety assessment (CSA) in accordance with Annex I indicates the need to investigate further the degradation of the substance.

5.1. Triggering of the information requirement

65 Therefore, this information requirement is triggered in case if for example additional information on degradation as set out in Annex XIII, point 3.2.1, is required to assess PBT or vPvB properties of the substance in accordance with subsection 2.1 of that Annex.

66 As already explained in request 3, the Substance is a potential PBT/vPvB substance.

67 Further, the Substance has a low water solubility (<0.05 mg/L) and a high partition coefficient (log K_{ow} >6 and predicted Koc of 1e+10 L/kg), indicating high potential to adsorb to sediment.

68 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.

5.2. Information requirement not fulfilled

69 Your registration dossier does not include any information on sediment simulation testing.

70 Therefore, the information requirement is not fulfilled.

71 In your comments to the draft decision you indicate that the study might be difficult to conduct "*as it is necessary to extract the sediment phase for analysis. When working with very low levels of test item it can be challenging to recover all of the radioactivity and obtain a mass balance. If the radioactivity is recovered partially in both the water and sediment phases then the levels may be too low to chromatograph*".

72 ECHA understands that you intend to rely on the general adaptation possibility under Annex XI, Section 2, which allows testing to be omitted if it is technically not possible to conduct the study.

5.3. Testing technically not feasible not demonstrated

73 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.

74 You claim that the study was difficult to conduct, however you do not provide evidence to demonstrate that it was technically not feasible which is a different legal criteria.

75 Therefore, your adaptation is rejected.

5.4. Study design

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

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

(4) 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.

77 In accordance with the specifications of the 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.

78 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.

79 In accordance with the specifications of the OECD TG 308, non-extractable residues (NER) must be quantified. The reporting of results must include a scientific justification of the used extraction procedures and solvents (Guidance on IRs and CSA, Section R.7.9.4.1.). By default, total NER is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NER may be differentiated and quantified as irreversibly bound or as degraded to biogenic NER, such fractions could be regarded as removed when calculating the degradation half-life(s) (Guidance on IRs and CSA, Section R.11.4.1.1.3.). Further recommendations may be found in the background note on options to address non-extractable residues in regulatory persistence assessment available on the ECHA website.

80 Relevant transformation/degradation products are at least those detected at ≥ 10% of the applied dose at any sampling time or those that are continuously increasing during the

study even if their concentrations do not exceed 10% of the applied dose, as this may indicate persistence (OECD TG 308; Guidance on IRs and CSA, Section R.11.4.1.).

6. Identification of degradation products

81 Under Annex VIII, Section 9.2., Column 2, further information on degradation or further testing as described in Annex IX must be generated if the chemical safety assessment (CSA) in accordance with Annex I indicates the need to investigate further the degradation of the substance.

6.1. Triggering of the information requirement

82 Therefore, this information requirement is triggered in case if for example additional information on degradation as set out in Annex XIII, point 3.2.1, is required to assess PBT or vPvB properties of the substance in accordance with subsection 2.1 of that Annex.

83 As already explained in request 3, the Substance is a potential PBT/vPvB substance.

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

6.2. Information requirement not fulfilled

85 You have not submitted any information for this requirement.

86 Therefore, the information requirement is not fulfilled.

6.3. Study design

87 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.

88 Identity, stability, behaviour, and molar quantity of the degradation/transformation products relative to the Substance must be evaluated and reported. In addition, identified transformation/degradation products must be considered in the CSA including PBT assessment.

89 You must obtain this information from the degradation studies requested in requests 3, 4 and 5.

90 To determine the degradation rate of the Substance, the requested study according to OECD TG 309 (request 3 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).

91 To determine the degradation rate of the Substance, the requested studies according to OECD TG 308 and 307 (requests 4 and 5) must be conducted at 12°C and at (a) test material application rate(s) 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).

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).
Guidance for monomers and polymers; ECHA (2023).
***Guidance on intermediates*;** ECHA (2010).
All guidance documents are 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

The information requirement for Bioaccumulation in aquatic species, preferably fish (Annex VIII) is not addressed in this decision. This is because the results from the biodegradation simulation studies are needed to conclude whether the Substance or relevant degradation products of the Substance is (are) P/vP and to decide whether a bioaccumulation study is needed to conclude on the PBT/vPvB properties of the Substance. In such case, the results of the requested biodegradation simulation studies will also inform on the most relevant test material to conduct the bioaccumulation study. This information requirement may be addressed in a separate decision at a later stage.

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 04 May 2023.

The deadline of the decision is set based on standard practice for carrying out OECD TG tests. It has been exceptionally extended by 6 months (first deadline) and 12 months (second deadline) from the standard deadline granted by ECHA to take into account currently longer lead times in contract research organisations.

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.

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: Addressee(s) 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 (https://echa.europa.eu/practical-guides).

(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.

With that detailed information, ECHA can confirm 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 (https://echa.europa.eu/manuals).

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 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, 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.

References to Guidance on REACH and other supporting documents can be found under Appendix 1.