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Helsinki, 16 January 2024

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

Date of submission of the dossier subject to this decision
31 March 2021

Registered substance subject to this decision ("the Substance")
Substance name: diisotridecyl phosphonate
EC number/List number: 275-063-2

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 ***23 January 2026***.

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: OECD TG 471, 2020);

4. If the study requested under request 1 above shows that the Substance's 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's 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);

7. 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) 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. If the study requested under request 1 above shows that the Substance's 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);

13. If the study requested under request 1 above shows that the Substance's 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);

14. Hydrolysis as a function of pH (Annex VIII, Section 9.2.2.1.; test method: EU C.7./OECD TG 111);

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

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 adaptations 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:

(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.

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

0.1.1. The prediction is not adequate for the purpose of classification and labelling and/or risk assessment

5 Under ECHA Guidance 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.

6 Your registration dossier provides the following information:

- In Section 1.1 of your technical dossier, you define the Substance as UVCB
- In Section 1.2, you indicate the following constituents in the composition of your Substance:
- [redacted]You base your predictions for the Substance on the SMILE of the following substance: Diisotridecyl Phosphonate

7 However, the representative structure you selected cannot be considered as such, because you have used for the calculations a SMILES, which does not correspond to the chemical name and the structure of the Substance.

8 In any case, the Substance is UVCB and a single component cannot represent adequately the substance. You have used only 1 structure for the predictions while the Substance is composed of 4 constituents (i-iv).

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

0.1.2. Conclusion on the (Q)SAR adaptation

10 Based on the above, your (Q)SAR adaptation under Annex XI, Section 1.3. is rejected.

0.2. Read-across adaptation rejected

11 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.)
- Hydrolysis as a function of pH (Annex VIII, Section 9.2.2.1)
- Ready biodegradability (Annex VII, Section 9.2.1.1.)

12 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.

13 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.

14 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 (eco-)toxicological properties

15 You predict the properties of the Substance from information obtained from the following source substance(s):

- triisodecyl phosphite, EC 246-998-3
- triisotridecyl phosphite, EC 278-758-9
- tridodecyl phosphite, EC 221-356-5

16 You have not provided any read-across documentation

17 We have identified the following issues with the predictions of (eco-)toxicological properties:

0.2.1.1. Absence of read-across documentation

18 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).

19 You have provided robust study summaries for studies conducted with other substances 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).

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

0.2.1.2. Source study not adequate for the information requirement

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

(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;

22 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 3, 8, 9 and 14.

0.2.2. Conclusion on the read-across approach

23 Based on the above, you have not established that relevant properties of the Substance can be predicted from data on the source substance(s).

24 Therefore, your read-across approach under Annex XI, Section 1.5. is rejected.

0.2.3. Assessment of your comments on the Draft Decision

25 In the comments to the draft decision you refer to your intention to adapt the repeated dose toxicity and reproductive/developmental toxicity information requirements according to Annex XI, Section 1.5. You have provided a stomach acid simulation hydrolysis study on TiTDP, which shows that it rapidly forms DiTDP and then mono-isotridecyl acid phosphite ("acid phosphite"), based on the rapid partial hydrolysis observed in this study. You believe that based on this information, TiTDP and DiTDP will both form the same isotridecyl acid phosphite metabolite in oral toxicology studies and thus have systemic exposure to the same metabolite (the acid phosphite). You have indicated that you are conducting a new stomach acid hydrolysis study comparing DiTDP and TiTDP, which will further clarify this relationship. You also mention new data on the source substance in the form of a 28-day, 90-day, and PNDT study and consider that these studies, in view of the newly generated hydrolysis data, could be used to address the information requirements applicable to the Substance by means of read-across.

26 ECHA acknowledges your intentions to improve the toxicological profile of the Substance and your plans to refine your read-across approach. Since you have indicated that you are conducting a new stomach acid hydrolysis study comparing DiTDP and TiTDP, ECHA understands that you are consolidating the set of supporting information with an additional hydrolysis study comparing the metabolic fate of the source substance and the Substance. The approach presented in your comments relies on data which is yet to be generated, therefore no conclusion on the validity of the read-across for the repeated dose toxicity and reproductive/developmental toxicity information requirements can currently be made. In addition, the new data on the source substance in the form of a 28-day, 90-day, and PNDT study that you mention are not provided in your comments or in your dossier. Therefore, ECHA cannot assess and conclude on the acceptability of this adaptation. You remain responsible for complying with this decision by the set deadline.

Reasons related to the information under Annex VII of REACH

1. Water solubility

27 Water solubility is an information requirement under Annex VII to REACH (Section 7.7).

1.1. Information provided

28 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 water solubility (Q)SAR prediction (2018) from WSKOW 1.42.

1.2. Assessment of the information provided

29 As explained in the reasons common to several requests, your adaptation is rejected.

30 Therefore, the information requirement is not fulfilled.

1.3. Assessment of your comments on the Draft Decision

31 In your comments on the draft decision you state that water solubility testing may not be possible if the Substance rapidly hydrolyses. You state that you are conducting a hydrolysis study on the Substance.

32 Under Column 2 of REACH Annex VII water solubility testing does not need to be conducted if the Substance is hydrolytically unstable at pH 4, 7 and 9 (half-life less than 12 hours).

33 You have not provided results from a hydrolysis study on the Substance demonstrating that the Substance is hydrolytically unstable at pH 4, 7 and 9 (half-life less than 12 hours). Since your comments are based on the conduct of an ongoing hydrolysis study, and the results are not yet available, no conclusion on compliance can currently be made.

34 The information provided in your comments does not fulfil the information requirement and you remain responsible for complying with this decision by the set deadline.

2. Partition coefficient n-octanol/water

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

2.1. Information provided

36 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 partition coefficient (Q)SAR prediction (2018) from KOWWIN 1.68.

2.2. Assessment of the information provided

37 As explained in the reasons common to several requests, your adaptation is rejected.

38 Therefore, the information requirement is not fulfilled.

2.3. Assessment of your comments on the Draft Decision

39 In your comments on the draft decision you state that testing to determine the partition coefficient n-octanol/water of the Substance may not be possible if the Substance rapidly hydrolyses. You state that you are conducting a hydrolysis study on the Substance.

40 The Guidance on IRs and CSA section 7.1.8.4. states that in case of rapid hydrolysis the registrant needs to provide evidence in the form of a hydrolysis endpoint study record (study summary). In addition, where information on the properties of (environmentally and toxicologically) relevant degradation products are needed for conducting the risk assessment of the substance, the hydrolysis products should be tested.

41 Since your comments are based on the conduct of an ongoing hydrolysis study, and the results are not yet available, no conclusion on hydrolysis properties can currently be made. Rapid hydrolysis of the Substance does not necessarily mean that partition coefficient n-octanol/water testing on the Substance is not possible, only that the study design should take into account the hydrolysis products. The results of the hydrolysis study (Request 14), when available, can be used in accordance with the Guidance on IRs and CSA section 7.1.8.4. to determine the appropriate test design.

42 The information provided in your comments does not fulfil the information requirement and you remain responsible for complying with this decision by the set deadline.

3. In vitro gene mutation study in bacteria

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

3.1. Information provided

44 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) an *in vitro* gene mutation study in bacteria (1980) with the source substance triisodecyl phosphite, EC 246-998-3;

(ii) an *in vitro* gene mutation study in bacteria (2014) with the source substance triisotridecyl phosphite, EC 278-758-9.

3.2. Assessment of the information provided

3.2.1. Read-across adaptation rejected

45 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.

3.2.2. *Source study not adequate for the information requirement*

46 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, in this case OECD TG 471.

47 Therefore, the following specifications must be met:

a) the test is performed with 5 strains: four strains of *S. typhimurium* (TA98; TA100; TA1535; TA1537 or TA97a or TA97) and one strain which is either *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101);
b) triplicate plating is used at each dose level;
c) the mean number of revertant colonies per plate is reported for the treated doses and the controls;
d) negative results are confirmed in a repeat experiment with modification of study parameters to extend the range of conditions assessed, or a justification why confirmation of negative results is not considered necessary is provided.

48 In study (i) described as an *in vitro* gene mutation study in bacteria:

a) the test was performed with the strains *S. typhimurium* TA98, TA100, TA1535, TA1537, and TA 1538 (i.e., the *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101) is missing);
b) triplicate plating was not used at each dose level;
c) the mean number of revertant colonies per plate for the treated doses and the controls was not reported;
d) no repeat experiment was performed to confirm the negative results and no justification was provided.

49 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.

50 Consequently, the information requirement is not fulfilled.

3.3. Specification of the study design

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

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

4. Short-term toxicity testing on aquatic invertebrates

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

4.1. Information provided

54 You have adapted this information requirement by using Column 2 of Annex VII, Section 9.1.1., claiming that the study does not need to be conducted because the substance is highly insoluble in water, hence indicating that aquatic toxicity is unlikely to occur.

4.1.1. The provided adaptation does not meet the criteria of Annex VII, Section 9.1.1., Column 2

55 Under Annex VII, Section 9.1.1., Column 2, first indent, the study may be omitted if aquatic toxicity is unlikely, for instance if the Substance is highly insoluble in water. Guidance on IRs and CSA, Section R.7.8.5 explains that there is no scientific basis to define a cut off limit for solubility below which toxicity is unlikely.

56 Therefore, the justification must demonstrate very low water solubility and low likelihood to cross biological membranes. For the latter, the indicators used for low likelihood of a high

bioaccumulation potential (Guidance on IRs and CSA, Figure R.11-4) must be considered, including:

- physico-chemical indicators of hindered uptake due to large molecular size (e.g. D_{max} > 17.4 Å and MW > 1100 or MML > 4.3 nm) or high octanol-water partition coefficient (Log K_{ow} > 10) or low potential for mass storage (octanol solubility (mg/L) < 0.002 x MW), and
- supporting experimental evidence of hindered uptake (no chronic toxicity for mammals and birds, no chronic ecotoxicity, no uptake in mammalian toxicokinetic studies, very low uptake after chronic exposure).

57 Unless it can reliably be demonstrated that aquatic toxicity is unlikely to occur, the Substance must be considered as poorly water soluble.

58 Your registration dossier provides:

- information on the solubility of the Substance in water (2.967e-006 mg/L) based on a water solubility (Q)SAR prediction (2018) from WSKOW 1.42.
- A molecular weight MW < 1100 based on the values provided in the Molecular and structural information section (MW= 445.7).

59 As explained under request 1, you have not provided valid information on the saturation concentration of the Substance. Most importantly, the molecular weight of the Substance is such that it does not indicate hindered uptake and no other supporting evidence of hindered uptake was provided. Therefore, you have not demonstrated that the likelihood to cross biological membranes and toxicity is unlikely to occur and your adaptation is rejected.

60 Therefore, the information requirement is not fulfilled.

4.2. Assessment of your comments on the Draft Decision

61 In your comments on the draft decision you state that conducting the short-term toxicity to invertebrates study on the Substance itself may not be possible as the Substance is expected to rapidly hydrolyse. In addition, you state in your comments that the aquatic toxicity endpoints should be based on the properties of the hydrolysis products. You do not provide results from a hydrolysis study on the Substance demonstrating the hydrolysis properties of the Substance and identifying the hydrolysis products, however, you state that a hydrolysis study is ongoing.

62 The OECD Guidance Document 23 (GD 23) provides guidance on conducting aquatic toxicity testing with substances that rapidly hydrolyse. The GD 23 Section 7.3 provides criteria to support the decision on whether to test the parent or the hydrolysis products in cases where the test chemical rapidly hydrolyses, for example, if the hydrolysis half-life is determined to be >3 days it is recommended to test the parent chemical; where the half-life is <1 hour it is recommended to test the hydrolysis products.

63 Therefore, rapid hydrolysis of the Substance does not necessarily mean that aquatic toxicity testing is not possible, only that the hydrolysis properties of the Substance should be taken into account in the study design.

64 ECHA acknowledges that the aquatic toxicity study designs should take into account the hydrolysis properties of the Substance. Your comments are based on the conduct of an ongoing hydrolysis study, and the results are not yet available, therefore no conclusion can currently be reached on the rate of hydrolysis of the Substance or the identity of the hydrolysis products. The results of the hydrolysis study (Request 14), when available, can be used according to the criteria in the GD 23 section 7.3 to determine whether to test the Substance and/or the hydrolysis products in the short-term toxicity on invertebrates study.

65 The information provided in your comments does not fulfil the information requirement and you remain responsible for complying with this decision by the set deadline.

5. Long-term toxicity testing on aquatic invertebrates

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

67 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.

5.1. Triggering of the information requirement

68 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.

69 As explained under request 1, you have not provided valid information on the saturation concentration of the Substance in water.

70 Therefore, if the study requested under request 1 shows that the Substance's solubility is below 1 mg/L, i.e. Substance is poorly water soluble, information on long-term toxicity on aquatic invertebrates must be provided.

5.2. Assessment of your comments on the Draft Decision

71 In your comments on the draft decision you state that conducting the long-term toxicity to invertebrates study on the Substance itself may not be possible as the Substance is expected to rapidly hydrolyse. In addition, you state in your comments that the aquatic toxicity endpoints should be based on the properties of the hydrolysis products. You do not provide results from a hydrolysis study on the Substance demonstrating the hydrolysis properties of the Substance and identifying the hydrolysis products, however, you state that a hydrolysis study is ongoing.

72 As already addressed under Request 4, the OECD GD 23 provides guidance on conducting aquatic toxicity testing with substances that rapidly hydrolyse.

73 Your comments are based on the conduct of an ongoing hydrolysis study, and the results are not yet available, therefore no conclusion can currently be reached on the rate of hydrolysis of the Substance or the identity of the hydrolysis products. The results of the hydrolysis study (Request 14), when available, can be used according to the criteria in the GD 23 section 7.3 to determine whether to test the Substance and/or the hydrolysis products in the long-term toxicity on invertebrates study.

74 The information provided in your comments does not fulfil the information requirement and you remain responsible for complying with this decision by the set deadline.

5.3. Study design and test specifications

75 If the study requested under request 1 above shows that the Substance's solubility is below 1 mg/L, the Substance would be difficult to test due to the low water solubility. OECD TG 211 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance.

76 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.

77 Therefore, you must monitor the test concentration(s) of the Substance throughout the exposure duration and report the results. If it is not possible to demonstrate the stability of exposure concentrations (i.e. measured concentration(s) not within 80-120% of the nominal concentration(s)), you must express the effect concentration based on measured values as described in OECD TG 211.

78 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.

79 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).

80 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.

6. Growth inhibition study aquatic plants

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

82 You have adapted this information requirement by using Column 2 of Annex VII, Section 9.1.2., claiming that the study does not need to be conducted because the substance is highly insoluble in water, hence indicating that aquatic toxicity is unlikely to occur.

6.1. The provided adaptation does not meet the criteria of Annex VII, Section 9.1.2., Column 2

83 Under Annex VII, Section 9.1.2., Column 2, first indent, the study may be omitted if aquatic toxicity is unlikely, for instance if the Substance is highly insoluble in water. Guidance on IRs and CSA, Section R.7.8.5 explains that there is no scientific basis to define a cut off limit for solubility below which toxicity is unlikely.

84 Therefore, the justification must demonstrate very low water solubility and low likelihood to cross biological membranes. For the latter, the indicators used for low likelihood of a high

bioaccumulation potential (Guidance on IRs and CSA, Figure R.11-4) must be considered, including:

- physico-chemical indicators of hindered uptake due to large molecular size (*e.g.* D_{max} > 17.4 Å and MW > 1100 or MML > 4.3 nm) or high octanol-water partition coefficient (log K_{ow} > 10) or low potential for mass storage (octanol solubility (mg/L) < 0.002 x MW), and
- supporting experimental evidence of hindered uptake (no chronic toxicity for mammals and birds, no chronic ecotoxicity, no uptake in mammalian toxicokinetic studies, very low uptake after chronic exposure).

85 Your registration dossier provides:

- information on the solubility of the Substance in water (2.967e-006 mg/L) based on a water solubility (Q)SAR prediction (2018) from WSKOW 1.42.
- A molecular weight MW < 1100 based on the values provided in the Molecular and structural information section (MW= 445.7).

86 As explained under request 1, you have not provided valid information on the saturation concentration of the Substance in water. Most importantly, the molecular weight of the Substance is such that it does not indicate hindered uptake and no other supporting evidence of hindered uptake was provided.

87 Therefore, you have not demonstrated that the likelihood to cross biological membranes and toxicity is unlikely to occur and your adaptation is rejected.

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

6.2. Assessment of your comments on the Draft Decision

89 In your comments on the draft decision you state that conducting the algal toxicity study on the Substance itself may not be possible as the Substance is expected to rapidly hydrolyse. In addition, you state in your comments that the aquatic toxicity endpoints should be based on the properties of the hydrolysis products. You do not provide results from a hydrolysis study on the Substance demonstrating the hydrolysis properties of the Substance and identifying the hydrolysis products, however, you state that a hydrolysis study is ongoing.

90 As already addressed under Request 4, the OECD GD 23 provides guidance on conducting aquatic toxicity testing with substances that rapidly hydrolyse.

91 Your comments are based on the conduct of an ongoing hydrolysis study, and the results are not yet available, therefore no conclusion can currently be reached on the rate of hydrolysis of the Substance or the identity of the hydrolysis products. The results of the hydrolysis study (Request 14), when available, can be used according to the criteria in the GD 23 section 7.3 to determine whether to test the Substance and/or the hydrolysis products in the algal toxicity study.

92 The information provided in your comments does not fulfil the information requirement and you remain responsible for complying with this decision by the set deadline.

6.1. Study design and test specifications

93 The OECD TG 201 specifies that, for difficult to test substances, the OECD GD 23 must be followed. As already explained above, if the study requested under request 1 above shows that the Substance` solubility is below 1 mg/L the Substance is difficult to test.

94 Therefore, in that case you must fulfil the requirements described in "Study design and test specifications" under request 5.

7. Ready biodegradability

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

7.1. Information provided

96 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 (2014) with the source substance triisotridecyl phosphite, EC 278-758-9.

7.2. Assessment of the information provided

97 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.

98 Therefore, the information requirement is not fulfilled.

7.3. Study design and test specifications

99 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).

100 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.

101 In Section 1.1. of your dossier you describe the Substance as UVCB. In Section 1.2, you describe the substance as UVCB substance with the following constituents: [redacted]

102]The Substance is a complex substance and contains constituents with structural differences described above.

103 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.

104 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.

105 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.

106 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.

107 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.

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

Reasons related to the information under Annex VIII of REACH

8. *In vitro* micronucleus study

109 An *in vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study is an information requirement under Annex VIII, Section 8.4.2.

8.1. Information provided

110 You have adapted this information requirement by using Annex VIII, Section 8.4., Column 2, the study usually does not need to be conducted "if adequate data from an *in vivo* cytogenicity test are available" in conjunction with Annex XI, Section 1.5. (grouping of substances and read-across approach) based on the following experimental data:

(i) an *in vivo* cytogenicity study (2014) with the source substance triisotridecyl phosphite, EC 278-758-9;

(ii) an *in vivo* cytogenicity study (1981) with the source substance triisodecyl phosphite, EC 246-998-3.

8.2. Assessment of the information provided

8.2.1. The provided adaptation does not meet the criteria of Annex VIII, Section 8.4., Column 2

111 Under Annex VIII, Section 8.4., Column 2, the study usually does not need to be conducted "if adequate data from an *in vivo* cytogenicity test are available". The Guidance on IRs and CSA, Section R.7.7.6.3 and Table R.7.7–3 clarifies that the *in vivo* somatic cell cytogenicity test must be either a micronucleus test or a chromosomal aberration test, performed according to the OECD TG 474 or 475, respectively.

112 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.

113 Furthermore, 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, in this case OECD TG 474.

114 For the data from an *in vivo* somatic cell cytogenicity test to be considered adequate, the in vivo study you submitted has to meet the requirements of the OECD TG 474.

115 Therefore, the following specifications must be met:

a) the proportion of immature erythrocytes among total (immature + mature) erythrocytes is determined for each animal by counting a total of at least 500 erythrocytes for bone marrow and 2000 erythrocytes for peripheral blood;

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

c) the proportion of immature erythrocytes among total (immature + mature) erythrocytes and the mean number of micronucleated immature erythrocytes are reported for each group of animals;

116 In study (i):

a) no information provided that the minimum number of erythrocytes (i.e. 500 erythrocytes for bone marrow) were counted to determine the proportion of immature erythrocytes among total (immature + mature) erythrocytes for each animal;

b) no information provided that the minimum number of immature erythrocytes per animal (i.e. 4000 immature erythrocytes) were scored to determine the incidence of micronucleated immature erythrocytes;

c) the proportion of immature erythrocytes among total (immature + mature) erythrocytes and the mean number of micronucleated immature erythrocytes were not reported for each group of animals;

117 The information provided does not cover the specification(s) required by the OECD TG 474.

118 In study (ii):

a) no information provided that the minimum number of erythrocytes (i.e. 500 erythrocytes for bone marrow) were counted to determine the proportion of immature erythrocytes among total (immature + mature) erythrocytes for each animal;

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

c) the proportion of immature erythrocytes among total (immature + mature) erythrocytes and the mean number of micronucleated immature erythrocytes were not reported for each group of animals;

119 The information provided does not cover the specification(s) required by the OECD TG 474.

120 Based on the above, your adaptation according to Annex VIII, Section 8.4., Column 2 is rejected and the information requirement is not fulfilled.

8.3. Specification of the study design

121 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*.

122 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).

123 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*.

124 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

125 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.

126 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)).

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

[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

128 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* cytogenicity test.

9.1. Triggering of the information requirement

129 Your dossier contains no data for *in vitro* gene mutation study in bacteria and for *in vitro* cytogenicity study in mammalian cells.

130 The result of the request 3 for information for an *in vitro* gene mutation study in bacteria and of the request 8 for an *in vitro* cytogenicity study in mammalian cells 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.

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

9.2. Information provided

132 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) an *in vitro* gene mutation study in mammalian cells (2018) with the source substance triisotridecyl phosphite, EC 278-758-9;

9.3. Assessment of the information provided

9.3.1. Read-across adaptation rejected

133 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.

9.3.2. Source study not adequate for the information requirement

134 As explained in Section 0.2., 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, in this case OECD TG 476.

135 Therefore, the following specifications must be met:

a) data on the cytotoxicity and the mutation frequency for the treated and control cultures are reported.

136 In study (i):

a) data on the cytotoxicity and the mutation frequency for the treated and control cultures were not reported.

137 The information provided does not cover the specification(s) required by the OECD TG 476.

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

9.4. Specification of the study design

139 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.

140 In the comments to the draft decision, you agree to perform the requested study if necessary.

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

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

10.1. Information provided

142 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) Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test with the source substance triisodecyl phosphite, EC 246-998-3.

10.2. Assessment of the information provided

143 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.

144 Your comments to the draft decision concerning ECHA's assessment of your read-across adaptation are addressed in Section 0.2.3. Therefore, the information requirement is not fulfilled.

10.3. Specification of the study design

145 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.).

146 The study design is addressed in request 11.

11. Screening study for reproductive/developmental toxicity

147 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

148 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) Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test with the source substance triisodecyl phosphite, EC 246,998-3.

11.2. Assessment of the information provided

149 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.

150 Your comments to the draft decision concerning ECHA's assessment of your read-across adaptation are addressed in Section 0.2.3.

151 Therefore, the information requirement is not fulfilled.

11.3. Specification of the study design

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

153 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).

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

12. If the study requested under request 1 above shows that the Substance's solubility is above 1 mg/L: Short-term toxicity testing on fish

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

12.1. Information provided

156 You have adapted this information requirement by using Column 2 of Annex VIII, Section 9.1.2. claiming that the study does not need to be conducted because the substance is highly insoluble in water, hence indicating that aquatic toxicity is unlikely to occur.

12.2. Assessment of the information provided

12.2.1. The provided adaptation does not meet the criteria of Annex VIII, Section 9.1.3., Column 2

157 Under Annex VIII, Section 9.1.3., Column 2, first indent, the study may be omitted if aquatic toxicity is unlikely, for instance if the Substance is highly insoluble in water. Guidance on IRs and CSA, Section R.7.8.5. explains that there is no scientific basis to define a cut off limit for solubility below which toxicity is unlikely.

158 Therefore, the justification must demonstrate very low water solubility and low likelihood to cross biological membranes. For the latter, the indicators used for low likelihood of a high bioaccumulation potential (Guidance on IRs and CSA, Figure R.11-4) must be considered, including:

- physico-chemical indicators of hindered uptake due to large molecular size (e.g. D_{max} > 17.4 Å and MW > 1100 or MML > 4.3 nm) or high octanol-water partition coefficient (Log K_{ow} > 10) or low potential for mass storage (octanol solubility (mg/L) < 0.002 x MW), and
- supporting experimental evidence of hindered uptake (no chronic toxicity for mammals and birds, no chronic ecotoxicity, no uptake in mammalian toxicokinetic studies, very low uptake after chronic exposure).

159 Your registration dossier provides:

- information on the solubility of the Substance in water (2.967e-006 mg/L) based on a water solubility (Q)SAR prediction (2018) from WSKOW 1.42.
- A molecular weight MW < 1100 based on the values provided in the Molecular and structural information section (MW= 445.7).

160 As explained under request 1, you have not provided valid information on the saturation concentration of the Substance. Most importantly, the molecular weight of the Substance is such that it does not indicate hindered uptake and no other supporting evidence of hindered uptake was provided.

161 Therefore, you have not demonstrated that the likelihood to cross biological membranes and toxicity is unlikely to occur and your adaptation is rejected.

162 You have not demonstrated that toxicity is unlikely to occur and your adaptation is rejected and the information requirement is not fulfilled.

13. Long-term toxicity testing on fish

163 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

164 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.

165 As already explained in request 1 you have not provided valid information on the saturation concentration of the Substance in water.

166 Therefore, if the study requested under request 1 shows that the Substance is poorly water soluble, information on long-term toxicity on aquatic invertebrates must be provided.

13.2. Information provided

167 You have not provided information on long-term toxicity on fish for the Substance.

168 In the absence of information on long-term toxicity on fish, this information requirement would not be fulfilled if the Substance is poorly water soluble.

13.3. Assessment of your comments on the Draft Decision

169 In your comments on the draft decision you state that conducting the long-term toxicity to fish study on the Substance itself may not be possible as the Substance is expected to rapidly hydrolyse. In addition, you state in your comments that the aquatic toxicity endpoints should be based on the properties of the hydrolysis products. You do not provide results from a hydrolysis study on the Substance demonstrating the hydrolysis properties of the Substance and identifying the hydrolysis products, however, you state that a hydrolysis study is ongoing.

170 As already addressed under Request 4, the OECD GD 23 provides guidance on conducting aquatic toxicity testing with substances that rapidly hydrolyse.

171 Your comments are based on the conduct of an ongoing hydrolysis study, and the results are not yet available, therefore no conclusion can currently be reached on the rate of hydrolysis of the Substance or the identity of the hydrolysis products. The results of the hydrolysis study (Request 14), when available, can be used according to the criteria in the GD 23 section 7.3 to determine whether to test the Substance and/or the hydrolysis products in the long-term toxicity to fish study.

172 The information provided in your comments does not fulfil the information requirement and you remain responsible for complying with this decision by the set deadline.

13.4. Study design and test specifications

173 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.).

174 The OECD TG 210 specifies that, for difficult to test substances, the OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in "Study design and test specifications" under request 5.

14. Hydrolysis as a function of pH

175 Hydrolysis as a function of pH is an information requirement under Annex VIII to REACH (Section 9.2.2.1.).

14.1. Information provided

176 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 key hydrolysis study (2003) with the source substance triisotridecyl phosphite, EC 278-758-9;

(ii) a supporting hydrolysis study (2008) according to EC protocol for hydrolysis of plastics monomers and additives in digestive fluids, with source substance: tridodecyl phosphite; EC 221-356-5;

(iii) a supporting hydrolysis study (2014) according to OECD TG 111, with source substance: triisotridecyl phosphite; EC 278-758-9.

14.2. Assessment of the information provided

14.2.1. Read-across adaptation rejected

177 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.

14.2.2. Source study not adequate for the information requirement

178 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 111. This TG is designed as a tiered approach and each tier is triggered by the results of the previous tier. Therefore, the following specifications (among others) must be met:

179 Preliminary test (Tier 1)

a) the test must be conducted at least in duplicate at 50± 0.5°C for 5 days;

b) the test must be conducted using buffered solutions at pH 4, 7 and 9;

Hydrolysis testing (Tier 2)

c) the test must be conducted at three temperatures, including the test temperature of 50°C;

Identification of hydrolysis products (Tier 3)

d) all major hydrolysis products observed in Tier 2 testing (i.e. at least those representing > 10% of the applied dose) must be identified using an appropriate analytical method (Tier 3);

Technical specifications impacting the sensitivity/reliability of the test

e) if necessary for adequate dissolution, the use of water miscible solvents (such as acetonitrile, acetone, ethanol) is permitted for application and distribution of the test material up to 1 % v/v, or higher when it can be shown that the solvent has no effect on the hydrolysis of the test material;

Reporting

f) the test design is reported (e.g., number of replicates, type of test vessels, test duration);

g) the test conditions are reported (e.g., initial test material concentration, test temperature, pH values, buffers used);

h) the analytical method is described including appropriate information on performance parameters (i.e. specificity, recovery efficiency, precision, limits of determination (i.e. detection and quantification) and working range);

i) the amounts of test material and of hydrolysis products, at the end of the tests, are given as % of applied initial concentration;

j) a graphical presentation of the log-transformed data of the concentration(s) of any hydrolysis product representing 10 % or more of the parent substance against time must be reported;

k) the amounts of test material and of hydrolysis products, if relevant, are reported for each sampling interval and for each pH and test temperature;

l) the results of the preliminary test are reported;

m) the proposed pathway of hydrolysis is reported;

180 In the provided studies (i-iii):

181 Tier 1

a) and b) Preliminary test was not performed.

182 Tier 2 and 3

c) hydrolysing testing (Tier 2) was only conducted at one temperature;

d) hydrolysis products were observed in the hydrolysis test (Tier 2) but were not identified. You have only provided unsubstantiated theoretical considerations on its identity referring to "corresponding alcohol" forms of the test substance.

183 Reporting

f) to m) information is not provided in the robust study summaries.

184 In the key study (i) and supporting study (iii):

185 Technical specifications impacting the sensitivity/reliability of the test

e) The tests were performed using 50% cosolvent. You have not shown that the solvent has no effect on the hydrolysis of the test material.

Based on the above, there are critical methodological deficiencies resulting in the rejection of the study results, specifically:

- Tier 1 test was not performed for any of the studies;
- You have not investigated the hydrolysis behaviour of the substance at the required temperatures, which can result in an underestimation of the results, and it is thus not possible to conclude on the hydrolysis products;
- The hydrolysis products were not correctly identified.

186 Furthermore, the reporting of the studies is not sufficient to conduct an independent assessment of its reliability.

187 Therefore, the studies submitted in your adaptation do not provide an adequate and reliable coverage of the key parameters of the OECD TG 111. On this basis, the specifications of OECD TG 111 are not met.

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

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

15. Adsorption/desorption screening

190 Adsorption/desorption screening is an information requirement under Annex VIII to REACH (Section 9.3.1).

15.1. Information provided

191 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 adsorption (Q)SAR prediction (2018) from KOCWIN 2.0.

15.2. Assessment of the information provided

192 As explained in the reasons common to several requests, your adaptation is rejected.

193 Therefore, the information requirement is not fulfilled.

15.3. Assessment of your comments on the Draft Decision

194 In your comments on the draft decision you state that it may not be possible to conduct adsorption/desorption testing if the Substance rapidly hydrolyses. You state that you are conducting a hydrolysis study on the Substance.

195 Adsorption/desorption test guidelines (e.g. OECD TG 106) provide guidance for testing substances that are unstable in the time scale of the test. For example, the OECD TG 106 (see Annex 1) recommends analysing both phases (aqueous and soil) in such cases. Furthermore, the Guidance on IRs and CSA Section 7.1.15.4 states that in cases where the substance and its relevant degradation products hydrolyse/decompose rapidly it might be more appropriate to also determine the degree of adsorption of the hydrolysis products. The need to test the hydrolysis products for adsorption/desorption will depend on their physico-chemical properties as further described in the Guidance on IRs and CSA Section 7.1.15.4.

196 Therefore, the fact that the Substance may hydrolyse rapidly does not mean that the adsorption/desorption testing is not feasible, only that the results of the hydrolysis study (Request 14) can be used to determine the study design and to conclude whether the hydrolysis products should also be tested.

197 You have not provided results from a hydrolysis study on the Substance to characterize the hydrolysis properties of the Substance and identify the hydrolysis products, nor have you provided information on the adsorption/desorption properties of the Substance or its hydrolysis products in your comments.

198 The information provided in your comments does not fulfil the information requirement and you remain responsible for complying with this decision by the set deadline.

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 02 May 2022.

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

ECHA took into account your comments and did not amend the request(s).

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

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

1.2. Test material

(1) Selection of the Test material(s)

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

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

(2) Information on the Test Material needed in the updated dossier

- You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
- 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 Regulation must be identified and quantified using the appropriate analytical methods,

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).