

Helsinki, 03 June 2024

Addressee(s)

Registrant as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision

29 May 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, also requested below (triggered by Annex VII, Section 9.1.1., Column 2).

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

2. Long-term toxicity testing on fish, also requested below (triggered by Annex VIII, Section 9.1.3., Column 2).
3. Simulation testing on ultimate degradation in surface water, also requested below (triggered by Annex VIII, Section 9.2., Column 2).
4. Soil simulation testing, also requested below (triggered by Annex VIII, Section 9.2., Column 2).
5. Sediment simulation testing, also requested below (triggered by Annex VIII, Section 9.2., Column 2).
6. Identification of degradation products, also requested below (triggered by Annex VIII, Section 9.2., Column 2).

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

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

8. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: EU C.20./OECD TG 211).
9. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: EU C.47./OECD TG 210).
10. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method: EU C.25/OECD TG 309) at a temperature of 12°C.
11. Soil simulation testing (Annex IX, Section 9.2.1.3.; 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.
12. Sediment simulation testing (Annex IX, Section 9.2.1.4.; 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.
13. Identification of degradation products (Annex IX, Section 9.2.3.; 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 addressee of the decision and its corresponding information requirements based on registered tonnage band are listed in Appendix 3.

In the requests above, the same study has been requested under different Annexes or for different information requirements.

In the case of the same study requested under different Annexes, this is because some information requirements may be triggered at lower tonnage band(s). In such cases, only the reasons why the information requirement is triggered are provided for the lower tonnage band(s). For the highest tonnage band, the reasons why the standard information requirement is not met and the specification of the study design are provided.

In all cases, only one study is to be conducted; all registrants concerned must make every effort to reach an agreement as to who is to carry out the study on behalf of the others under Article 53 of REACH.

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.

Authorised¹ 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.

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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 OECD TG 105 study (1996), the saturation concentration of the Substance in water was determined to be 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 The information provided, its assessment and the specifications of the study design are addressed under request 8.

Reasons related to the information under Annex VIII of REACH**2. Long-term toxicity testing on fish**

5 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

6 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

7 The information provided, its assessment and the specifications of the study design are addressed under request 9.

3. Simulation testing on ultimate degradation in surface water

8 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

9 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. This is the case if the Substance itself or any of its constituent or impurity present in concentration $\geq 0.1\%$ (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, and
- it is potentially bioaccumulative or very bioaccumulative (B/vB) as it has a high potential to partition to lipid storage (e.g. $\log K_{ow} > 4.5$);

10 Your registration dossier provides the following

- The Substance is not readily biodegradable ($<2\%$ degradation after 28 days in OECD TG 301 B);
- The Substance has a high potential to partition to lipid storage ($\log K_{ow}$ of >6 based on OECD TG 117);

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

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

- Bioaccumulation models indicate a very low potential for bioaccumulation.

13 You provide the following information under IUCLID section 5.3.1 for Bioaccumulation:

- a predicted (QSAR, BCFBAF v.3.01, 2017) BFC of 6.94 L/kg wet-wt

14 ECHA notes the following shortcomings in your conclusion on non B/vB:

3.1.1. Provided BCF estimation is not reliable

15 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.

16 Under Appendix C of the OECD Guidance document on the validation of (Q)SAR models (ENV/JM/MONO(2007)2) and the 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 a (Q)SAR Prediction Reporting Format document (QPRF).

17 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.

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

19 Therefore, the additional information from your PBT assessment and IUCLID Section 5.3.1. are not adequate to conclude that the Substance is not a potential PBT/vPvB substance.

20 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.

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

3.2. Information requirement not fulfilled

22 The information provided, its assessment and the specifications of the study design are addressed under request 10.

4. Soil simulation testing

23 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

24 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.

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

26 Further, the Substance has low water solubility (<0.05 mg/L) and high partition coefficient ($\log K_{ow} > 6$), indicating high potential to adsorb to soil.

27 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

28 The information provided, its assessment and the specifications of the study design are addressed under request 11.

5. Sediment simulation testing

29 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

30 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.

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

32 Further, the Substance has low water solubility (<0.05 mg/L) and high partition coefficient ($\log K_{ow} > 6$), indicating high potential to adsorb to sediment.

33 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

34 The information provided, its assessment and the specifications of the study design are addressed under request 12.

6. Identification of degradation products

35 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

36 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.

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

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

6.2. Information requirement not fulfilled

39 The information provided, its assessment and the specifications of the study design are addressed under request 13.

Reasons related to the information under Annex IX of REACH**7. Pre-natal developmental toxicity study in one species**

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

7.1. Information provided

41 You have provided a reproduction/developmental toxicity screening study (2017) with the Substance (study i).

7.2. Assessment of the information provided

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

- a) at least 20 female animals with implantation sites are included for each test and control group to ensure a statistical power equivalent to OECD TG 414;
- b) the fetuses are examined for external, skeletal and soft tissue alterations (variations and malformations), measurement of anogenital distance in live rodent fetuses.

43 The study (i) has been conducted using the OECD TG 421 which is a screening study rather than a conclusive developmental toxicity study.

44 In study (i):

- a) only 10 female animals (i.e., less than 20 female animals) with implementation sites are included in each group, and therefore the statistical power is not equivalent to OECD TG 414;
- b) the fetuses are not examined for external, skeletal and soft tissue alterations (variations and malformations, anogenital distance is not measured in live rodent fetuses).

45 The information provided does not cover the specification(s) required by the OECD TG 414.

46 On this basis, the study is not adequate for the information requirement and the information requirement is not fulfilled.

7.3. Study design

47 A PNDT study according to the test method OECD TG 414 should be performed in rats or rabbits as preferred species.

48 As the Substance is a solid, the study must be conducted with oral administration of the Substance (Annex IX, Section 8.7.2., Column 1).

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

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

8. Long-term toxicity testing on aquatic invertebrates

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

8.1. Information provided

52 You have adapted this information requirement by using Annex XI, Section 2. (testing is technically not possible). To support the adaptation, you have provided the following justification: "This substance is a solid and is highly insoluble in water."

8.2. Assessment of the information provided

53 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 the OECD TG 211, more specifically on the technical limitations of a specific method, shall always be respected.

54 As regards to water solubility, no lower limit is specified under which the study would be not feasible.

55 You claim that due to the Substance being a solid and highly insoluble in water the study is technically not feasible.

56 Your claim does not take into account the specific technical limitations, or lack thereof, of the applicable test method. You do not provide any further information or evidence of attempting to perform the study and not being able to do so.

57 Therefore, your adaptation is rejected and the information requirement is not fulfilled.

8.3. Study design

58 The Substance is difficult to test due to the low water solubility (< 0.05 mg/L) and adsorptive properties ($\text{Log } K_{ow} > 6$). 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.

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

9. Long-term toxicity testing on fish

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

9.1. Information provided

61 You have adapted this information requirement by using Annex XI, Section 2. (testing is technically not possible). To support the adaptation, you have provided the following justification: "This substance is a solid and is highly insoluble in water.";

9.2. Assessment of the information provided

- 62 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 the OECD TG 210, more specifically on the technical limitations of a specific method, shall always be respected.
- 63 As regards to water solubility, no lower limit is specified under which the study would not be feasible.
- 64 You claim that due to the Substance being a solid and highly insoluble in water, the study is technically not feasible. You do not provide any further information or evidence of attempting to perform the study and not being able to do so.
- 65 Therefore, your claim does not take into account the specific technical limitations, or lack thereof, of the applicable test method.
- 66 Based on the above, your adaptation is rejected and the information requirement is not fulfilled.

9.3. Study design

- 67 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.).
- 68 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 8.
- 69 In your comments to the draft decision you agree to perform the requested study.

10. Simulation testing on ultimate degradation in surface water

- 70 Simulation testing on ultimate degradation in surface water is an information requirement under Annex IX to REACH (Section 9.2.1.2.).

10.1. Information provided

- 71 You have adapted this information requirement by using Annex XI, Section 2. (testing is technically not possible). To support the adaptation, you have provided the following justification: "the study does not need to be conducted because the substance is highly insoluble in water".
- 72 ECHA understands that your justification refers to the adaptation possibility under Annex XI, Section 2 ('Testing is technically not possible').

10.2. Assessment of the information provided

- 73 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.
- 74 The OECD TG 309 provides in particular that this test is applicable to water-soluble and poorly water-soluble compounds. As regards to water solubility, no lower limit is specified under which the study would not be feasible. However, the OECD TG 309 specifies that concentrations as low as 1 µg/L can be applied and that for poorly water soluble substances the concentration of the test substance must be below water solubility.

75 You claim that due to the Substance being highly insoluble in water the study is not technically feasible. You do not provide any further information or evidence of attempting to perform the study and not being able to do so.

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

77 Based on the above, your adaptation is rejected and the information requirement is not fulfilled.

78 In your comments to the draft decision we understand that you rely on the adaptation possibility for this information requirement under Annex IX, Section 9.2.1.2, Column 2.

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

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

80 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.

81 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.

82 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.

83 In the provided OECD TG 105 study (1996), the saturation concentration of the Substance in water was determined to be below the limit of detection of the analytical method (i.e. < 0.05 mg/L).

84 Therefore, the adaptation is rejected.

10.3. Study design

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

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

- 86 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.).
- 87 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.
- 88 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.
- 89 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

- 90 Relevant transformation/degradation products are at least those detected at $\geq 10\%$ 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.).

11. Soil simulation testing

- 91 Soil simulation testing is an information requirement under Annex IX to REACH (Section 9.2.1.3.) for substances with a high potential for adsorption to soil.

11.1. Triggering of the information requirement

- 92 A high potential for adsorption is indicated by lipophilicity e.g. when $\log K_{ow} > 4$, $\log K_{oc,soil} > 4$ (Guidance on IRs and CSA R.7.9.4.3) or other mechanisms than driven by the lipophilicity e.g. ionising substances (at pH 4-9), surface active substances, substances that bind chemically with soil components.
- 93 The Substance has a high partition coefficient based on $\log K_{ow} \geq 6$ and therefore has high potential for adsorption to soil.

11.2. Information provided

- 94 You have adapted this information requirement by using Column 2 of Annex IX, Section 9.2.1.3. To support the adaptation, you have provided the following justification: "the study does not need to be conducted because direct and indirect exposure of soil is unlikely".

11.3. Assessment of the information provided

- 95 Under Annex IX, Section 9.2.1.3., Column 2, the study may be omitted if direct and indirect exposure to soil is unlikely. The requirements for absence of direct and indirect exposure to soil must be met for all uses throughout the life-cycle including the waste stage (Guidance on IRs and CSA, R.5).
- 96 Your exposure assessment for industrial uses (i.e. formulation and other industrial uses) is based on specific environmental release categories (SpERC). These SpERC assume that some releases to soil can occur.
- 97 Regarding wide dispersive uses, i.e. service life of rubber products containing the substance, the information you have provided does not demonstrate that the Substance is permanently embedded in the rubber matrix:
- there is no indication that the Substance is covalently bound to the matrix or reacts during the formulation process/inclusion in the material,
 - you mention that migration studies exist with the Substance, but in the context of its use in food contact materials. You claim that no detectable migration was observed. However, the study records are not provided in your dossier, so it is not possible to evaluate the validity of this information. Besides, those studies are not necessarily relevant for other uses of the Substance. In particular, the duration was limited to 10 days, and potential abrasion or environmental weathering was not investigated. Your dossier does not explain what the rubber products containing the substance are, and how they are used, but some uses (e.g. if used in tyres) would imply a high potential for releases to the environment and in particular to soil.
- 98 Therefore, you have not demonstrated the absence of direct and indirect environmental exposure to the Substance and exposure to the soil compartment may occur.
- 99 Furthermore, indirect exposure through spreading of sewage sludge on land cannot be excluded. Finally, you have not included any information on articles service life for the Substance.
- 100 On this basis, you have not demonstrated that exposure to soil is unlikely.
- 101 Based on the above, your adaptation is rejected and the information requirement is not fulfilled.

11.4. Study design

- 102 Simulation degradation studies must include two types of investigations (Guidance on IRs and CSA, Section R.7.9.4.1):
- (4) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and
 - (5) 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.
- 103 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).
- 104 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.

- 105 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.
- 106 Relevant transformation/degradation products are at least those detected at $\geq 10\%$ 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.).
- 107 In your comments to the draft decision you agree to perform the requested study.

12. Sediment simulation testing

- 108 Sediment simulation testing is an information requirement under Annex IX to REACH (Section 9.2.1.4.) for substances with a high potential for adsorption to sediment.

12.1. Triggering of the information requirement

- 109 A high potential for adsorption is indicated by lipophilicity e.g. when $\log K_{ow} > 4$, $\log K_{oc, sediment} > 4$ (Guidance on IRs and CSA R.7.9.4.3) or by other mechanisms than driven by the lipophilicity e.g. ionising substances (at pH 4-9), surface active substances, substances that bind chemically with sediment components
- 110 The Substance has a high partition coefficient based on $\log K_{ow} \geq 6$ and therefore has high potential for adsorption to sediment.

12.2. Information provided

- 111 You have adapted this information requirement by using Annex XI, Section 2. (testing is technically not possible). To support the adaptation, you have provided the following justification: "the study does not need to be conducted because the substance is highly insoluble in water".

12.3. Assessment of the information provided

12.3.1. Testing not technically possible adaptation rejected

- 112 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 the OECD TG 308, more specifically on the technical limitations of a specific method, shall always be respected.
- 113 The OECD TG 308 provides in particular that this test is applicable to water-soluble and poorly water-soluble compounds. As regards to water solubility, no lower limit is specified under which the study would be not feasible. The OECD TG 308 specifies that "*The limit of detection (LOD) of the analytical method for the test substance and for the transformation products should be at least 0.01 mg/kg in water or sediment (as test substance) or 1% of the initial amount applied to a test system whichever is lower*".

- 114 You claim that due to the Substance being highly insoluble in water, the study is technically not feasible. You do not provide any further information or evidence of attempting to perform the study and not being able to do so.
- 115 Your claim does not take into account the specific technical limitations, or lack thereof, of the applicable test method.
- 116 Based on the above, your adaptation is rejected and the information requirement is not fulfilled.

12.4. Study design

- 117 Simulation degradation studies must include two types of investigations (Guidance on IRs and CSA, Section R.7.9.4.1.):
- (6) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and
 - (7) 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.
- 118 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.
- 119 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.
- 120 In accordance with the specifications of 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.
- 121 Relevant transformation/degradation products are at least those detected at $\geq 10\%$ 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.).
- 122 In your comments to the draft decision you agree to perform the requested study.

13. Identification of degradation products

- 123 Identification of abiotic and biotic degradation products is an information requirement under Annex IX to REACH (Section 9.2.3.).
- 124 You have not submitted any information for this requirement.

13.1. Therefore, the information requirement is not fulfilled. Study design

- 125 Simulation degradation studies must include two types of investigations (Guidance on IRs and CSA, Section R.7.9.4.1.):
- (8) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and
 - (9) 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.
- 126 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.
- 127 You must obtain this information from the degradation studies requested in requests 10, 11 and 12.
- 128 To determine the degradation rate of the Substance, the requested study according to OECD TG 309 (request 10) 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).
- 129 To determine the degradation rate of the Substance, the requested studies according to OECD TG 308 and 307 (requests 11 and 12) 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).
- 130 In your comments to the draft decision you agree to perform the requested study.

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/IX) 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 01 September 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
████████████████████	████████████████████	██████

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

(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 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.

With that detailed information, ECHA can confirm 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 (<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.