~~Confidential~~

Helsinki, 01 September 2023

Addressee
Registrant of JS_DMOP_246-904-0 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
15/05/2013

Registered substance subject to this decision ("the Substance")
Substance name: Dimethyl octadecylphosphonate
EC/List number: 246-904-0

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 ***8 June 2028***.

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)

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

3. Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: EU C.4. C/D/E/F/ OECD TG 301B/C/D/F or EU C.29./OECD TG 310)

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

4. Long-term toxicity testing on fish also requested below (triggered by Annex VIII, Section 9.1.3., column 2)

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

5. Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.; test method: OECD TG 408) by oral route, in rats

6. 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)

7. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: EU C.20./OECD TG 211)

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

9. 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.

10. 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.

11. 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.

12. Identification of degradation products (Annex IX, 9.2.3.; test method: EU C.23/OECD TG 307, EU C.24/OECD TG 308 and EU C.25/OECD TG 309)

13. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2; test method: EU C.13./OECD TG 305), aqueous or dietary exposure

14. Long-term toxicity testing on terrestrial invertebrates (triggered by Annex IX, Section 9.4.1., column 2; test method: EU C.33/OECD TG 222 or EU C.32/OECD TG 220 or EU C.35/OECD TG 232)

15. Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: EU C.21./OECD TG 216)

16. Long-term toxicity on terrestrial plants (triggered by Annex IX, Section 9.4.3., column 2; test method: EU C.31./OECD TG 208 with at least six species or ISO 22030)

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 addressee(s) of the decision and their corresponding information requirements based on registered tonnage band are listed in Appendix 3.

In the requests above, the same study has been requested under different Annexes. This is because some information requirements may be triggered at lower tonnage band(s). In such cases, only the reasons why the information requirement is triggered are provided for the lower tonnage band(s). For the highest tonnage band, the reasons why the standard information requirement is not met and the specification of the study design are provided. Only one study is to be conducted; all registrants concerned must make every effort to reach an agreement as to who is to carry out the study on behalf of the others under Article 53 of REACH.

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 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)

Contents

0. Reasons common to several requests

0.1. Assessment of adaptations based on unlikely direct and indirect exposure

1 You have adapted the following standard information requirements by using arguments of unlikely direct and indirect exposure under column 2 of:

- Soil simulation testing (Annex IX, Section 9.2.1.3.)
- Sediment simulation testing (Annex IX, Section 9.2.1.4.)
- Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.)
- Long-term toxicity testing on terrestrial invertebrates (triggered by Annex IX, Section 9.4.1., column 2)
- Effects on soil micro-organisms (Annex IX, Section 9.4.2.
- Long-term toxicity on terrestrial plants (triggered by Annex IX, Section 9.4.3., column 2)

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

3 We have identified the following issue(s) with the adaptations:

0.1.1. Low probability of exposure not demonstrated

4 Column 2 of Annex IX, Section 9.2.1.3., 9.2.1.4., 9.3.2., and 9.4. respectively, to REACH states that a study is not necessary if direct and indirect exposure is unlikely (implying a low probability of – rather than low extent of – exposure). Low probability of exposure can be demonstrated by the properties of the substance, reported uses and handling the waste. For example, it is assumed that soil exposure will occur unless it can be shown that there is no sludge application to land from exposed STPs, aerial deposition are negligible, and the relevance of other exposure pathways such as irrigation and/or contact with contaminated waste is unlikely (Guidance on IRs and CSA, Section R.7.11.2.1.). If there are uses of the substance that may result in direct or indirect exposure of the relevant compartment, it would have to be demonstrated (by measurement or other evidence) that there is no release of the substance to such a compartment at any stage in the life cycle of the substance (Guidance on IRs and CSA, Section R.7.10.4.5.).

5 In your chemical safety assessment, you report the following uses:

- Industrial formulation of lubricant additives and lubricants (includes material transfers, mixing, large and small scale packing, sampling, maintenance and associated laboratory activities)
- Industrial and professional use of lubricants in open systems (including application of lubricant to work pieces or equipment by dipping, brushing or spraying)
- General industrial use of lubricants in vehicles or machinery (includes filling and draining of containers and enclosed machinery e.g. engines)
- General consumer use of lubricants in vehicles or machinery
- Consumer use of lubricants in open systems

6 To support your adaptations, you provide the following arguments:

- Exposure to aquatic environment is expected to be limited because user sites are assumed to be provided with oil/water separators or equivalent and for waste

water to be discharged via public sewer system.
- No direct exposure to soil is expected for industrial uses, as no biosolids of industrial origin are applied to land and are incinerated. For professional and consumer uses the SpERCs indicated very limited emissions.
- Exposure and risk assessment indicates that there is no cause for concern for the environment (Risk Characterisation Ratios were <1).

7 You have not provided evidence that there is no release of the Substance to the aquatic or terrestrial environment as a result from these uses.

8 Your arguments are not a sufficient basis to demonstrate that direct and indirect exposure is unlikely because:

- You do not clearly explain and demonstrate how the assumed use of oil/water separators and discharge of waste water via public sewer system would lead to unlikely exposure of aquatic compartment resulting from all reported uses
- While you state that there is no sludge application to land from industrial uses, you have not demonstrated that there is no sludge application to land from professional and consumer uses. You have not demonstrated that aerial deposition are negligible or other exposure pathways to soil are unlikely.
- The wide spread uses of the Substance and your statements demonstrate that exposure of aquatic and soil compartments is likely (implying a high probability of exposure)
- in the absence of evidence to demonstrate that there is no release to soil or aquatic environment (including sediment), your assumptions of unlikely direct and indirect exposure are not substantiated.

9 Furthermore, your claim that there is no cause for concern for the environment (i.e. RCRs < 1) is invalid, as there is no reliable information to assess the hazardous properties of the Substance and establish a reliable PNEC for aquatic and terrestrial compartments for the reasons explained under requests 1, 2, 4, 7, 8, 14, 15 and 16.

0.1.2. No conclusion on PBT/vPvB is yet reached

10 Information required under Annex IX, Section 9.2.1.3., 9.2.1.4 and 9.3.2 is essential in assessment of PBT/vPvB properties of substances (Annex XIII, Section 3.2). Therefore, to adapt simulation degradation and bioaccumulation studies by using arguments of unlikely direct and indirect exposure, the Substance must be demonstrated to not be a PBT/vPvB candidate (Guidance on IRs and CSA, Section R.7.9.2.3. and R.7.10.4.5).

11 Under Section 2.3 of your IUCLID dossier ('PBT assessment'), you conclude that the Substance is not P/vP nor B/vB. In support of your conclusion you state that the value from BIOWIN 3 is > 2.2 (a value of 2.6963 was derived for DMOP from BIOWIN 3). You also consider the Substance not bioaccumulative because the estimated BCFs derived from a (Q)SAR models are <2000 L/kg and thus does not meet the criteria for bioaccumulation.

12 As explained in requests 3 and 13, the information on ready biodegradability and bioaccumulation based on (Q)SARs is not reliable. In addition, such (Q)SAR predictions indicating that the Substance degrades rapidly would not be alone sufficient to conclude on non-persistence (Guidance on IRs and CSA, Section R.11.4.1.1.4). The Substance screens for bioaccumulative/very bioaccumulative as indicated by its log Kow of 8.41.

13 Therefore, you have not demonstrated that the Substance does not screen as a potential PBT or vPvB substance nor that it does not fulfil the PBT and vPvB criteria.

0.1.3. Conclusion on the adaptations based on unlikely direct and indirect exposure

14 As explained above, you have not demonstrated that the exposure to environmental compartments (surface water, sediment and soil) is unlikely. Therefore your adaptations are rejected.

Reasons related to the information under Annex VII of REACH

1. Long-term toxicity testing on aquatic invertebrates

15 Short-term toxicity testing on aquatic invertebrates is an information requirement under Annex VII, Column 1, Section 9.1.1.

16 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

17 Poorly water soluble substances require longer time to reach steady-state conditions. As a result, the short-term tests do not give a true measure of toxicity for this type of substances and the long-term test is required.

18 In the provided OECD TG 105 (2013), the saturation concentration of the Substance in water was determined to be below 1.07 mg/L. While this study did not provide an exact value, you report that the estimated water solubility of the Substance is 0.000765 mg/L using U.S. EPA software WSKOW v1.42.

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

20 In your comments to the draft decision you have attached a document i.e. "[redacted] in which you indicate under the "Long-term toxicity on terrestrial plants" section that you agreed to develop the aquatic toxicity dataset. Moreover, you did not provide specific information addressing the issues identified above. Therefore, the information provided in your comments does not change the assessment outcome.

1.2. Information requirement not fulfilled

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

2. Growth inhibition study aquatic plants

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

2.1. Information provided

23 You have adapted this information requirement and provided the following justification: "US EPA ecotoxicity estimation software ECOSAR v1.1, predicts No Effects at Saturation (NES) for this (and other aquatic toxicity endpoints—acute and chronic) based on the experimentally measured log Kow of 8.41. This combined with the fact that an acute daphnia immobilization study showed no effects and daphnia are likely to be the more sensitive species for this substance, make this study not necessary."

2.2. Assessment of the information provided

2.2.1. Your justification to omit the study has no legal basis

24 A registrant may only adapt this information requirement based on the general rules set out in Annex XI or the specific rules set out in Annex VII, Section 9.1.2., Column 2.

25 Your justification to omit this information does not refer to any legal ground for adaptation under Annex XI to REACH or Annex VII, Section 9.1.2., Column 2. In your argumentation you refer that there would be no effects observed for any aquatic toxicity endpoint and that daphnia is assumed to be more sensitive to the Substance than algae but ECHA cannot identify from this any legal basis to your intended adaptation.

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

27 In your comments to the draft decision you have attached a document i.e. "[redacted] in which you indicate under the "Long-term toxicity on terrestrial plants" section that you agreed to develop the aquatic toxicity dataset. Moreover, you did not provide specific information addressing the issues identified above. Therefore, the information provided in your comments does not change the assessment outcome.

28 Therefore, the information requirement is not fulfilled.

2.3 Study design and test specifications

29 The Substance is difficult to test due to the low water solubility (0.000765 mg/L) and adsorptive properties (log K_{OC} >5.63). 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.

30 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.

31 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.

32 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.

3. Ready biodegradability

33 Ready biodegradability is an information requirement in Annex VII to REACH (Section 9.2.1.1.).

3.1. Information provided

34 You have adapted this information requirement by using Annex XI, Section 2. (testing not technically possible). To support the adaptation, you have provided following justification:

(i) "DMOP is highly insoluble in water (the water solubility of DMOP was visually assessed to be <1.07E-03 g/l at 20.0 ± 5°C (Fox, 2013) which is supported by the value of 7.656E-07 g/l 25°C derived from the (Q)SAR WSKOW (v1.42)"

35 In addition, you have adapted this information requirement by using Annex XI, Section 1.3. (Qualitative or Quantitative Structure-Activity Relationships, (Q)SARs). To support the adaptation, you have provided the following information:

(ii) a prediction from BIOWIN (v4.10).

3.2. Assessment of information provided

3.2.1. The provided adaptation does not meet the criteria of Annex XI, Section 2

36 Under Annex XI Section 2, a study may be omitted if it is not technically possible to conduct the study as a consequence of the properties of the substance. The technical limitations of the test method must always be respected. Annex III of OECD test guideline 301 provides guidance for testing the biodegradability of poorly soluble substances. Any of the four respirometric tests (301 B, 301 C, 301 D, 301 F) can be used to study the biodegradability of poorly soluble compounds.

37 You estimated the water solubility of the Substance as 0.000765 mg/L.

38 You have neither explained nor demonstrated why the test methods of OECD 301 B, 301 C, 301 D, 301 F would not be feasible to the Substance using the recommendations in Annex III of OECD TG 301.

39 Therefore, your adaptation is rejected.

3.2.2. (Q)SAR adaptation rejected

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

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

41 With regard to these conditions, we have identified the following issue(s):

3.2.2.1. Lack of documentation of the model (QMRF)

42 Under Appendix C of the OECD Guidance document on the validation of (Q)SAR models (ENV/JM/MONO(2007)2) and Guidance on IRs and CSA R.6.1.6.3., adequate and reliable documentation must include a (Q)SAR Model Reporting Format document (QMRF) which reports, among others, the following information:

- the predicted endpoint, including information on experimental protocol and data quality for the data used to develop the model;
- an unambiguous definition of the algorithm, the descriptor(s) of the model and its applicability domain,
- an estimate of the goodness-of-fit and of the predictivity of the model, including information on training set and validation statistics.

43 You have not provided information about the model.

44 In absence of such information, ECHA cannot establish that the model can be used to meet this information requirement.

3.2.2.2. Lack of documentation of the prediction (QPRF)

45 Guidance on IRs and CSA R.6.1.6.3. states that the information specified in or equivalent to the (Q)SAR Prediction Reporting Format document (QPRF) must be provided to have adequate and reliable documentation of the applied method. For a QPRF this includes, among others:

- the relationship between the modelled substance and the defined applicability domain (descriptor domain, structural fragment domain),
- the identities of close analogues, including considerations on how predicted and experimental data for analogues support the prediction.

46 You have not provided information about the prediction. Therefore you have not demonstrated that the Substance, being an ester of phosphonic acid, is within the descriptor or structural fragment domain of the model. Similarly, you have not provided documentation on close analogues and demonstrated how predicted and experimental data for analogues support the prediction.

47 In absence of such information, ECHA cannot establish that the prediction can be used to meet this information requirement.

3.2.2.3. The prediction does not cover all constituents of the Substance

48 Under Guidance on IRs and CSA R.6.1.7.3. a prediction is adequate for the purpose of classification and labelling and/or risk assessment if the following conditions are met:

- the composition of the substance is clearly defined, and
- different components of the same substance are predicted individually.

49 Your registration dossier provides the following information:

- In Section 1.2., you indicate that the Substance contains an impurity [redacted]
- For the assessment, you provided predictions for the following structures: dimethyl octadecylphosphonate, EC 246-904-0.

50 As you have used only the linear structure EC 246-904-0 for the prediction while the Substance contains an impurity [redacted] which you have not covered in your prediction.

51 Therefore, you have not demonstrated that the prediction is adequate for the purpose of classification and labelling and/or risk assessment.

52 Based on the above, your adaptation is rejected.

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

54 In your comments to the draft decision you have attached a document i.e. [redacted] in which you indicate under the "Identification of degradation products" section the following:

55 "If the requested Ready biodegradability study indicates that this substance is readily biodegradable, this endpoint will not be required […]". Although you did not specifically claim that a new ready biodegradability study will performed, ECHA understands that you intend to submit a new ready biodegradability study. However, that study is not yet available and you did not provide specific information addressing the issues identified above. Therefore, the information provided in your comments does not change the assessment outcome.

Reasons related to the information under Annex VIII of REACH

4. Long-term toxicity testing on fish

56 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.

4.1. Triggering of the information requirement

57 Poorly water soluble substances require longer time to reach steady-state conditions. As a result, the short-term tests do not give a true measure of toxicity for this type of substances and the long-term test is required.

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

59 In your comments to the draft decision you have attached a document i.e. [redacted] in which you indicate under the "Long-term toxicity on terrestrial plants" section that you agreed to develop the aquatic toxicity dataset. Moreover, you did not provide specific information addressing the issues identified above. Therefore, the information provided in your comments does not change the assessment outcome.

4.2. Information requirement not fulfilled

60 The information provided, its assessment and the specifications of the study design are addressed under request 8.

Reasons related to the information under Annex IX of REACH

5. Sub-chronic toxicity study (90-day)

61 A sub-chronic toxicity study (90 days) is an information requirement under Annex IX, Section 8.6.2.

5.1. Information provided

62 You have adapted this information requirement and provided the following justification: "On the basis of animal welfare and conserving the number of animals used in toxicity testing, it was considered that sufficient information was available to characterise the repeat-dose toxicity of DMOP and a 90-day study is not scientifically justified".

63 To support the adaptation, you have provided following information:

(i) Screening for reproductive/developmental toxicity study (2013) with the Substance

5.2. Assessment of the information provided

5.2.1. Your justification to omit the study has no legal basis

64 A registrant may only adapt this information requirement based on the general rules set out in Annex XI or the specific rules set out in Annex IX, Section 8.6.2., Column 2.

65 Your justification to omit this information does not refer to any legal ground for adaptation under Annex XI to REACH or Annex IX, Section 8.6.2., Column 2.

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

67 Minimisation of vertebrate animal testing is not on its own a legal ground for adaptation under the general rules of Annex XI or Annex IX, Section 8.6.2., Column 2.

Study not adequate for the information requirement

68 To fulfil the information requirement, a study must comply with the OECD TG 408 (Article 13(3) of REACH). Therefore, the following specifications must be met, among others:

a) the exposure duration is at least 90 days.

69 The study (i) is described as a screening for reproductive/developmental toxicity study. This study has been conducted using the OECD TG 422 and the exposure duration was only 36 days for males and 47-60 days for females.

70 The information provided does not cover the specification(s) required by the OECD TG 408.

71 Therefore, the information requirement is not fulfilled.

5.3. Specification of the study design

72 Following the criteria provided in Annex IX, Section 8.6.2., Column 2, and considering the Guidance on IRs and CSA, Section R.7.5.6.3.2., the oral route is the most appropriate route of administration to investigate repeated dose toxicity of the Substance.

73 According to the OECD TG 408, the rat is the preferred species.

74 Therefore, the study must be performed in rats according to the OECD TG 408 with oral administration of the Substance.

6. Pre-natal developmental toxicity study in one species

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

6.1. Information provided

76 You have adapted this information requirement by using Annex IX, Section 8.7., Column 2. To support the adaptation, you have provided the following information: you referred to all specific rules in column 2, concluding that "*With regard to the criteria in column 2 all of the categories are negative for DMOP (i.e. the Substance) with the exception that although DMOP is considered to be of low toxicological activity with no significant toxicity identified at exposures up to and including 600 mg/kg bw/day, some systemic exposure is known to occur. […] It was concluded that based on these results the NOAEL for reproductive and developmental effects was at least 600 mg/kg bw/day. On the basis of animal welfare and conserving the number of animals used in toxicity testing, it may therefore be concluded that there is no evidence of a reproductive toxic effect for DMOP at dose levels up to and including 600 mg/kg bw/day and information*".

77 To support the adaptation, you have provided following information:

(i) Screening for reproductive/developmental toxicity study (2013) with the Substance

6.2. Assessment of the information provided

78 We have assessed the provided information and identified the following:

79 Firstly, ECHA notes that you have correctly concluded that the Substance does not meet the classification criteria listed in Column 2, Section 8.7., Annex IX, for genotoxic carcinogen (1st paragraph, 1st indent), germ cell mutagen (1st paragraph, 2nd indent) as well as for reproductive toxicity for fertility (2nd paragraph) and development (3rd paragraph). Since these criteria are not met, the information requirement cannot be adapted on this basis.

80 Secondly, you claim that the Substance is "considered to be of low toxicological activity with no significant toxicity identified at exposures up to and including 600 mg/kg bw/day" even though "some systemic exposure is known to occur".

81 Based on your statement ECHA assessed your adaptation in accordance with Annex IX, Section 8.7, Column 2, 1st paragraph, 3rd indent and identified the following issue:

Criteria for the application of the adaptation for Annex IX, Section 8.7., Column 2 not met

82 Under Annex IX, Section 8.7., Column 2, the study does not need to be conducted if the following criteria are met:

- the substance is of low toxicological activity, demonstrated by a comprehensive and informative dataset showing no toxicity in any of the tests available; and
- that it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure; and

- that there is no or no significant human exposure.

83 The study (i) shows mortality and severe weight loss at the initial dose of 1000 mg/kg bw/day. You also reported other findings "considered to be treatment related" in adrenal gland, liver and mesenteric lymph nodes at lower doses (600 mg/kg bw/day). Based on this information it cannot be concluded that the Substance is of low toxicological activity.

84 Further, as you correctly noted, the effects observed proved that the Substance has systemic absorption.

85 Finally, the Substance is used as lubricating agent in vehicles and machinery that indicate widespread professional and consumer use leading to significant human exposure.

86 On this basis, you have not demonstrated that the criteria for this adaptation are fulfilled.

87 Based in the above, your adaptation is rejected.

Study not adequate for the information requirement

88 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 foetuses are examined for skeletal and soft tissue alterations (variations and malformations)

89 The study (i) has been conducted using the OECD TG 422 which is a screening test rather than a conclusive developmental toxicity study.

90 In study (i):

c) 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;
d) the foetuses are not examined for skeletal and soft tissue alterations (variations and malformations)

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

92 On this basis, the study is not adequate for the information requirement.

93 Therefore, the information requirement is not fulfilled.

6.3. Specification of the study design

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

95 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).

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

7. Long-term toxicity testing on aquatic invertebrates; and

8. Long-term toxicity testing on fish

97 Long-term toxicity testing on aquatic invertebrates and on fish are information requirements under Annex IX to REACH (Section 9.1.5. and Section 9.1.6.).

8.1. Information provided

98 You have adapted these information requirements by using Column 2 of Annex IX, Section 9.1. To support the adaptations, you have provided following information: "As stated in Column 2 of Annex IX, Regulation (EC) No 1907/2006, "long-term toxicity testing shall be proposed by the registrant if the chemical safety assessment according to Annex I indicates the need to investigate further the effects on aquatic organisms". The chemical safety assessment does not indicate any need to perform further testing as the risk assessment for formulation (note:- formulation is considered to represent a worst case scenario relative to professional and consumer use) of DMOP, based on EU tonnage, and calculated using OECD ESD No. 10 for Lubricants and Lubricant Additives combined with EUSES v2.1.2, indicates that there is no cause for concern for the aquatic environment. No further testing is therefore recommended."

8.2. Assessment of the information provided

8.2.1. Annex IX, Section 9.1., Column 2 is not a valid basis to omit the studies

99 Under Annex IX, Section 9.1., Column 2 is not a basis for omitting information on long-term toxicity to aquatic invertebrates or fish, referred to, respectively, under Column 1, Section 9.1.5. and Section 9.1.6.

100 Therefore, your adaptations are rejected.

101 As already mentioned under Request 1 and 4, in your comments to the draft decision you have attached a document i.e. [redacted] in which you indicate under the "Long-term toxicity on terrestrial plants" section that you agreed to develop the aquatic toxicity dataset. Moreover, you did not provide specific information addressing the issues identified above. Therefore, the information provided in your comments does not change the assessment outcome.

8.3 Study design and test specifications

102 To fulfil the information requirement on long-term toxicity to aquatic invertebrates, the Daphnia magna Reproduction Test (test method OECD TG 211) is the most appropriate (Guidance on IRs and CSA, Section R.7.8.4.1).

103 To fulfil the information requirement on long-term toxicity to 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.).

104 OECD TG 210 and 211 specify that, for difficult to test substances, OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design and test specifications' under request 2.

9. Simulation testing on ultimate degradation in surface water

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

9.1. Information provided

106 You have adapted this information requirement by using arguments on

(i) high insolubility set out under Column 2 of Annex IX, Section 9.2.1.2. To support the adaptation, you have provided following information: *"Dimethyl octadecylphosphonate (DMOP) is highly insoluble in water. The water solubility of DMOP was visually assessed to be <1.07E-03 g/l at 20.0 ± 5°C (Fox, 2013) which is supported by the value of 7.656E-07 g/l 25°C derived from the (Q)SAR WSKOW (v1.42)."*

(ii) Chemical Safety Assessment set out under Column 2 of Annex IX, Section 9.2. To support the adaptation, you have provided following information: *"the exposure to aquatic environment is expected to be limited. According to* [redacted] *Specific Environmental Release Categories (SpERCs) factsheet for formulation of lubricant additives, lubricants and greases (*[redacted]*) "User sites are assumed to be provided with oil/water separators or equivalent and for waste water to be discharged via public sewer system". In addition, the chemical safety assessment does not indicate any need to perform further testing as the risk assessment for formulation (note:-formulation is considered to represent a worst case scenario relative to professional and consumer use) of DMOP, based on EU tonnage, and calculated using the OECD ESD No. 10 for Lubricants and Lubricant Additives combined with EUSES v2.1.2, indicates that there is no cause for concern for the aquatic environment."*

9.2. Assessment of information provided

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

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

108 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.

109 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 equal to or at least ten times lower to the water solubility of the substance.

110 In the provided OECD TG 105 (2013), the saturation concentration of the Substance in water was determined to be below 1.07 mg/L.

111 You did not provide any argument in relation to the specific technical limitations of the OECD TG 309 as regards testing of your Substance.

112 Therefore, you have not demonstrated that the Substance is insoluble and the adaptation is rejected.

113 In your comment to the draft decision, you reiterate your adaptation of the information requirement according to Column 2 of Annex IX, Section 9.2.1.2, indicating the following "[redacted] *believes that the substance does meet the criteria for 'insoluble in water' and therefore this endpoint can be waived in accordance with column II rules for adaptation. However, it is recognised that the existing waiver can be improved to further clarify this point"*. To support your adaptation, you suggest investigating further the water solubility properties of the Substance.

114 In this context you indicate that a new water solubility study will be performed. You explain that despite the fact that there is already an existing water solubility study in the dossier, you consider that it was not possible from the current study to obtain a dissolution of the test material at the concentrations tested and that therefore it was not possible to obtain a reliable analytical results of dissolved material due to the Tyndall effect. Consequently, you propose to re-run a water solubility study to improve the analytical methodology. According to the results of that study, you will either waive the standard information requirement according to the Annex IX, Column 2 adaptation or you would investigate the analytical feasibility of undertaking the OECD TG 309 study.

115 You also specify that in case the study fails to quantify the solubility of the Substance, the study cannot be considered technically feasible and therefore you will update the dossier *in accordance with column II rules for adaptation*. However, in case the solubility of the Substance can be determined, you will investigate further the feasibility of the OECD TG 309 study.

116 Further you claim that the Substance is a UVCB and that the OECD TG 309 is not intended for UVCBs. Therefore, you propose that rather than testing the whole substance, a representative constituent of the UVCB will be identified (i.e. using OASIS CATALOGIC v5.15.2.11 model on each constituent to simulate degradation in an OECD 301C study and exclude the constituent that are readily biodegradable) and then the study will be conducted on the most relevant constituent. In this context, you explain that it might be necessary to radiolabel the representative constituent and in such case you would appreciate a discussion with ECHA on the appropriate methodology for radiolabelling.

117 Based on the above, ECHA understands that you present a strategy relying on the generation of additional supporting information on the Substance. You indicate your intention to provide this in a future update of your registration dossier.

118 ECHA acknowledges your intentions to provide a new water solubility study to improve the analytical methodology of the Substance and your plans to refine the quantification of the solubility of the Substance. However, as indicated in your comments, this strategy relies essentially on data which is yet to be generated, therefore no conclusion on the compliance can currently be made.

119 In your comment you also indicate that if the new water solubility study fails to quantify the solubility of the Substance you would propose to waive this study based on column 2 rules for adaptation as the study cannot be considered as technically feasible.

120 ECHA would like to remind you that Annex IX, Section 9.2., Column 2 provides that "further" biodegradation testing must be proposed if the chemical safety assessment according to Annex I indicates the need to investigate further the degradation of the substance and its degradation products. That provision allows a registrant to propose, or ECHA to require, biotic degradation testing not covered by the information on degradation listed under Annex IX, section 9.2., Column 1. Therefore, this provision cannot be used as a justification for omitting the submission of information on simulation testing on ultimate degradation in surface water required under Annex IX, Section 9.2.1.2, Column 1.

121 Furthermore, regarding your intention to adapt the information requirement according to Annex XI, Section 2 (i.e. technically not feasible), as already explained under Section 9.1.2

above (paragraph 106), 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, including the concentrations of the test substance that must be below its water solubility, and the limit of quantification (LOQ) that should be equal to or less than 10% of the applied concentration.

122 However, as explained above as the water solubility data of the new study is yet to be generated, therefore no conclusion on the compliance can currently be made.

123 Finally, you state that if the solubility of the Substance can be determined, you will investigate further the feasibility to perform the OECD TG 309 study. You also claim that the Substance is an UVCB and that the OECD TG 309 study is not intended for UVCBs. Therefore, rather than testing the whole substance, you would propose to identify a representative constituent of the UVCB and undertake the study on this constituent. ECHA notes that in your current registration dossier under Section 1.1. of the IUCLID dossier, the type of substance is indicated as a mono-constituent and you have not provided any information to demonstrate that the Substance is identified as an UVCB. Therefore, the information provided in your comments does not change the assessment outcome and the requested information must be generated using the Substance (i.e. mono-constituent) unless otherwise is justified.

9.2.2. Annex IX, Section 9.2., Column 2 is not a valid basis to omit the study

124 Annex IX, Section 9.2., Column 2 provides that "further" biodegradation testing must be proposed if the chemical safety assessment according to Annex I indicates the need to investigate further the degradation of the substance and its degradation products. That provision allows a registrant to propose, or ECHA to require, biotic degradation testing not covered by the information on degradation listed under Annex IX, section 9.2., Column 1.

125 Therefore, this provision cannot be used as a justification for omitting the submission of information on simulation testing on ultimate degradation in surface water required under Annex IX, Section 9.2.1.2, Column 1.

126 Based on the above, your adaptation under Annex IX, Section 9.2., Column 2 is rejected and the information requirement is not fulfilled.

9.3. Study design and test specifications

127 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.

128 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.).

129 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.

130 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.

131 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)).

132 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.)

10. Soil simulation testing

133 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.

134 The Substance has a high adsorption coefficient (logKoc >5.63, OECD TG 121) and therefore has high potential for adsorption to soil.

10.1. Information provided

135 You have adapted this information requirement by using exposure considerations set out under Column 2 of Annex IX, Section 9.2.1.3. (unlikely direct and indirect exposure).

10.2. Assessment of information provided

10.2.1. Column 2 adaptation based on exposure considerations rejected

136 As explained in Section 0.1., your adaptation based on unlikely direct or indirect exposure under Column 2 of Annex IX, Section 9.2.1.3. is rejected.

137 Therefore, the information requirement is not fulfilled.

138 In your comments to the draft decision, you indicate your intention to adapt the information requirement according to Annex XI, Section 2, you state the following: "[redacted] *believes that it is not technically feasible to conduct a soil simulation test in accordance with OECD 307"*

139 In addition, you have also indicated that you agree that "*the information presented in the dossier are currently insufficient to demonstrate that the study cannot be considered*

technically feasible". In this context you propose to provide new physico-chemicals studies including a new water solubility study that would improve the analytical method to quantify the solubility of the Substance (as indicated under Request 9, paragraph 111), and in case this study fails you suggest to perform an additional study (that is not required by REACH regulation) which would allow to determine the solubility of the substance in organic solvents. You consider that the results of both studies (i.e. water solubility and solubility in organic solvents) will be relevant to examine the feasibility of the OECD TGs 307 and 308 studies .

140 Further, you specify that "*in case the study of solubility in organic solvents demonstrates that either the substance does not dissolve in organic solvents, or will only dissolve at concentrations that would influence microbial activity, the study will be waived on the basis of the study cannot be considered technically feasible in accordance with Annex XI. However, in case the water solubility of the substance can be determined, or the substance is soluble in organic solvents at concentrations that would not influence microbial activity, this study will be considered using the same approach described above* (under Request 9) *of identifying a representative constituent of the UVCB substance. And in that situation you would welcome ECHA's guidance on the determination of a representative constituent, and potential radiolabelling approaches"*

141 Finally, you conclude that *"if after this investigation, a representative constituent cannot be identified that would allow the OECD 307 study to be conducted,* [redacted] *would propose to waive this study on the basis that the study cannot be considered technically feasible"*.

Based on your comments, ECHA understands that you indicate your intention to first provide supporting information (i.e. water solubility study and if needed a solubility study in organic solvent) that would allow to determine a most accurate solubility value of the Substance, and then in case the water solubility of the substance can be determined, an OECD TG 307 study will be considered by using the same approach as described above (under Request 9) of identifying a representative constituent of the UVCB substance. And in case the substance does not dissolve in organic solvents or is toxic to microbial activity or a representative constituent cannot be identified, you specified your intention to waive this information requirements on the basis that the study cannot be considered technically feasible.

142 Regarding your intention to adapt the information requirement according to Annex XI, section 2 (i.e. technically not feasible), ECHA notes that for such an adaptation it is necessary to demonstrate that the study is not technically feasible, because of the properties of the Substance according to the guidance given in the test methods referred to in Article 13(3), in this case OECD TG 307. In that context, the OECD TG 307 states that the method is applicable to all chemical substances including water insoluble compounds for which an analytical method with sufficient accuracy and sensitivity is available.

143 However, as this strategy relies essentially on data which is yet to be generated, no conclusion on the compliance can currently be made. Therefore, the information provided in your comments does not change the assessment outcome.

144 In particular, regarding your approach of identifying a representative constituent of the UVCB and undertake the study on this constituent, ECHA notes that as already explained under request 9, your current registration dossier describes the Substance as a mono-constituent and you have not provided any information to demonstrate that the Substance is identified as an UVCB. Therefore, the information provided in your comments does not change the assessment outcome and the Substance is still considered a mono-constituent.

10.3. Study design and test specifications

145 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.

146 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).

147 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.

148 In accordance with the specifications of 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.

149 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.).

150 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.

151 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.).

11. Sediment simulation testing

152 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.

153 The Substance has a high adsorption coefficient (logKoc >5.63, OECD TG 121) and therefore has high potential for adsorption to sediment.

11.1. Information provided

154 You have adapted this information requirement by using exposure considerations set out under Column 2 of Annex IX, Section 9.2.1.4. (unlikely direct and indirect exposure).

11.2. Assessment of information provided

11.2.1. Column 2 adaptation based on exposure considerations rejected

155 As explained in Section 0.1., your adaptation based on unlikely direct or indirect exposure under Column 2 of Annex IX, Section 9.2.1.4. is rejected.

156 Therefore, the information requirement is not fulfilled.

157 In your comments to the draft decision, you have provided the same approach and justification as provided for the soil simulation study (request 10).

158 ECHA notes that for the same reasons as explained under request 10, no conclusion on the compliance can currently be made. The requested study must be conducted on the Substance (i.e. mono-constituent) unless otherwise is justified. Therefore, the information provided in your comments does not change the assessment outcome

11.3. Study design and test specifications

159 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.

160 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.

161 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.

162 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.

163 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.

164 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.).

12. Identification of degradation products

165 Identification of abiotic and biotic degradation products is an information requirement under Annex IX to REACH (Section 9.2.3.).

12.1. Information provided

166 You have adapted this information requirement by using Column 2 of Annex IX, Section 9.2. To support the adaptation, you have provided arguments described already under request 9.

12.2. Assessment of information provided

167 For the same reasons as explained under 9.2.2, your adaptation under Column 2 of Annex IX, Section 9.2. is rejected.

168 In your comments to the draft decision you mention your intention to waive the information requirement according to Column 2 of Annex IX, Section 9.2.3 in case the requested ready biodegradability study indicates that the Substance is readily biodegradable. Further you also mention that based on similar substances, you consider that it is unlikely that the Substance will meet the criteria for ready biodegradation and therefore this endpoint requires consideration.

169 In addition of that, you also indicate your intention to waive the endpoint according to Annex XI, Section 2in case the experimental studies (i.e. simulation testing) are not technically feasible, you state the following "*As* [redacted] *currently does not consider it technically feasible to undertake an OECD 307, 308 or 309 study on this substance, it is not possible to determine degradation products from these studies. We believe that this is grounds to waive this endpoint under Annex XI*". However, you indicate that in case any of these studies is undertaken, they will only be possible with a representative constituent, and therefore the degradation products would potentially only be provided on a single constituent". Furthermore, you propose to develop QSAR predictions in accordance with OECD principles and adequate documentation (c.f. a QPRF and QMRF), which will include identification of degradation products, and provide further information if necessary, on relevant degradation products (those predicted to account for >10% of substance) to determine if any have properties that may indicate the potential for persistence and bioaccumulation

170 Based on the above, ECHA understands that according to the results of the supporting information which you intend to provide you are considering different scenarios of adaptation, as the following:

i. Column 2 adaptation of Annex IX, Section 9.2.3, in case the ready biodegradation study shows that the Substance is readily biodegradable;

ii. you indicate that based on similar substances you consider that the Substance is unlikely to meet the ready biodegradability criteria. On this basis ECHA understands that you intend to adapt this information requirement by means of grouping and read-across according to Annex XI, Section 1.5, of the REACH Regulation;

iii. Annex XI, Section 2 in case the simulation testing is technically not feasible

iv. Annex XI, Section 1.3 i.e. QSAR prediction to identify the relevant degradation products

171 ECHA acknowledges your approach. However, regarding point (i) and (iii) listed above, as indicated in your comments, this strategy relies essentially on data, which is yet to be generated, therefore no conclusion on the compliance can currently be made.

172 Regarding point (ii) i.e. read across adaptation, in your comments you did not provide any justification to support your adaptation. Therefore, this strategy is relying on a category/read-across approach that has not yet been fully described and justified Therefore, no conclusion on the compliance of the proposed adaptation can be made.

173 With regard to your intention to develop QSAR prediction to identify the relevant degradation products, ECHA acknowledge your intention, however the information in your comments is not sufficient for ECHA to make an assessment, because while you have described your intentions, you have not provided any new scientific information addressing the information requirement.

174 Therefore, the information provided in your comments does not change the assessment outcome

175 Consequently, the information requirement is not fulfilled.

12.3. Study design and test specifications

176 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.

177 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.

178 You must obtain this information from the degradation studies requested in requests 9, 10 and 11.

179 To determine the degradation rate of the Substance, the requested study according to OECD TG 309 (request 9) 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).

180 To determine the degradation rate of the Substance, the requested studies according to OECD TG 308 and 307 (requests 10 and 11) must be conducted at 12°C and at 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).

13. Bioaccumulation in aquatic species

181 Bioaccumulation in aquatic species is an information requirement under Annex IX to REACH (Section 9.3.2.).

13.1. Information provided

182 You have adapted this information requirement by using:

(i) exposure considerations set out under Column 2 of Annex IX, Section 9.3.2. (unlikely direct and indirect exposure). To support the adaptation, you have provided following information: *Column 2 of the Corrigendum to Regulation (EC)*

No 1907/2006, Annex IX, states, "The study need not be conducted if: - direct and indirect exposure to the aquatic compartment is unlikely". Exposure to the aquatic environment is expected to be limited, according to [redacted] *Specific Environmental Release Categories (SpERCs) factsheet for formulation of lubricant additives, lubricants and greases (*[redacted]*) "User sites are assumed to be provided with oil/water separators or equivalent and for waste water to be discharged via public sewer system". In addition, the exposure and risk assessment for formulation (note:- formulation is considered to represent a worst case scenario relative to professional and consumer use) of DMOP based on EU tonnage, and calculated using OECD ESD No. 10 for Lubricants and Lubricant Additives combined with EUSES v2.1.2, indicates that there is no cause for concern for the environment. The Risk Characterisation Ratios for the aquatic environment were all <1.*

(ii) Statements on estimated bioaccumulation factors: The estimated BCF derived from BCFBAF v3.01 is 686.4 L/kg and the estimated BCF value derived from the Arnot-Gobas method is <141.5 l/kg. BCFBAF v3.01 meets the OECD principles of (Q)SAR and the experimental Log Kow of 8.41 is within the limits of the model.

13.2. Assessment of information provided

13.2.1. Column 2 adaptation based on exposure considerations rejected

183 As explained in Section 0.1., your adaptation based on unlikely direct or indirect exposure under Column 2 of Annex IX, Section 9.3.2. is rejected.

13.2.2. (Q)SAR adaptation rejected

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

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

185 Guidance on IRs and CSA R.6.1.6.3. states that adequate and reliable documentation must include information specified in or equivalent to a (Q)SAR Model Reporting Format document (QMRF) and the (Q)SAR Prediction Reporting Format document (QPRF).

186 You have not provided information about the model and the prediction.

187 In absence of such information, ECHA cannot confirm whether the above conditions are fulfilled and your adaptation under Annex XI, Section 1.3. is rejected.

188 In your comments to the draft decision you refer to an adaptation according to Column 2 of Annex IX, Section 9.3.2.. You indicate the following: "[redacted] *considers that this substance will have low potential to cross biological membranes. According to OASIS CATALOGIC v5.15.2.11, the DMAXaver of this substance is 19.946 Å. This is equivalent to 1.99 nm. [..]. Therefore, it can be concluded that the DMAXaver of this substance indicates that it will have low potential to cross biological membranes".*

189 Further you also refer to ECHA guidance R.11. stating the following "*[…] Chapter R.11: PBT/vPvB assessment states at log Kow values between 4 and 5, Log BCF increases linearly with log Kow* […] *However, at very high log Kow (>6), a decreasing relationship between the two parameters is observed. Therefore, this is further supporting evidence against bioaccumulation of this substance in aquatic organisms".* In that context you consider that an additional Log Kow study will be beneficial to confirm the low potential of

bioaccumulation. In addition, you propose to conduct a new octanol-water partition coefficient study and generating a new QSAR study using OASIS CATALOGIC to support the conclusion on the non accumulative nature of the Substance. You specified that this QSAR will be conducted in accordance with OECD principles and adequate documentation (c.f. a QPRF and QMRF).

190 Further you indicate that this new QSAR, the two log Kow studies and a summary of the DMAXave will be used as a weight-of-evidence approach to fulfil this endpoint.

191 ECHA has identified the following issue(s) with the adaptations you are considering in your comments:

I. Annex XI, Section 1.2. of REACH (weight of evidence)

192 According to your comments you consider adapting the information requirement by weight of evidence supported with the following sources of information:

i. Physico-chemicals indicators of hindered uptake i.e. large molecule size (Dmax > 1.7 nm) and log kow studies (I.e. current study in the dossier and new study) that would indicate a high log kow

ii. QSAR prediction study using OASIS CATALOGIC to demonstrate a low bioaccumulation potential

193 ECHA acknowledges your approach, however ECHA would like to remind you that according to Annex XI, Section 1.2 there may be sufficient weight of evidence from several independent sources of information leading to assumption/conclusion that a substance has or has not a particular dangerous (hazardous) property, while information from a single source alone is insufficient to support this notion.

194 Furthermore, according to ECHA Guidance R.4.4, a weight of evidence adaptation involves an assessment of the relative values/weights of different sources of information submitted. The weight given is based on the reliability of the data, consistency of results/data, nature and severity of effects, and relevance of the information for the given regulatory information requirement. Subsequently, relevance, reliability, consistency and results of these sources of information must be balanced in order to decide whether they together provide sufficient weight to conclude that the Substance has or has not the dangerous property investigated by the required study

195 To fulfil the information requirement, normally a study performed according to OECD TG 305 is required. OECD TG 305 requires the study to investigate the following key parameters:

1. the uptake rate constant (k_1) and loss rate constants including the depuration rate constant (k_2), and/or
2. the steady-state bioconcentration factor (BCF_{SS}), and/or
3. the kinetic bioconcentration factor (BCF_K), and/or
4. the biomagnification factor (BMF).

196 Based on the approach proposed in your comments, the source of information (ii) may provide relevant information on the key parameters (1) and (2). However, the source of information (i) does not investigate any of the key parameters listed above (from 1 to 4).

197 As a consequence, you would provide only one source of information to build a weight of evidence adaptation, which is not sufficient to draw a conclusion (Annex XI, Section 1.2.) on the bioaccumulation properties of the substance.

198 Therefore, your intention to adapt this information requirement by means of weight of evidence according to Annex XI, Section 1.2, as described in your comments, would currently not be valid.

II. Column 2 of Annex IX, Section 9.3.2

199 ECHA understands that your comments related the low potential of the Substance to cross the biological membrane refer to an adaptation under Column 2 of Annex IX, Section 9.3.2. In that context, ECHA would like to highlight the flowing:

200 Under Section 9.3.2., Column 2, first indent, Annex IX to REACH, the study may be omitted if the Substance is unlikely to cross biological membranes. Guidance on IRs and 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 and CSA, Section R.11, Figure R.11-4) must be considered, including:

- physico-chemical indicators of hindered uptake due to large molecular size (e.g. Dmax > 17.4 Å and MW > 1100 or MML > 4.3 nm) or high octanol-water partition coefficient (log Kow > 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).

201 Based on that, ECHA acknowledges your intention to provide physico-chemicals information that would indicate the Substance is unlikely to cross the membrane due to large molecular size (e.g. Dmax > 17.4 Å) or high octanol-water partition coefficient (log Kow > 10). However, as your current dossier is missing supporting experimental evidences (e.g. Toxicokinetic study, repeated-dose toxicity (90) days, aquatic toxicity studies), there is not enough evidence to conclude that the Substance is unlikely to cross the biological membrane.

III. QSAR prediction

202 Regarding the QSAR prediction that you suggest to provide, ECHA acknowledges your intention. However, as indicated in your comments, this strategy relies essentially on data which is yet to be generated, therefore no conclusion on the compliance can currently be made.

203 Therefore, the information requirement is not fulfilled.

13.3. Study design and test specifications

204 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.

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

206 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).

14. Long-term toxicity on terrestrial invertebrates

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

14.1. Triggering of the information requirement

208 Under Annex IX, Section 9.4., Column 2, for substances that have a high potential to adsorb to soil or that are very persistent, long-term toxicity testing must be considered instead of short-term. Guidance on IRs and CSA, Section R.7.11.5.3. clarifies that a substance is considered to be very persistent in soil if it has a half-life >180 days. In the absence of specific soil data, high persistence is assumed unless the substance is readily biodegradable. A substance is considered to be highly adsorptive if the logK_{ow} > 5 or it is ionisable.

209 As explained under request 3, you have not demonstrated that the Substance is readily biodegradable and therefore in the absence of data, high persistence is assumed.

210 Moreover, the Substance is considered highly adsorptive based on its log K_{ow} of 8.41 and a log K_{oc} of > 5.63.

211 On this basis, information on long-term toxicity on terrestrial invertebrates must be provided.

14.2. Information provided

212 You have adapted this information requirement by using Column 2 of Annex IX, Section 9.4. To support the adaptation, you have provided a justification based on the following arguments:

(i) No direct exposure of dimethyl octadecylphosphonate (DMOP) to soil is expected for industrial uses, as supported by the [redacted]SpERCs (…) because no biosolids of industrial origin are applied to land.
(ii) the SpERCs indicated very limited emissions from professional and consumer uses
(iii) *"Exposure and risk assessment (…), indicates that there is no cause for concern with regard to the environment."*
(iv) *"The Risk Characterisation Ratios, calculated using the soil PNEC derived using equilibrium partitioning method, were all <1".*

14.3. Assessment of information provided

14.3.1. Column 2 adaptation based on exposure considerations rejected

213 As explained in Section 0.1., your adaptation based on unlikely direct or indirect exposure under Column 2 of Annex IX, Section 9.4. is rejected.

14.3.2. Adaptation based on EPM method rejected

214 Under Annex X, Section 9.4., Column 2, in the absence of toxicity data to soil organisms, the equilibrium partitioning method (EPM) may be applied to assess the hazard to soil organisms. Where the data available are sufficient to derive a PNEC for aquatic organisms,

this PNEC can be used in a screening assessment for soil risks through the use of the EPM approach (Guidance on IRs and CSA, Section R.7.11.5.3).

215 In this context, Guidance on IRs and CSA, Section R.7.11.6. describes an integrated testing strategy (ITS) for Effects on Terrestrial Organisms. This approach relies on the assignment of the Substance to a "soil hazard category" and on an initial screening assessment using the EPM, in order to decide the information needed for the chemical safety assessment.

216 For a substance which is adsorptive (logKow >5) or very persistent, Soil Hazard Category 3 or 4 is applicable. If the aquatic toxicity studies indicate EC/LC50 > 1 mg/L for algae, daphnia and fish, Soil Hazard Category 3 applies and one long-term soil toxicity test may be sufficient to confirm the hazards predicted by the EPM. If the aquatic toxicity studies indicate EC/LC50 < 1 mg/L for algae, daphnia or fish, Soil Hazard Category 4 applies and the screening assessment based on EPM is not applicable.

217 You have claimed to apply the EPM approach to derive a $PNEC_{soil}$.

218 Based on the information on adsorption (log K_{ow} of 8.41), the Substance belongs to the Soil Hazard category 3 or 4.

219 You have not provided any terrestrial toxicity studies.

220 For the reasons explained under request 1, 2, 4, 7 and 8, your dossier does not include sufficient data to assess the hazards and derive a PNEC for aquatic organisms. Therefore, as there is no reliable PNEC for aquatic organisms, screening assessment for soil risks through the use of the EPM approach cannot be used.

221 Furthermore, in the absence of any terrestrial toxicity studies, you have not confirmed that the risks to the terrestrial environment are controlled using the EPM for the Substance which belongs to the Soil Hazard Category 3 or 4.

222 Based on the above, your adaptation is rejected.

14.4. Study design and test specifications

223 To fulfil the information requirement, the test method(s) according to OECD TG 222, OECD TG 220, and OECD TG 232 are appropriate to cover the information requirement for long-term toxicity on terrestrial invertebrates (Guidance on IRs and CSA, Section R.7.11.3.1). You can choose any of these methods, but you must ensure that the Substance is within the applicability domain of the chosen test method.

15. Effects on soil micro-organisms

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

15.1. Information provided

225 You have provided the same information as summarised under request 14, section 14.2.

15.2. Assessment of information provided

15.2.1. Column 2 adaptation based on exposure considerations rejected

226 As explained in Section 0.1., your adaptation based on unlikely direct or indirect exposure under Column 2 of Annex IX, Section 9.4. is rejected.

15.2.2. EPM method cannot be used to adapt the information requirement

227 Under Annex X, Section 9.4., Column 2, in the absence of toxicity data to soil organisms, the equilibrium partitioning method (EPM) may be applied to assess the hazard to soil organisms.

228 Intrinsic properties of chemicals on soil microbial communities are not addressed through the EPM extrapolation method because the standard aquatic toxicity data set (i.e. studies on fish, invertebrates and algae) used for derivation of PNEC for aquatic organisms does not include information on toxicity to microbial communities.

229 Therefore the potential adaptation possibility outlined in Annex IX, Section 9.4., Column 2, Second paragraph does not apply for the information requirement on Effects on soil micro-organisms.

230 You have derived the $PNEC_{soil}$ using only the EPM and provided no information or justification why the EPM method would be protective for soil microorganisms.

231 Therefore, your adaptation is rejected.

15.3. Study design and test specifications

232 Guidance on IRs and CSA, Section R.7.11.3.1. specifies that the nitrogen transformation test (EU C.21/OECD TG 216) is considered suitable for assessing long-term adverse effects on soil microorganisms for most non-agrochemicals.

16. Long-term toxicity on terrestrial plants

233 Short-term toxicity to terrestrial plants is an information requirement under Annex IX to REACH (Section 9.4.3). Long-term toxicity testing must be considered (Annex IX, Section 9.4., column 2) if the substance has a high potential to adsorb to soil or is very persistent.

16.1. Triggering of the information requirement

234 As already explained under request 14, the Substance has a high potential to adsorb to soil. Therefore, information on long-term toxicity on terrestrial plants must be provided.

16.2. Information provided

235 You have provided the same information as summarised under request 14, section 14.2.

16.3. Assessment of information provided

236 Your adaptation is rejected based on the same reasons as explained under request 14, section 14.3.1. and 14.3.2.

237 In your comments to the draft decision you acknowledge that there is currently insufficient information on the aquatic toxicity of the substance to justify the use of EPMsoil for PNEC derivation. In that context, you claim that based on data on similar substances the substance would meet the criteria of Hazard Category 3.

238 On this basis ECHA understands that you agreed to develop the aquatic toxicity dataset and undertake a long-term toxicity study in a terrestrial invertebrate species. You indicate that the data on similar substances will be sufficient to develop a robust PNECsoil using EPM and validate that PNECsoil with confirmatory long-term soil toxicity testing data. According to these results Sections 9 and 10 of the CSA will be revised.

239 Further you also refer to Column 2 of Annex X, Section 9.4. and to the described conditions of Table R.7.11-2. According to that, you mention that based on the risk assessment results you will either decide to perform a new study of terrestrial toxicity in plant if PEC/PNECscreen > 1 or there is indication of risk from confirmatory long-term soil toxicity test. Alternatively, you consider that there is no need to conduct further toxicity testing for soil organisms in case there is no indication of risk from PEC/PNECscreen rate i.e. < 1 and no indication of risk from confirmatory long-term soil toxicity testing.

240 Based on the above, ECHA understands that you consider the Substance as Hazard category 3 based on a grouping and read-across approach (according to Annex XI, Section 1.5, of the REACH Regulation),. To identify the toxicity effects of the Substance on the terrestrial organisms you intend to follow the testing strategy described in R.7.11.2 for substances of "Hazard category 3" which indicates that the screening assessment could be performed based on an EPM approach with confirmatory long-term soil toxicity testing data.

241 ECHA acknowledges you strategy. However, ECHA would like to highlight regarding the read-across approach explained in your comments that you did not provide any justification to support your adaptation. Therefore, this strategy is relying on a category/read-across approach that has not yet been fully described and justified. Therefore, no conclusion on the compliance of the proposed adaptation can be made.

242 Therefore, the information provided in your comments does not change the assessment outcome

16.4. Study design and test specifications

243 The Terrestrial Plant Test (EU C.31./OECD TG 208, with at least six species) is appropriate to cover the information requirement for long-term toxicity on terrestrial plants.

244 The OECD TG 208 (EU C.31.) considers the need to select the number of test species according to relevant regulatory requirements, and the need for a reasonably broad selection of species to account for interspecies sensitivity distribution. For long-term toxicity testing, ECHA considers six species as the minimum to achieve a reasonably broad selection. Testing must be conducted with species from different families, as a minimum with two monocotyledonous species and four dicotyledonous species, selected according to the criteria indicated in the OECD TG 208.

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 (2012).
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

This decision does not prevent ECHA from initiating further compliance checks at a later stage.

The compliance check was initiated on 02 May 2022.

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

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

ECHA took into account your comments and did not amend the requests.

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

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

As no amendments were proposed, ECHA adopted the decision under Article 51(3) of REACH.

Appendix 3: 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[2].

(4) Under the introductory part of Annexes VII/VIII/IX/X to REACH, where a test method offers flexibility in the study design, for example in relation to the choice of dose levels or concentrations, the chosen study design must ensure that the data generated are adequate for hazard identification and risk assessment.

1.2. Test material

(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] https://echa.europa.eu/practical-guides
[3] 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, 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.