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Helsinki, 27 April 2023

Addressee(s)
Registrant(s) as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
05/11/2019

Registered substance subject to this decision ("the Substance")
Substance name: Poly (dipropyleneglycol) Phenyl phosphite
EC number/List number: 601-420-2

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

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by ***5 May 2025***.

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

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

1. Water solubility (Annex VII, Section 7.7.; test method: EU A.6./OECD TG 105/OECD GD 29);

2. Partition coefficient n-octanol/water (Annex VII, Section 7.8.; using an appropriate test method);

3. *In vitro* gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: Bacterial reverse mutation test OECD TG 471 (2020));

4. If the study requested under request 1 above shows that the Substance solubility is above 1 mg/L: Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.; test method: EU C.2./OECD TG 202);

5. If the study requested under request 1 above shows that the Substance solubility is below 1 mg/L:Long-term toxicity testing on aquatic invertebrates (triggered by Annex VII, Section 9.1.1., Column 2; test method: EU C.20./OECD TG 211);

6. Growth inhibition study on aquatic plants (Annex VII, Section 9.1.2.; test method: EU C.3/OECD TG 201 OR EU C.26/OECD TG 221);

7. Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: EU C.4. A/B/C/D/E/F/OECD TG 301A/B/C/D/E/F or EU C.29./OECD TG 310) on relevant constituent(s)/fraction(s) of the Substance, as described under the corresponding appendix on reasons for the request.

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

8. In vitro micronucleus study (Annex VIII, Section 8.4.2., test method: OECD TG 487). The aneugenic potential of the Substance must be assessed with an additional

control group for aneugenicity on top of the control group for clastogenicity, if the Substance induces an increase in the frequency of micronuclei;

9. Only if a negative result in Annex VII, Section 8.4.1. and Annex VIII, Section 8.4.2. is obtained, *in vitro* gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method: EU B.17./OECD TG 476 or EU B.67./OECD TG 490);

10. Short-term repeated dose toxicity (28 days) (Annex VIII, Section 8.6.1.) by oral route, in rats, to be combined with the screening for reproductive/developmental toxicity requested below;

11. Screening study for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.; test method: EU B.64/OECD TG 422) by oral route, in rats;

12. Adsorption/desorption screening (Annex VIII, Section 9.3.1.; test method: EU C.18/OECD TG 106 or EU C.19/OECD TG 121);

13. If the study requested under request 1 above shows that the Substance solubility is above 1 mg/L: Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.; test method: EU C.1./OECD TG 203);

14. If the study requested under request 1 above shows that the Substance solubility is below 1 mg/L: Long-term toxicity testing on fish (triggered by Annex VIII, Section 9.1.3., Column 2; test method: EU C.47./OECD TG 210).

The reasons for the request(s) are explained in Appendix 1.

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you in accordance with Articles 10(a) and 12(1) of REACH. The addressee of the decision and its corresponding information requirements based on registered tonnage band are listed in Appendix 3.

How to comply with your information requirements

To comply with your information requirements, you must submit the information requested by this decision in an updated registration dossier by the deadline indicated above. You must also **update the chemical safety report, where** relevant, including any changes to classification and labelling, based on the newly generated information.

You must follow the general requirements for testing and reporting new tests under REACH, see Appendix 4.

Appeal

This decision, when adopted under Article 51 of REACH, may be appealed to the Board of Appeal of ECHA within three months of its notification to you. Please refer to http://echa.europa.eu/regulations/appeals for further information.

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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

Reasons common to several requests

0.1. QSAR adaptation rejected

1 You seek to adapt the following standard information requirements by applying (Q)SAR approaches in accordance with Annex XI, Section 1.3.:

- Water solubility (Annex VII, Section 7.7.);
- Partition Coefficient n-octanol/water (Annex VII, Section 7.8.);
- Adsorption/desoprtion screeening (Annex VIII, Section 9.3.1.).

2 ECHA has considered the scientific and regulatory validity of your (Q)SAR adaptation(s) in general before assessing the specific standard information requirements in the following appendices.

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

(4) the prediction needs to be derived from a scientifically valid model,

(5) the substance must fall within the applicability domain of the model,

(6) results need to be adequate for the purpose of risk assessment or classification and labelling, and

(7) adequate and reliable documentation of the method must be provided.

4 Regarding these conditions, we have identified the following issue(s):

0.1.1. The substance is outside the applicability domain of the model

5 Under ECHA Guidance R.6.1.5.3., a substance must fall within the applicability domain specified by the model developer.

6 In the registration dossier you have provided predictions generated by different models of the QSAR software EPISUITE (i.e. EPISUITE 4.1 program and the WSKOW v1.42 model for water solubility, EPISUITE 4.1 program and the KOWWIN v1.68 model for partition Coefficient and US EPA KOCWIN v2.00 model for adsorption/desorption Log Koc). The applicability domain of these models is defined as molecular weight (MW) and Partition Coefficient n-octanol (log Kow) ranges. More specifically, regarding the MW the applicability domain of the models is defined between a range of MW_{MIN} of 27 to MW_{MAX} of 628. With regard to the Partition Coefficient n-octanol (log Kow) the applicability domain of the models is defined between a range of Log kow of 3.9 and Log kow of 8.3

7 The substance used as input for the prediction has the following properties related to the estimation of applicability domain: molecular weight (MW) of 2104 and the Partition Coefficient n-octanol (log Kow) of 20.

8 The substance used as input for the prediction is out of the applicability domain. This is due to its properties related to the high MW and high log Kow (compared to the members included in the training set of the model, i.e. the applicability domain of the models), as indicated above. You also admit in your registration dossier that the substance used as input for the prediction does not fall within the applicability domain of the model.

9 Therefore, the model does not reliably predict the properties of the Substance.

0.1.2. Lack of justification of the representativeness of the structure(s)used in the prediction

10 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
- representative structure(s) for the assessment are selected.

11 Your registration dossier provides the following information:

- In Section 1.1. of your technical dossier, you define the Substance as a UVCB;
- In Section 1.2., you indicate the following constituents in the composition of your Substance: [redacted];
- You provided predictions for the following structures: Oxybispropylenebis[(1,5,9,13,17,21-hexamethyl-7,15,23,23-tetraphenoxy-3,6,8,11,14,16,19,22-octaoxa-7,15,23-triphosphatricos-1-yl)(phenyl)phosphine.

12 You have considered Oxybispropylenebis[(1,5,9,13,17,21-hexamethyl-7,15,23,23-tetraphenoxy-3,6,8,11,14,16,19,22-octaoxa-7,15,23-triphosphatricos-1-yl)(phenyl)phosphine as representative structure. However, this structure is not part of the composition of the Substance and you have not provided any justification to explain the reasons for which you have considered the selected structure as representative of the registered Substance.

13 On this basis, ECHA disagrees with the representative structure(s) you selected.

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

0.1.3. Conclusion on the (Q)SAR adaptations

15 Based on the above, your (Q)SAR adaptations under Annex XI, Section 1.3. are rejected

0.2. Read-across adaptation rejected

16 You have adapted the following standard information requirements by using grouping and read-across approach under Annex XI, Section 1.5:

- *In vitro* gene mutation study in bacteria (Annex VII, Section 8.4.1.);
- *In vitro* micronucleus study (Annex VIII, Section 8.4.2.);
- *In vitro* gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.);
- Short-term repeated dose toxicity (28 day), (Annex VIII, Section 8.6.1.);
- Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.).

17 In addition, for the following information requirements you have provided experimental data conducted with another substance than the Substance:

- Growth inhibition study on aquatic plants (Annex VII, Section 9.1.2.);
- Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.);
- Ready biodegradability (Annex VII, Section 9.2.1.1.);
- Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.).

18 While you have not reported read-across adaptations as such for these information requirements, the description of the test material used indicates that the information is not on the Substance, but is on another substance Oxybispropylenebis[(1,5,9,13,17,21-hexamethyl-7,15,23,23-tetraphenoxy-3,6,8,11,14,16,19,22-octaoxa-7,15,23-triphosphatricos-1-yl)(phenyl)phosphine], EC 279-499-4. Therefore, the studies conducted

with the substance EC 279-499-4 will be evaluated as a read-across adaptation under Annex XI, Section 1.5 of REACH.

19 ECHA has considered the scientific and regulatory validity of your read-across approach(es) in general before assessing the specific standard information requirements in the following sections.

20 Annex XI, Section 1.5. specifies two conditions which must be fulfilled whenever a read-across approach is used. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group.

21 Additional information on what is necessary when justifying a read-across approach can be found in the Guidance on IRs and CSA, Chapter R.6. and related documents (RAAF, 2017; RAAF UVCB, 2017).

0.2.1. Predictions for toxicological properties

22 You predict the properties of the Substance from information obtained from triphenyl phosphite (TPP), EC 202-908-4 as source substance.

23 You have provided a read-across justification document under the relevant endpoint study records.

24 For toxicological properties you provide the following reasoning for the prediction of toxicological properties: *"The available toxicology data on D25 -207, whilst limited, does not indicate a hazard potential. However, D25 -207 contains triphenyl phosphite (TPP) at a concentration of 5 -10% w/w. This TPP impurity drives the classification of this substance and thus it was decided that the use of TPP data represented a worst-case read-across for the hazard assessment of D25 -207."*

25 ECHA understands that your read-across hypothesis assumes that different compounds have the same type of effects. You predict the properties of your Substance based on a worst-case approach.

26 We have identified the following issue(s) with the prediction(s) of toxicological properties:

0.2.1.1. Missing supporting information to substantiate worst-case consideration

27 Annex XI, Section 1.5. requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must provide supporting information to scientifically justify the read-across explanation for prediction of properties. The set of supporting information should strengthen the rationale for the read-across in allowing to verify the crucial aspects of the read-across hypothesis and establishing that the properties of the Substance can be predicted from the data on the source substance(s) (Guidance on IRs and CSA R.6, Section R.6.2.2.1.f.).

28 Supporting information must include information to confirm your claimed worst-case prediction such as the impact of exposure to other constituents of the Substance on the prediction.

29 As indicated above, your read-across hypothesis is based on the assumption that the TPP, an impurity of the Substance, constitutes a worst-case for the prediction of the property under consideration of the Substance. In this context, in addition to the source substance TPP, exposure to the Substance may also lead to exposure to other constituents. The impact

of exposure to these other constituents on the prediction of properties of the Substance needs to be assessed to ensure that a reliable prediction can be made.

30 Therefore, relevant, reliable and adequate information allowing to compare the properties of the Substance and the source substance is necessary to confirm a conservative prediction of the properties of the Substance from the data on the source substance.

31 You have indicated that the limited data available for the Substance does not show a hazard potential. As a support, you have provided an acute oral toxicity study on the Substance showing low toxicity. Based on this limited data on the Substance (acute toxicity), you consider that the impurity TPP present in the composition of the Substance at a concentration of 5 -10% w/w represents a worst-case for the toxicological properties of the Substance.

32 We have evaluated the information and identified the following issues:

33 First, the information on the acute toxicity properties of the Substance does not inform on the genetic toxicity, repeated dose toxicity or reproductive toxicity properties of the Substance, and therefore is not considered as relevant supporting information for your read-across hypothesis.

34 Second, you have provided information only on the impurity TPP covering 5-10 % of the Substance. You have not provided information characterising the exposure to the remaining 90-95 % of the Substance composition (non-common constituents) to support that exposure to the other constituents of the Substance would not lead to higher toxicity than exposure to TPP alone. No relevant supporting information on the Substance or other adequate and reliable information addressing the impact of exposure to these other constituents is included in the documentation of your read-across approaches.

35 Based on above, you have not substantiated your claim that the source substance TPP, which is an impurity of the Substance, will present a worst case for the toxicological properties of the Substance.

36 In the absence of such information, you have not established that the source substance constitutes a worst-case for the prediction of the property under consideration of the Substance. Therefore you have not provided sufficient supporting information to scientifically justify the read-across.

0.2.1.2. Inadequate or unreliable source studies

37 According to Annex XI, Section 1.5., if the grouping concept is applied then in all cases the results to be read across must among others:

(1) have adequate and reliable coverage of the key parameters addressed in the corresponding study that shall normally be performed for a particular information requirement.

38 Specific reasons why the studies on the source substance(s) do not meet these criteria are explained further below under the applicable information requirement sections 8 and 9. Therefore, no reliable predictions can be made for these information requirements.

0.2.2. Predictions for environmental and ecotoxicological properties

39 You predict the properties of the Substance from information obtained from the following source substance(s):Oxybispropylenebis[(1,5,9,13,17,21-hexamethyl-7,15,23,23-tetraphenoxy-3,6,8,11,14,16,19,22-octaoxa-7,15,23-triphosphatricos-1-yl)(phenyl)phosphine], EC 279-499-4.

40 We have identified the following issue(s) with the prediction(s) of toxicological properties:

0.2.2.1. Absence of read-across documentation

41 Annex XI, Section 1.5. requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must include an explanation why the properties of the Substance may be predicted from information on the source substance(s).

42 You have provided robust study summaries for studies conducted with an other substance than the Substance in order to comply with the REACH information requirements. However, you have not provided documentation as to why this information is relevant for the Substance and thus why the properties of the Substance may be predicted from information on the source substance(s).

43 In the absence of such documentation, the properties of the Substance cannot be reliably predicted from the data on the source substance(s).

0.2.2.2. Inadequate or unreliable source studies

44 According to Annex XI, Section 1.5., if the grouping concept is applied then in all cases the results to be read across must among others:

(1) have adequate and reliable coverage of the key parameters addressed in the corresponding study that shall normally be performed for a particular information requirement.

45 Specific reasons why the studies on the source substance(s) do not meet these criteria are explained further below under the applicable information requirement sections 4, 5 and 12. Therefore, no reliable predictions can be made for these information requirements.

0.2.3. Conclusion on the read-across approach

46 For the reasons above, you have not established that relevant properties of the Substance can be predicted from data on the source substance(s). Your read-across approaches under Annex XI, Section 1.5. are rejected.

Reasons related to the information under Annex VII of REACH

1. Water solubility

47 Partition coefficient n-octanol/water is an information requirement under Annex VII to REACH (Section 7.8).

1.1. Information provided

48 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 a prediction from QSAR using the EPISUITE 4.1 program and the WSKOW v1.42 model. The water solubility was estimated to be 3.455e-026 mg/L.

1.2. Assessment of the information provided

49 As explained in Section 0.1., your adaptation based on Qualitative or Quantitative Structure-Activity Relationships ((Q)SARs) under Annex XI, Section 1.3. is rejected.

50 Therefore, the information requirement is not fulfilled

2. Partition coefficient n-octanol/water

51 Partition coefficient n-octanol/water is an information requirement under Annex VII to REACH (Section 7.8).

2.1. Information provided

52 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 a prediction from QSAR using the EPISUITE 4.1 program and the KOWWIN v1.68 model. The log Kow was estimated to be 20.22.

2.2. Assessment of the information provided

53 As explained in Section 0.1., your adaptation based on Qualitative or Quantitative Structure-Activity Relationships ((Q)SARs) under Annex XI, Section 1.3. is rejected.

54 Therefore, the information requirement is not fulfilled

3. *In vitro* gene mutation study in bacteria

55 An *in vitro* gene mutation study in bacteria is an information requirement under Annex VII, Section 8.4.1.

3.1. Information provided

56 You have adapted this information requirement by using Annex XI, Section 1.5. (grouping of substances and read-across approach) based on the following experimental data:

(i) *in vitro* gene mutation study in bacteria (2017) with the source substance triphenyl phosphite, EC 202-908-4.

3.2. Assessment of the information provided

57 As explained in Section 0.2., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected.

58 Therefore, the information requirement is not fulfilled.

3.3. Specification of the study design

59 To fulfil the information requirement for the Substance, the in vitro gene mutation study in bacteria (OECD TG 471) is considered suitable.

4. Growth inhibition study aquatic plants

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

4.1. Information provided

61 You have adapted this information requirement by using Annex XI, Section 1.5. (grouping of substances and read-across approach) based on the following experimental data:

(i) Growth inhibition study on aquatic algae (1995) with the source substance (EC 279-499-4)

4.2. Assessment of the information provided

4.2.1. Read-across adaptation rejected

62 As explained in Section 0.2., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected.

63 In addition, ECHA identified endpoint-specific issue(s) addressed below.

64 Under Annex XI, Section 1.5., the study to be read across must have an adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3), in this case OECD TG 201. Therefore, the following specifications must be met:

Characterisation of exposure

a) analytical monitoring must be conducted. Alternatively, a justification why the analytical monitoring of exposure concentrations is not technically feasible must be provided.

Reporting of the methodology and results

b) the results of algal biomass determined in each flask at least daily during the test period are reported in a tabular form.

65 In study (i):

Characterisation of exposure

a) no analytical monitoring of exposure was conducted.

Reporting of the methodology and results

b) tabulated data on the algal biomass determined daily for each treatment group and control are not reported.

66 Based on the above,

- there are critical methodological deficiencies resulting in the rejection of the study results. More, specifically you have not conducted the analytical monitoring, therefore there is not information available on the stability of the source substance during the test. Consequently, it is not possible to conclude whether the algae organisms have been exposed to the source substance during the test.
- You have not reported the information related on the algal biomass during the test. Therefore, it is not possible to conclude if the validity criteria were met. Consequently, the reporting of the study is not sufficient to conduct an independent assessment of its reliability .

67 On this basis, the specifications of OECD TG 201 are not met.

68 Based on the above, the study does not provide an adequate and reliable coverage of the key parameter(s) addressed by the OECD TG 201 and this study is not an adequate basis for your read-across predictions.

69 Therefore your adaptation under Annex XI, Section 1.5 is rejected and the information requirement is not fulfilled.

4.3. Study design and test specifications

70 The Substance appears to be difficult to test due to the low water solubility(as indicated for the information requirement of hydrolysis, Section 5.1.2 of the IUCLID dossier) and adsorptive properties. OECD TG 201 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified and documented. Due to the properties of Substance, it may be difficult to achieve and maintain the desired exposure concentrations.

71 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.

72 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.

73 For multi-constituents/UVCBs, the analytical method must be adequate to monitor qualitative and quantitative changes in exposure to the dissolved fraction of the test material during the test (e.g. by comparing mass spectral full-scan GC or HPLC chromatogram peak areas or by using targeted measures of key constituents or groups of constituents).

74 If you decide to use the Water Accommodated Fraction (WAF) approach, in addition to the above, you must:

- use loading rates that are sufficiently low to be in the solubility range of most constituents (or that are consistent with the PEC value). This condition is mandatory to provide relevant information for the hazard and risk assessment (Guidance on IRs and CSA, Appendix R.7.8.1-1, Table R.7.8-3);
- provide a full description of the method used to prepare the WAF (including, among others, loading rates, details on the mixing procedure, method to separate any remaining non-dissolved test material including a justification for the separation technique);
- prepare WAFs separately for each dose level (i.e. loading rate) and in a consistent manner.

5. Short-term toxicity testing on aquatic invertebrates (if the results of request 1 showed a water solubility above 1 mg/L)

75 Short-term toxicity testing on aquatic invertebrates is an information requirement under Annex VII to REACH (Section 9.1.1.).

5.1. Information provided

76 You have adapted this information requirement by using Annex XI, Section 1.5. (grouping of substances and read-across approach) based on the following experimental data:

(i) short-term toxicity study on *daphnia magna* (1995) with the source substance (EC 279-499-4)

5.2. Assessment of the information provided

5.2.1. Read-across adaptation rejected

77 As explained in Section 0.2., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected.

78 In addition, ECHA identified endpoint specific issue(s) addressed below.

79 Under Annex XI, Section 1.5., the study to be read across must have an adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3), in this case OECD TG 202. Therefore, the following specifications must be met:

Characterisation of exposure

a) analytical monitoring must be conducted. A reliable analytical method for the quantification of the test material in the test solutions with reported specificity, recovery efficiency, precision, limits of determination (i.e. detection and quantification) and working range must be available.

Reporting of the methodology and results

b) the number of immobilised daphnids is determined at 24 and 48 hours. Data are summarised in tabular form, showing for each treatment group and control, the number of daphnids used, and immobilisation at each observation;

c) the dissolved oxygen at least at the beginning and at the end of the test is reported.

80 In study (i):

Characterisation of exposure

a) no analytical monitoring of exposure was conducted.

Reporting of the methodology and results

b) tabulated data on the number of immobilised daphnids after 24 and 48 hours for each treatment group and control are not reported;

c) the dissolved oxygen at least at the beginning and at the end of the test is not reported.

81 Based on the above,

- there are critical methodological deficiencies resulting in the rejection of the study results. More, specifically you have not conducted the analytical monitoring, therefore there is not information available on the stability of the source substance during the test. Consequently, it is not possible to conclude whether the daphnia organisms have been exposed to the source substance during the test.
- You have not reported the information related to the number of immobilised daphnids of each treatment group and control. The dissolved oxygen concentration is not reported neither. Therefore, it is not possible to conclude if the validity criteria were met. Consequently, the reporting of the study is not sufficient to conduct an independent assessment of its reliability.

82 On this basis, the specifications of OECD TG 202 are not met.

83 Based on the above, the study does not provide an adequate and reliable coverage of the key parameter(s) addressed by the OECD TG 202 and this study is not an adequate basis for your read-across predictions.

84 Therefore, your adaptation under Annex XI, Section 1.5 is rejected and the information requirement is not fulfilled.

5.3. Study design and test specifications

85 OECD TG 202 specifies that, for difficult to test substances, OECD GD 23 must be followed. As already explained above, the Substance appears to bedifficult to test. Therefore, you must fulfil the requirements described in 'Study design and test specifications' under request 4.

6. Long-term toxicity testing on aquatic invertebrates (if the results of request 1 showed a water solubility below 1 mg/L)

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

6.1. Triggering of the information requirement

87 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.

88 In your dossier you have provided a water solubility value based on QSAR prediction. The saturation concentration of the Substance was determined to be 3.455e-026 mg/L.

89 However, as mentioned under Request 1, the reliability of the value reported in the dossier is uncertain. Therefore, if the results of the water solubility test requested in this decision will show that the water solubility is below 1 mg/L, the Substance will be considered as poorly water soluble, and information on long-term toxicity on aquatic invertebrates will need to be provided.

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

91 Therefore, if the information on water solubility (i.e request 1) indicates that the Substance is poorly soluble, this information requirement will need to be fulfilled.

6.2. Study design and test specifications

92 OECD TG 211 specifies that, for difficult to test substances, OECD GD 23 must be followed. As already explained above, the Substance appears to be difficult to test. Therefore, you must fulfil the requirements described in "Study design and test specifications" under request 4.

7. Ready biodegradability

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

7.1. Information provided

94 You have adapted this information requirement by using Annex XI, Section 1.5. (grouping of substances and read-across approach) based on the following experimental data:

(i) a ready biodegradability study (1995) with the source substance, EC 279-499-4

7.2. Assessment of the information provided

95 As explained in Section 0.2., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected.

96 Therefore, the information requirement is not fulfilled.

7.3. Study design and test specifications

97 The revised introduction to the OECD Guidelines For Testing Of Chemicals, Section 3 Part I states that ready biodegradability tests are intended for pure substances but may also be relevant, on a case-by-case basis, to mixtures of structurally similar chemicals (i.e. which are composed of constituents expected to show similar degradation kinetics). However, such tests are not generally applicable for complex mixtures or substances (i.e. UVCB or multi-constituent substances) containing different types of constituents. For complex substances, a single ready biodegradability test does not allow to conclude on the ready biodegradability of all constituents and therefore, does not fulfil the information requirement. The registered Substance is a UVCB that is a complex mixture of different phosphorous acid esters which are trialkyl-, dialky-aryl, alkyl-diaryl and triaryl substituted.

98 The Substance is a complex substance and contains constituents with significant structural differences described above.

99 For the reasons provided above, testing on the Substance as a whole does not fulfil the information requirement. For the generation of information on ready biodegradability, you must consider the level of information required for the purposes of classification and labelling and, if applicable to your registration, the PBT/vPvB assessment and the exposure assessment/risk characterisation. In order to conclude on which of constituents of the Substance are and which are not readily biodegradable, you may have to consider conducting more than one study using selected individual constituents and/or fractions. If you choose to test one (or more) fraction(s) of the Substance, you must provide a justification that their constituents within chosen fraction(s) are similar enough so that similar degradation kinetics can be assumed. If you decide to conduct a single study in order to prove that all constituents of the Substance are readily biodegradable, you must provide a justification that the selected constituent/fraction can be considered a reasonable worst-case for the Substance as a whole in terms of degradation kinetics.

100 Justification for selection of relevant constituent and/or fractions for the testing, must consider degradation kinetics of constituents of the Substance based, as minimum, on the similarity/differences of the chemical structures and the physico-chemical properties of constituents of the Substance. For that purpose, tools and approaches mentioned in Guidance on IRs and CSA, Sections R.7b and R.11 should be considered.

Reasons related to the information under Annex VIII of REACH

8. *In vitro* micronucleus study

101 An *in vitro* mammalian chromosomal aberration study or *in vitro* mammalian micronucleus study is an information requirement under Annex VIII, Section 8.4.2.

8.1. Information provided

102 You have adapted this information requirement by using Annex XI, Section 1.5. (grouping of substances and read-across approach) based on the following experimental data:

(i) *in vitro* mammalian cells micronucleus test (2017) with the source substance triphenyl phosphite, EC 202-908-4.

103 In addition, as you have provided information for the Genetic toxicity *in vivo* which is not a standard information requirement at Annex VIII, ECHA understands that you have provided this information in order to adapt the information requirement of Annex VIII, 8.4.2 according to Section 8.4, Column 2 of Annex VIII to REACH in conjunction with Annex XI, Section 1.5 (grouping of substances and read-across approach) based on experimental data from the following substance:

(ii) *In vivo* mammalian erythrocyte micronucleus test (1981) with the source substance triphenyl phosphite, EC 202-908-4.

8.2. Assessment of the information provided

8.2.1. Read-across adaptation rejected

104 As explained in Section 0.2., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected. In addition, ECHA identified endpoint-specific issue(s) addressed below.

8.2.1.1. Inadequate or unreliable source study (study ii)

105 As explained in the Appendix on Reasons common to several requests, under Annex XI, Section 1.5., the results to be read across must have an adequate and reliable coverage of the key parameters addressed in the test guideline for the corresponding study that shall normally be performed for a particular information requirement. The Guidance on IRs and CSA, Section R.7.7.6.3 and Table R.7.7–3 clarifies that the *in vivo* micronucleus study must be performed according to the OECD TG 474. Therefore, the following specifications must be met:

a) at least 4000 immature erythrocytes per animal are scored for the incidence of micronucleated immature erythrocytes;

b) when two or more doses are administered at 24-hour intervals, samples of bone marrow should be collected between 18 and 24 hours after the final treatment.

106 In study (ii) described as *in vivo* micronucleus study:

a) 1000 polychromatic erythrocytes per animal (i.e. less than 4000 immature erythrocytes) were scored to determine the incidence of micronucleated;

b) only one sampling time six hours after the second dose of administration was used.

107 The information provided does not cover the specification(s) required by the OECD TG 474. Therefore, the study submitted in your adaptation does not provide an adequate and reliable coverage of the key parameter(s) of the corresponding OECD TG.

108 Based on the above, your adaptation under Annex XI, Section 1.5 is rejected.

8.2.2. Adaptation under Annex VIII, Section 8.4., Column 2 in conjunction with Annex XI, Section 1.5 fails

109 Under Annex VIII, Section 8.4., Column 2, the study referred to in Annex VIII, Section 8.4.2, does not need to be conducted if adequate data from an *in vivo* micronucleus or *in vivo* chromosomal aberration study are available. The Guidance on IRs and CSA, Section R.7.7.6.3 and Table R.7.7–3, clarifies that such an *in vivo* study must be performed according to the OECD TG 474 or 475.

110 You have provided an *in vivo* micronucleus study conducted on the source substance (study ii).

111 As explained in Section 0.2. and Section 8.2.1 above, your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected.

112 Therefore, you have not provided adequate data from the corresponding in vivo study, and your adaptation under Annex VIII, Section 8.4, Column 2 is rejected.

8.3. Therefore, the information requirement is not fulfilled.Specification of the study design

113 According to the Guidance on IR & CSA, Section R.7.7.6.3., either the in vitro mammalian chromosomal aberration ("CA") test (test method OECD TG 473) or the in vitro mammalian cell micronucleus ("MN") test (test method OECD TG 487) can be used to investigate chromosomal aberrations in vitro. However, while the MN test detects both structural chromosomal aberrations (clastogenicity) and numerical chromosomal aberrations (aneuploidy), the CA test detects only clastogenicity, as OECD TG 473 is not designed to measure aneuploidy (see OECD TG 473, paragraph 2).Therefore, you must perform the MN test (test method OECD TG 487), as it enables a more comprehensive investigation of the chromosome damaging potential in vitro.Moreover, in order to demonstrate the ability of the study to identify clastogens and aneugens, you must include two concurrent positive controls, one known clastogen and one known aneugen [1] (OECD TG 487, paragraphs 33 to 35).

8.3.1. Assessment of aneugenicity potential

114 If the result of the MN test is positive, i.e. your Substance induces an increase in the frequency of micronuclei, you must assess the aneugenic potential of the Substance.

115 In line with the OECD TG 487 (paragraph 4), you should use one of the centromere labelling or hybridisation procedures to determine whether the increase in the number of micronuclei is the result of clastogenic events (i.e. micronuclei contain chromosome fragment(s)) and/or aneugenic events (i.e. micronuclei contain whole chromosome(s)).

[1] According to the TG 487 (2016) "At the present time, no aneugens are known that require metabolic activation for their genotoxic activity" (paragraph 34).

9. *In vitro* gene mutation study in mammalian cells

116 An *in vitro* gene mutation study in mammalian cells is an information requirement under Annex VIII, Section 8.4.3., in case of a negative result in the *in vitro* gene mutation test in bacteria and the *in vitro* mammalian chromosomal aberration study or in vitro mammalian micronucleus study.

9.1. Triggering of the information requirement

117 Your dossier contains an adaptation for an in vitro gene mutation study in bacteria, and an adaptation for an in vitro mammalian micronucleus study.

118 The information for the in vitro gene mutation study in bacteria and for the in vitro micronucleus study provided in the dossier are rejected for the reasons provided in requests 3 and 8.

119 The result of the requests 3 and 8 will determine whether the present requirement for an in vitro mammalian cell gene mutation study in accordance with Annex VIII, Section 8.4.3. is triggered.

120 Consequently, you are required to provide information for this information requirement, if the *in vitro* gene mutation study in bacteria and the *in vitro* micronucleus study provides a negative result.

9.2. Information provided

121 You have not provided any information for this endpoint.

9.3. Specification of the study design

122 To fulfil the information requirement for the Substance, either the in vitro mammalian cell gene mutation tests using the hprt and xprt genes (OECD TG 476) or the thymidine kinase gene (OECD TG 490) are considered suitable.

10. Short-term repeated dose toxicity (28 days)

123 A short-term repeated dose toxicity study (28 days) is an information requirement under Annex VIII, Section 8.6.1.

10.1. Information provided

124 You have adapted this information requirement by using Annex XI, Section 1.5. (grouping of substances and read-across approach) based on the following experimental data:

(i) a Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test (2004) with the source substance triphenyl phosphite, EC 202-908-4.

10.2. Assessment of the information provided

125 As explained in Section 0.2., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected and the information requirement is not fulfilled.

10.3. Specification of the study design

126 When there is no information available neither for the 28-day repeated dose toxicity (EU B.7, OECD TG 407), nor for the screening study for reproductive/developmental toxicity (OECD TG 421 or TG 422), the conduct of a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422) is preferred to ensure that unnecessary animal testing is avoided (Guidance on IRs and CSA, Section R.7.6.2.3.2.).

127 The study design is addressed in request 11.

11. Screening study for reproductive/developmental toxicity

128 A screening study for reproductive/developmental toxicity study (OECD 421 or OECD 422) is an information requirement under Annex VIII, Section 8.7.1., if there is no evidence from analogue substances, QSAR or *in vitro* methods that the substance may be a developmental toxicant.

11.1. Information provided

129 You have adapted this information requirement by using Annex XI, Section 1.5. (grouping of substances and read-across approach) based on the following experimental data:

(i) a Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test (2004) with the source substance triphenyl phosphite, EC 202-908-4.

11.2. Assessment of the information provided

130 As explained in Section 0.2., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected and the information requirement is not fulfilled.

11.3. Specification of the study design

131 A study according to the test method EU B.64/OECD TG 422 must be performed in rats.

132 As the Substance is a liquid, the study must be conducted with oral administration of the Substance (Annex VIII, Section 8.7.1, Column 1).

133 Therefore, the study must be conducted in rats with oral administration of the Substance.

12. Short-term toxicity testing on fish (if the results of request 1 showed a water solubility above 1 mg/L)

134 Short-term toxicity testing on fish is an information requirement under Annex VIII to REACH (Section 9.1.3.).

12.1. Information provided

135 You have adapted this information requirement by using Annex XI, Section 1.5. (grouping of substances and read-across approach) based on the following experimental data:

(i) a short-term toxicity study on fish (1995) with the source substance (EC 279-499-4).

12.2. Assessment of the information provided

12.2.1. Read-across adaptation rejected

136 As explained in Section 0.2., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected. In addition, ECHA identified endpoint specific issue(s) addressed below.

137 Under Annex XI, Section 1.5., the study to be read across must have an adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3), in this case OECD TG 202. Therefore, the following specifications must be met:

12.2.1.1. Source study not adequate for the information requirement

Characterisation of exposure

a) analytical monitoring must be conducted. A reliable analytical method for the quantification of the test material in the test solutions with reported specificity, recovery efficiency, precision, limits of determination (i.e. detection and quantification) and working range must be available;

Reporting of the methodology and results

b) the dissolved oxygen and pH measured are reported

c) mortalities and sub-lethal effects (*e.g.* with regard to equilibrium, appearance, ventilator and swimming behaviour) are reported. The frequency of observations includes at least 2 observations within the first 24 hours and at least two observations per day from day 2 to 4.

138 In study (i):

Characterisation of exposure

a) no analytical monitoring of exposure was conducted;

Reporting of the methodology and results

b) the dissolved oxygen and pH measured are not reported;

c) tabulated data on mortalities and sub-lethal effects (e.g. with regard to equilibrium, appearance, ventilator and swimming behaviour) obtained on at least 2 observations within the first 24 hours and at least two observations per day from day 2 to 4 for each treatment group and control are not reported.

139 Based on the above:

- there are critical methodological deficiencies resulting in the rejection of the study results. More specifically you have not conducted the analytical monitoring, therefore there is not information available on the stability of the source substance during the test. Consequently, it is not possible to conclude whether the fish organisms have been exposed to the source substance during the test.
- You have not reported the information related to the test parameters (e.g. dissolved oxygen), to the mortality data during the test. Therefore, it is not possible to conclude if the validity criteria were met. Consequently, the reporting

of the study is not sufficient to conduct an independent assessment of its reliability.

140 On this basis, the specifications of OECD TG 203 are not met.

141 Based on the above, the study does not provide an adequate and reliable coverage of the key parameter(s) addressed by the OECD TG 203 and this study is not an adequate basis for your read-across predictions.

142 On this basis, your adaptation under Annex XI, Section 1.5 is rejected and the information requirement is not fulfilled.

12.3. Study design and test specifications

143 OECD TG 203 specifies that, for difficult to test substances, OECD GD 23 must be followed. As already explained above, the Substance appears to be difficult to test. Therefore, you must fulfil the requirements described in "Study design and test specifications" under request 4.

13. Long-term toxicity testing on fish (if the results of request 1 showed a water solubility below 1 mg/L)

144 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.

13.1. Triggering of the information requirement

145 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.

146 As already explained in request 6, the reliability of the value reported in the dossier is uncertain. Therefore, if the results of the water solubility study requested in this decision show that the water solubility is below 1 mg/L, the Substance will be considered as poorly water soluble, and information on long-term toxicity on aquatic invertebrates will need to be provided.

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

148 Therefore, if the information on water solubility (i.e request 1) indicates that the Substance is poorly soluble, this information requirement will need to be fulfilled.

13.2. Study design and test specifications

149 To fulfil the information requirement for the Substance, the Fish, Early-life Stage Toxicity Test (test method OECD TG 210) is the most appropriate (Guidance on IRs and CSA, Section R.7.8.2.).

150 OECD TG 210 specifies that, for difficult to test substances, OECD GD 23 must be followed. As already explained above, the Substance appears to be difficult to test. Therefore, you must fulfil the requirements described in "Study design and test specifications" under request 4.

14. Adsorption/ desorption screening

151 Adsorption/desorption screening is an information requirement under Annex VIII to REACH (Section 9.3).

14.1. Information provided

152 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 a prediction from QSAR using the US EPA KOCWIN v2.00 model, the Log KoC was estimated to be 11.5 L/kg.

14.2. Assessment of the information provided

153 As explained in Section 0.1., your adaptation based on Qualitative or Quantitative Structure-Activity Relationships ((Q)SARs) under Annex XI, Section 1.3. is rejected.

154 Therefore, the information requirement is not fulfilled

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 on the registrations present.

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

The compliance check was initiated on 30 June 2022.

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

ECHA did not receive any comments within the commenting period.

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

(8) 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.

(9) 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.

(10) 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].

(11) 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

(12) Selection of the Test material(s)

The Test Material used to generate the new data must be selected taking into account the following:

- the variation in compositions reported by all members of the joint submission,
- the boundary composition(s) of the Substance,
- the impact of each constituent/ impurity on the test results for the endpoint to be assessed. For example, if a constituent/ impurity of the Substance is known to have an impact on (eco)toxicity, the selected Test Material must contain that constituent/ impurity.

(13) 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 the careful identification and description of the characteristics of the Tests Materials in accordance with OECD GLP (ENV/MC/CHEM(98)16) and EU Test Methods Regulation (EU) 440/2008 (Note, Annex), namely all the constituents must be identified as far as possible as well as their concentration. Also any constituents that have harmonised classification and labelling according to the CLP

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

Regulation must be identified and quantified using the appropriate analytical methods,

- The reported composition must also include other parameters relevant for the property to be tested.

With that detailed information, ECHA can confirm whether the Test Material is relevant for the Substance.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers (https://echa.europa.eu/manuals).

2. General recommendations for conducting and reporting new tests

2.2. Environmental testing for substances containing multiple constituents

Your Substance contains multiple constituents and, as indicated in Guidance on IRs & CSA, Section R.11.4.2.2, you are advised to consider the following approaches for persistency, bioaccumulation and aquatic toxicity testing:

- the "known constituents approach" (by assessing specific constituents), or
- the "fraction/block approach, (performed on the basis of fractions/blocks of constituents), or
- the "whole substance approach", or
- various combinations of the approaches described above

Selection of the appropriate approach must take into account the possibility to characterise the Substance (i.e. knowledge of its constituents and/or fractions and any differences in their properties) and the possibility to isolate or synthesize its relevant constituents and/or fractions.

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