~~Confidential~~

Helsinki, 05 January 2023

Addressees
Registrant(s) of [redacted]_JS_DBP as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
04/10/2013

Registered substance subject to this decision ("the Substance")
Substance name: Dibutyl phthalate
EC/List number: 201-557-4

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

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information under Request 2 by ***11 April 2024*** and all other information listed below by ***12 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. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method: EU C.3./OECD TG 201 or EU C.26./OECD TG 221)

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

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

3. Only if the information requested under 2 shows that the Substance is not readily biodegradable: Sediment simulation testing also requested below (triggered by Annex VIII, Section 9.2.)

4. Only if the information requested under 2 shows that the Substance is not readily biodegradable: Bioaccumulation in aquatic species also requested below (triggered by Annex I, Sections 0.6.1. and 4; Annex XIII, Section 2.1.)

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

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

6. Sediment simulation testing (Annex IX, Section 9.2.1.4.; test method: EU C.24./OECD TG 308) at a temperature of 12°C. Non-extractable residues (NER) must be quantified and a scientific justification of the selected extraction procedures and solvents must be provided.

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

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

Information required depends on your tonnage band

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

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

You are only required to share the costs of information that you must submit to fulfil your information requirements.

How to comply with your information requirements

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

You must follow the general requirements for testing and reporting new tests under REACH, see Appendix 4. In addition, the studies relating to biodegradation and bioaccumulation are necessary for the PBT assessment. However, to determine the testing needed to reach the conclusion on the persistency and bioaccumulation of the Substance you should consider the sequence in which these tests are performed and other conditions described in this Appendix.

Appeal

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

Failure to comply

If you do not comply with the information required by this decision by the deadline indicated above, ECHA will notify the enforcement authorities of your Member State.

Authorised[1] under the authority of Mike Rasenberg, Director of Hazard Assessment

[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 related to the information under Annex VII of REACH

1. Growth inhibition study aquatic plants

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

1.1. Information provided

2 You have provided the following information on the Substance:

(i) a non-guideline growth inhibition study on aquatic algae (1984)
(ii) a growth inhibition study on aquatic algae according to ISO 8692 (2003)
(iii) a growth inhibition study on aquatic algae according to EU method C.3 (2007)

1.2. Assessment of the information provided

1.2.1. *Test material not representative of the Substance (studies (i) and (iii))*

3 To comply with this information requirement, the test material in a study must be representative for the Substance; Article 10 and Recital 19 of REACH; Guidance on IRs and CSA, Section R.4.1.

4 The studies (i) and (iii) have been conducted with a test material described as "dibutyl phthalate", EC No. 201-557-4 (CAS RN 84-74-2), without further information, including the purity profile and the presence of impurities.

5 In the absence of composition information on the test materials for studies (i) and (iii), the identity of the corresponding test materials and their impurities cannot be assessed, and you have not demonstrated that the test materials used in these studies were representative for the Substance.

1.2.2. *The provided studies (i) to (iii) are not reliable*

6 To fulfil the information requirement, a study must have an adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3) of RACH, in this case the OECD TG 201. Therefore, the following specifications must be met:

7 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;

8 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;
c) adequate information on the results of the analytical determination of exposure concentrations is provided.

9 Your registration dossier provides the studies (i) to (iii) for which the following issues have been identified:

10 Characterisation of exposure

a) no analytical monitoring of exposure was conducted for study (iii) and you have not provided a justification that the analytical monitoring of exposure concentrations was not technically feasible;

11 Reporting of the methodology and results

b) tabulated data on the algal biomass determined daily for each treatment group and control are not reported for studies (i), (ii) and (iii);
c) the results of the analytically determined exposure concentrations are not provided for study (ii).

12 Based on the above,

- there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, no analytical monitoring was conducted in study (iii), therefore you have not demonstrated that exposure was satisfactorily maintained throughout the test. For study (ii), you claim that analytical monitoring of exposure was conducted. However, you reported no information and therefore an independent assessment is not possible.
- the reporting of the study is not sufficient to conduct an independent assessment of its reliability. More specifically, you have not provided biomass data for studies (i), (ii) and (iii). Therefore, it is not possible to independently assess whether validity criteria of the test guideline were met and whether the interpretation of the results is adequate. Furthermore, in study (i), you report that the test duration was 10 days. In the absence of raw biomass data, you have not demonstrated that exponential growth was maintained throughout the exposure phase as required by the OECD TG 201.

13 Therefore, the requirements of OECD TG 201 are not met by any of the studies provided in your dossier.

1.3. Study design and test specifications

14 The Substance is difficult to test due to the adsorptive properties (log Kow of 4.46). 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. 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. 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.

2. Ready biodegradability

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

2.1. Information provided

16 You have provided the following information on the Substance:

(i) an inherent biodegradability study according to EPA OTS 796.3340: Inherent Modified SCAS Test (1984)
(ii) a non guideline study on anaerobic biodegradability (1989)
(iii) a ready biodegradability study according to EU method C.4-C (1995)
(iv) a ready biodegradability study according to OECD TG 301B study (1996)
(v) an anaerobic biodegradability study according to OECD TG 311 (2005)

2.2. Assessment of information provided

2.2.1. *Test material not representative of the Substance (studies (i), (iii), (iv) and (v))*

17 To comply with this information requirement, the test material in a study must be representative for the Substance; Article 10 and Recital 19 of REACH; Guidance on IRs and CSA, Section R.4.1.

18 The studies (i), (iii) and (iv) have been conducted with a test material described as "dibutyl phthalate", EC No. 201-557-4 (CAS No. 84-74-2), without further information, including the purity profile and the presence of impurities. Furthermore, you report for study (v) that the test was conducted on a "mixture of DBP+DEHP or DEHP alone (1, 2 or 5 µg/g)", while you claim that the study was conducted on the Substance.

19 Therefore, the test material used in study (v) was not representative of the Substance. Furthermore, for studies (i), (iii) and (iv), in the absence of composition information on the test material, the identity of the corresponding test materials and their impurities cannot be assessed, and you have not demonstrated that the test materials used in these studies were representative for the Substance.

2.2.2. *The provided studies (i) to (v) are not reliable*

20 To fulfil the information requirement, a study must have an adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3) of REACH, in this case the OECD TG 301 or 310. Therefore, the following requirements must be met:

21 Key parameter to be measured

a) the ultimate aerobic biodegradation (as measured by parameters such as DOC removal, CO2 production and oxygen uptake) of the test material under low inoculum concentration is measured at sufficiently frequent intervals to allow the identification of the beginning and end of biodegradation;

22 Technical specifications impacting the sensitivity/reliability of the test

b) for a study according to OECD TG 301B, the concentration of the inoculum is set to reach a bacterial cell density of 10^7 to 10^8 cells/L in the test vessel.

23 Reporting of the methodology and results

c) the source of the inoculum, its concentration in the test and any pre-conditioning treatment are reported;
d) the test conditions are described (*e.g.*, test material concentration, test temperature, test medium composition, nature and concentration of organic solvent if relevant)
e) the results of measurements at each sampling point in each replicate are reported in a tabular form;
f) the inorganic carbon content (IC) and total carbon content (TC) of the test

material suspension in the mineral medium at the beginning of the test are reported;

24 Your registration dossier provides the studies (i) to (v) for which the following issues have been identified:

25 Key parameter to be measured

a) studies (ii) and (v) investigate biodegradation under anaerobic conditions and not ultimate aerobic biodegradation. Furthermore, study (i) corresponds to an inherent biodegradability study similar to OECD TG 302A and therefore does not provide an adequate coverage of the key parameters investigated in a ready biodegradability study. ECHA also notes that adsorptive substances such as the Substance are outside the applicability domain of the OECD TG 302A.

26 Technical specifications impacting the sensitivity/reliability of the test

b) for study (iv), you report that the inoculum density was "*roughly 60 x 10^4 cfu / ml (colony forming units)*" which corresponds to 6 x 10^8 cells/L. Therefore, the inoculum density was c.a. 6 times higher than the maximum value specified in the OECD TG 301B;

27 Reporting of the methodology and results

c) the inoculum concentration in the test is not reported in study (iii);
d) you have not provided adequate information on the test conditions for study (iii) and, in particular, the test temperature, the test medium composition, and, if relevant, the nature and concentration of organic solvent;
e) the results of measurements at each sampling point in each replicate is not reported for studies (iii) and (iv);
f) the inorganic carbon content (IC) and total carbon content (TC) of the test material suspension in the mineral medium at the beginning of the test is not reported in studies (iii) and (iv).

28 Based on the above,

- studies (i), (ii) and (v) do not provide information on the key parameters foreseen to be investigated in a ready biodegradability study;
- there are critical methodological deficiencies resulting in the rejection of the results of study (iv). More specifically, the inoculum density was significantly higher (*i.e.*, approximately 6 times) than the maximum inoculum concentration specified in the corresponding test guideline. This may have led to test conditions that are too favourable and to false positive results;
- the reporting of the studies (iii) and (iv) is not sufficient to conduct an independent assessment of their reliability. More specifically, the information provided on the inoculum and test conditions for study (iii) does not allow verifying whether the study was conducted under conditions that are consistent with the corresponding test guideline requirements. Furthermore, in the absence of the inorganic carbon content (IC) and total carbon content (TC) of the test material suspension at the beginning of the test and of adequate reporting of measurements throughout the test, it is not possible to verify that the validity criteria of the corresponding test guideline were met and that the interpretation of the results is adequate.

29 Therefore, none of the reported studies meets the requirements of the OECD TG 301 or 310 and the information requirement is not fulfilled.

Reasons related to the information under Annex VIII of REACH

3. Only if the information requested under 2 shows that the Substance is not readily biodegradable: Sediment simulation testing

30 Further degradation testing must be considered if the chemical safety assessment (CSA) according to Annex I indicates the need to investigate further the degradation of the substance (Annex VIII, Section 9.2., Column 2).

3.1. Triggering of the information requirement

31 This information requirement is triggered in case the chemical safety assessment (CSA) indicates the need for further degradation investigation (Annex I, Section 4; Annex XIII, Section 2.1), such as if the substance is a potential PBT/vPvB substance (Guidance on IRs and CSA, Section R.11.4.). This is the case if the Substance itself or any of its constituent or impurity present in concentration ≥ 0.1% (w/w) or relevant transformation/degradation product meets the following criteria:

- it is potentially bioaccumulative or very bioaccumulative (B/vB) as it has a high potential to partition to lipid storage (*e.g.* log K_{ow} > 4.5);
- it meets the T criteria set in Annex XIII: NOEC or EC_{10} < 0.01 mg/L or classification as carc. 1A or 1B, muta. 1A or 1B, repro. 1A, 1B or 2, or STOT RE 1 or 2.

32 Your registration dossier provides the following:

- the Substance has a high potential to partition to lipid storage (Log K_{ow} ranging from 4.22 to 4.6 depending on the acetonitrile to water ratio of the eluent as determined in a study based on EU method A.8.);
- the Substance meets the T criteria as it is subject to harmonised classification as Repr. 1B.

33 Furthermore, the information in your dossier is not incompliant and therefore:

- it is currently not possible to conclude on the persistency potential of the Substance (see Request 6 of this decision), and
- it is not possible to conclude on the bioaccumulation potential of the Substance (see Request 7 of this decision).

34 Under section 8 of the CSR ('PBT assessment') and section 2.3 of IUCLID, you conclude that the Substance does no meet the P/vP or B/vB criteria. In support of your conclusion, you provide the following justification:

- On your conclusion that the Substance is not P/vP, you state the following:
  - "*Clearly, the 10 day window has been reached, and DBP* [dibutyl phthalate, referred to as the Substance in the decision] *can be considered as readily biodegradable*". However, for the reasons explained under Request 2, the information requirement on ready biodegradability is not met.

  In this respect ECHA notes the following:

  - You state that "*According to shake-flask screening test designed by* [redacted]*, 1984 determined. Half-life for active water (AW) range from 3.4 d to 17 d (average of half-life for AW was 7.01d)*". However, this information is not adequate to meet the information requirement for

Simulation testing on ultimate degradation in surface water because of lack of information on (i) the purity profile and presence of impurities of the Substance used, (ii) the analytical method used for the quantification of the substance and its transformation/degradation products and (iii) the method used for the identification of transformation/degradation products. Also, the test material was tested at a concentration that is 50 times higher than the specifications of the OECD TG 309. Therefore, it does not provide conclusive evidence on degradation half-life in the water compartment. In addition, the fact that a substance does not meet the P/vP criteria in water does not allow excluding the substance to be P/vP in another compartment such as the sediment compartment.

- "According to shake-flask screening test designed by [redacted], 1984 determined. Half-life for active sediment (AS) range from 0.6 d to 10.8 d (average of half-life for AS was 2.96d)". However, for the reasons explained under Request 6, this information is not adequate to meet the information requirement for Sediment simulation testing and therefore does not provide conclusive evidence on degradation half-life in the sediment compartment.

Therefore, you have not provided adequate information in your dossier to exclude that the Substance might be P/vP.

- On your conclusion that the Substance is not B/vB, you state the following:
  - You consider that the study provided under Section 5.3.1. of your dossier indicates no biomagnification potential for the Substance. However, for the reasons explained under Request 7, this information is not adequate to meet the information requirement for Bioaccumulation in aquatic species and therefore does not provide conclusive evidence on the bioaccumulation potential of the Substance.
  - You state that "[redacted] *(2008) studied the uptake of 5 polycyclic-aromatic hydrocarbons and 2 phthalic acid esters (including DBP) in radish (Raphanus sativus)*" and "*the BCF where < 1*". However, ECHA notes that this study does not inform on bioaccumulation in aquatic species and is therefore of limited use to conclude whether or not the Substance meets the criteria set out in section 1.1.2 and 1.2.2. of Annex XIII to REACH
  - You state that "*According to peer reviewed information from EU RAR for DBP, 2004 bioaccumulation test according to international guidelines (OECD 305E) has been carried out under GLP by industry (*[…] *1996). Carp (Cyprinus carpio) were exposed to 10 and 50 µg/L of DBP for 28 days. Based on measurements for the highest exposure concentration in water and fish a BCF value of 1.8 l/kg was found*". First ECHA notes that this study is not provided in your registration dossier and therefore cannot be assessed in the context of this compliance check. ECHA further notes that significant shortcomings with this study were identified in the context of the EU RAR for the Substance. In particular it is stated that "*some shortcomings* [were identified] (*e.g., rather weak recovery performance, unidentified background contamination and a remarkable (unclarified) drop in DBP levels during the exposure phase). Apart from these inconsistencies it should be noted that also in this test the major metabolite, i.e. the mono-ester MBP, was not analysed*". Therefore, it appears that this study on its own cannot be regarded a valid piece of evidence to conclude that the Substance is not B/vB.

Therefore, you have not provided adequate information in your dossier to exclude that the Substance might be B/vB.

35 Based on the above, the available information on the Substance indicates that it is a potential PBT/vPvB substance. Further, the additional information from your PBT assessment is not adequate to conclude on the PBT/vPvB properties of the Substance.

36 Further, the Substance has high partition coefficient (Log K_{ow} ranging from 4.22 to 4.6) and therefore high potential to adsorb to sediment.

37 Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation. Based on the adsorptive properties of the Substance, sediment represents a relevant environmental compartment.

38 The examination of the available information or adaptations, as well as the selection of the requested test and the test design are addressed respectively in Request 6.

4. Only if the information requested under 2 shows that the Substance is not readily biodegradable: Bioaccumulation in aquatic species

39 Bioaccumulation in aquatic species is required for the purpose of PBT/vPvB assessment (Annex I, Sections 0.6.1 and 4 to REACH).

4.1. Triggering of the information requirement

40 This information requirement is triggered in case the chemical safety assessment (CSA) indicates the need for further investigation on bioaccumulation in aquatic species (Annex I, Section 4; Annex XIII, Section 2.1), such as if the substance is a potential PBT/vPvB substance (Guidance on IRs and CSA, Section R.11.4.).

41 As already explained in Request 3.1., the Substance is a potential PBT/vPvB substance.

42 Therefore, the chemical safety assessment (CSA) indicates the need for further investigation on bioaccumulation in aquatic species.

43 The examination of the available information or adaptations, as well as the selection of the requested test and the test design are addressed in Request 7.

Reasons related to the information under Annex IX of REACH

5. Long-term toxicity testing on aquatic invertebrates

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

5.1. Information provided

45 You have provided the following information on the Substance:

(i) a non-guideline long-term toxicity study on *Gammarus pulex* (1991)

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

(ii) a long-term toxicity study on *Daphnia magna* equivalent to OECD 211 (1987) with bis(2-ethylhexyl) phthalate (EC No. 204-211-0, CAS RN 117-81-7)

(iii) a non-guideline long-term toxicity study on the marine copepod *Eurytemora affinis* (2005) with bis(2-ethylhexyl) phthalate (EC No. 204-211-0, CAS RN 117-81-7)

5.2. Assessment of the information provided

5.2.1. *Assessment of the information provided on the Substance*

5.2.1.1. *Test material not representative of the Substance (study (i))*

47 To comply with this information requirement, the test material in a study must be representative for the Substance; Article 10 and Recital 19 of REACH; Guidance on IRs and CSA, Section R.4.1.

48 The study (i) has been conducted with a test material described as "dibutyl phthalate", EC No. 201-557-4 (CAS RN 84-74-2), without further information, including the purity profile and the presence of impurities.

49 In the absence of composition information on the test materials for studies (i) and (iii), the identity of the corresponding test materials and their impurities cannot be assessed, and you have not demonstrated that the test materials used in these studies were representative for the Substance.

5.2.1.2. *The provided study is not reliable (study (i))*

50 To fulfil the information requirement, a study must have an adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3) of REACH, in this case the OECD TG 211. Therefore, the following specifications must be met:

51 Key parameter to be measured

a) the concentrations of the test material leading to no observed effect (NOECs) on the following parameters are estimated:

(i) the reproductive output expressed as the total number of living offspring produced at the end of the test, and

(ii) the survival of the parent animals during the test, and
(iii) the time to production of the first brood.

52 Your registration dossier provides the study (i) for which the following issues have been identified:

53 Key parameter measured

a) the study investigates locomotor activity of the freshwater amphipod *Gammarus pulex* under flow-through condition and does not provide information of the key parameters listed above under point (a).

54 Based on the above, study (i) does not provide an adequate and reliable coverage of the key parameters addressed in the OECD TG 211. As a result, this study does not meet the information requirement.

5.2.2. *Assessment of your read-across adaptation*

55 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.

56 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).

57 You have not provide a read-across justification document in either IUCLID or your CSR.

58 You predict the properties of the Substance from information obtained from the following source substance:

- bis(2-ethylhexyl) phthalate (EC No. 204-211-0, CAS RN 117-81-7)

59 ECHA assumes that your read-across hypothesis assumes that different compounds have the same type of effects. You predict the properties of your Substance to be quantitatively equal to those of the source substance.

60 We have identified the following issues with the prediction of long-term toxicity on aquatic invertebrates:

5.2.2.1. *Absence of read-across documentation*

61 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 a an explanation why the properties of the Substance may be predicted from information on the source substance(s).

62 You have provided robust study summaries for studies (ii) and (iii) conducted with another 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. This documentation should also include bridging studies to compare the properties of the target and source substances.

63 In the absence of such documentation, the properties of the Substance cannot be reliably predicted from the data on the source substance.

5.2.2.2. *Inadequate or unreliable studies on the source substance*

64 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 211, and meet the requirements of OECD GD 23 if the substance is difficult to test. Therefore, the following specifications must be met:

65 Reporting of the methodology and results

a) adequate information is provided on the identity of the test material (e.g., purity, presence of impurities)
b) the test design is reported (*e.g.* number of replicates, number of parents per replicate);
c) the test procedure is reported (*e.g.* loading in number of *Daphnia* per litre, test medium composition);
d) the methods used to prepare stock and test solutions is reported;
e) detailed information on feeding, including amount (in mgC/daphnia/day) and schedule is reported;
f) water quality monitoring within the test vessels (*i.e.* pH, temperature and dissolved oxygen concentration, and TOC and/or COD and hardness where applicable) is reported;
g) the full record of the daily production of living offspring during the test in each replicate is provided;
h) the number of deaths among the parent animals (if any) and the day on which they occurred is reported;
i) the coefficient of variation for control reproductive output is reported;
j) adequate information on the analytical method (including performance parameters of the method) and on the results of the analytical determination of exposure concentrations is provided.

66 In studies (ii) and (iii) described as long-term toxicity studies on aquatic invertebrates:

a) adequate information on the identity of the test material (e.g., purity, presence of impurities) is not provided for studies (ii) and (iii);
b) key information is missing on the test design for study (ii), and in particular the number of replicates and the number of parents per replicate;
c) key information is missing on the test procedure for study (ii), and in particular the loading in number of *Daphnia* per litre, the test medium composition;
d) the methods used to prepare stock and test solutions is not reported for studies (ii) and (iii);
e) detailed information on feeding, including amount (in mgC/daphnia/day) and schedule is not reported for studies (ii) and (iii);
f) water quality monitoring within the test vessels (*i.e.* pH, temperature and dissolved oxygen concentration, and TOC and/or COD and hardness where applicable) is not reported for studies (ii) and (iii);
g) the full record of the daily production of living offspring during the test in each replicate is not reported for studies (ii) and (iii);
h) the number of deaths among the parent animals (if any) and the day on which they occurred is not reported for studies (ii) and (iii);
i) the coefficient of variation for control reproductive output is not reported for studies (ii) and (iii);
j) adequate information on the analytical method (including performance parameters of the method) and on the results of the analytical determination of exposure is not reported for studies (ii) and (iii).

67 In the absence of the above information, it is not possible to conduct an independent assessment as to whether the study was conducted under conditions that are consistent with the specifications of the OECD TG 211, whether the validity criteria of the test guideline were met and whether the interpretation of the results is adequate.

5.2.2.3. *Conclusion on the read-across approach*

68 For the reasons above, you have not established that relevant properties of the Substance can be predicted from data on the source substance. Your read-across approach under Annex XI, Section 1.5. is rejected.

69 Therefore, the information requirement is not fulfilled.

5.3. Study design and test specifications

70 OECD TG 211 specifies that, for difficult to test substances, OECD GD 23 must be followed. As already explained under Request 1, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design and test specifications' under Request 1.

6. Sediment simulation testing

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

72 Further, the Substance has high partition coefficient (Log K_{ow} ranging from 4.22 to 4.6) and therefore high potential to adsorb to sediment.

6.1. Information provided

73 You have provided the following information on the Substance:

(i) an aerobic and anaerobic biodegradation study in sediment ([redacted], publication, 1984)

(ii) an aerobic and anaerobic biodegradation study in sediment ([redacted], publication, 1975)

(iii) a non-guideline shake-flask screening test in water or sediment ([redacted], publication, 1984)

6.2. Assessment of information provided

6.2.1. *Test material not representative of the Substance (studies (ii) and (iii))*

74 To comply with this information requirement, the test material in a study must be representative for the Substance; Article 10 and Recital 19 of REACH; Guidance on IRs and CSA, Section R.4.1.

75 The studies (ii) and (iii) have been conducted with "dibutyl phthalate", EC No. 201-557-4 (CAS No. 84-74-2), without further information, including the purity profile and the presence of impurities.

76 In the absence of composition information on the test material, the identity of the test material and its impurities cannot be assessed, and you have not demonstrated that the test material is representative for the Substance.

6.2.2. *The provided studies (i) to (iii) are not reliable*

77 To fulfil the information requirement, a study must have an adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3) of REACH, in this case the OECD TG 308. Therefore, the following specifications must be met:

78 Technical specifications impacting the sensitivity/reliability of the test

a) for an aerobic study, two sediments differing with respect to organic carbon content and texture are used, including:
   - a sediment with high organic carbon content (2.5-7.5%) and a fine texture, and
   - a sediment with low organic carbon content (0.5-2.5%) and a coarse texture;

b) the test material concentration is based on predictions from environmental emissions. However, higher doses (e.g. 10 times) is acceptable if environmentally realistic test concentrations are close to the limit of detection at the start of the study and/or if major transformation/degradation products cannot be readily detected when present at 10% of the test material application rate. In all case, a justification of the test concentration is provided;

c) at least two different concentrations of test material are used, which must differ from each other by a factor of 5 to 10;

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d) the analytical method used for the quantification of the test material and its transformation/degradation products is described;

e) the recovery efficiency, precision, limits of determination (*i.e.* detection and quantification) and working range are reported;

f) the method used for the identification of transformation/degradation products is described;

g) the results of microbial activity determination are provided;

h) tabulated results expressed as % of the applied dose and in mg/kg in water, sediment and total system (% only) for the test material and, if appropriate, for transformation products and non-extractable radioactivity in each replicate test vessel are provided;

i) the mass balances during and at the end of the study are provided;

j) the results of the quantification of released CO_2 and other volatile compounds during and at the end of the study are provided;

k) an assessment of transformation kinetics (*i.e.* lag phase, degradation rate constant and degradation half-life) for the test material and, where appropriate, for major transformation products is provided.

80 Your registration dossier provides the studies (i) and (ii) for which the following issues have been identified:

81 Technical specifications impacting the sensitivity/reliability of the test

a) the test was conducted with a single sediment sample in studies (i) to (iii);

b) you have not provided a justification for the selection of the test material concentration(s) in studies (i) to (iii). For study (i), you report that the test concentration was 2 mg/kg sediment (wet weight). For study (ii), you report concentrations ranging from 0.018 to 10 mg/kg sediment (wet weight). For study (iii), you state that the test concentration was 0.5 mg/L. You have not expressed this value in mg/kg sediment. In your CSR, you report PECs for the sediment compartment ranging from 0.0008 to 0.433 mg/kg sediment (dry weight). Therefore, with the exception of the lowest concentration(s) tested in study (ii),

the test concentrations were well above predictions from environmental emissions;
c) a single test material concentration was used to conduct studies (i) and (iii);

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d) the analytical method used for the quantification of the substance and its transformation/degradation products is not described in studies (i) to (iii);
e) the recovery efficiency, precision and limits of determination (i.e. detection and quantification) of the analytical method are not reported in studies (i) to (iii);
f) the method used for the identification of transformation/degradation products is not described in studies (i) to (iii);
g) the results of microbial activity determination are not provided in studies (i) to (iii)
h) tabulated results expressed as % of the applied dose and in mg/kg in water, sediment and total system (% only) for the test material and, if appropriate, for transformation products and non-extractable radioactivity in each replicate test vessel are not provided in studies (i) to (iii);
i) the mass balances during and at the end of the study were not provided in study (i) to (iii);
j) the results of the quantification of released CO_2 and other volatile compounds during and at the end of the study are not provided in studies (i) to (iii);
k) an assessment of transformation kinetics (*i.e.* lag phase, degradation rate constant and degradation half-life) for the test material and, where appropriate, for major transformation products is not provided in studies (i) to (iii).

83 Based on the above,

- there are critical methodological deficiencies resulting in the rejection of the study results. More, specifically studies (i) to (iii) were conducted using only one type of sediment. Furthermore, the test material concentration used to conduct studies (i) and (iii) and most test concentrations in study (ii) did not comply with the test guideline requirements which significantly impacts the reliability of these studies.
- the reporting of the studies (i) to (iii) is not sufficient to conduct an independent assessment of its reliability. You have not provided adequate reporting of the analytical method(s) used to conduct these studies and of the results of the measurements conducted to monitor degradation. In the absence of this information ECHA cannot conduct an independent assessment of the reliability and interpretation of the results.

84 None of the provided studies meets the requirement of the OECD TG 308 and, therefore, this information requirement is not fulfilled.

6.3. Study design and test specifications

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

(1) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and
(2) a kinetic study where the degradation rate constants (and degradation half-lives) of the parent substance and of relevant transformation/degradation products are experimentally determined.

86 In accordance with the specifications of OECD TG 308, you must perform the test using two sediments. One sediment should have a high organic carbon content (2.5-7.5%) and a fine texture, the other sediment should have a low organic carbon content (0.5-2.5%) and a coarse texture. If the Substance may also reach marine waters, at least one of the water-sediment systems should be of marine origin.

87 The required test temperature is 12°C, which corresponds to the average environmental temperature for the EU (Guidance on IRs and CSA, Table R.16-8) and is in line with the applicable test conditions of the OECD TG 308.

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

89 Relevant transformation/degradation products are at least those detected at ≥ 10% of the applied dose at any sampling time or those that are continuously increasing during the study even if their concentrations do not exceed 10% of the applied dose, as this may indicate persistence (OECD TG 308; Guidance on IRs and CSA, Section R.11.4.1.).

7. Bioaccumulation in aquatic species

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

7.1. Information provided

91 You have provided the following information on the Substance:

(i) a bioaccumulation study in fish (aqueous exposure) according to the OECD TG 305 (1996)

(ii) a biomonitoring study of the Substance in 18 marine species representing 4 trophic levels (2004).

7.2. Assessment of information provided

7.2.1. *The provided studies (i) and (ii) are not reliable*

92 To fulfil the information requirement, a study must comply with the OECD TG 305 (Article 13(3) of REACH). Therefore, the following specifications must be met:

93 Key parameters

a) the study covers the following key parameters:
- the uptake rate constant (k_1) and loss rate constants including the depuration rate constant (k_2), and/or
- the steady-state bioconcentration factor (BCF_{SS}), and/or
- the kinetic bioconcentration factor (BCF_K), and/or
- the biomagnification factor (BMF).

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b) the analytical method used for the quantification of the test material in the test solutions and in fish tissues is described. The recovery efficiency, precision, limits of determination (*i.e.* detection and quantification) and working range are reported;

c) the lipid content measured at least before the beginning and at the end of the uptake phase and the method used for its determination are reported;
d) individual fish wet weights and total lengths for all sampling intervals are provided, and be linked to the analysed chemical concentration for that individual. The data are used to correct the BCF (or BMF when determined) for growth dilution;
e) tabulated test material concentration data in individual fish and water (including mean values for test group and control, standard deviation and range, if appropriate) for all sampling times are provided;

95 Your registration dossier provides the studies (i) and (ii) for which the following issues have been identified:

96 Key parameters

a) the parameter monitored in study (ii) is the distribution of the Susbtance in the aquatic food web (18 marine species) from which a food-web magnification factor is estimated. Therefore, it does not correspond to any of the key parameters of the OECD TG 305;

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b) the analytical method used for the quantification of the substance in the solutions and in fish tissues is not described in study (i);
c) the lipid content measured before the beginning and at the end of the uptake phase are not reported in study (i);
d) individual fish wet weights and total lengths for all sampling intervals are not reported in study (i);
e) tabulated test material concentration data in individual fish and water (including mean values for test group and control, standard deviation and range, if appropriate) for all sampling times are not reported in study (i);

98 Based on the above,

- the information provided in study (ii) does not cover the key parameters required foreseen to be investigated in the OECD TG 305;
- the reporting of the study (i) is not sufficient to conduct an independent assessment of its reliability.

99 Therefore, none of the provided studies meet the requirements of the OECD TG 305 and accordingly this information requirement is not met.

7.3. Study design and test specification

100 Bioaccumulation in fish: aqueous and dietary exposure (Method EU C.13 / OECD TG 305) is the preferred test to investigate bioaccumulation (Guidance on IRs and CSA, Section R.7.10.3.1.). Exposure via the aqueous route (OECD TG 305-I) must be conducted unless it can be demonstrated that:

- a stable and fully dissolved concentration of the test material in water cannot be maintained within ± 20% of the mean measured value, and/or
- the highest achievable concentration is less than an order of magnitude above the limit of quantification (LoQ) of a sensitive analytical method.

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

102 You may only conduct the study using the dietary exposure route (OECD 305-III) if you justify and document that testing through aquatic exposure is not technically possible as indicated above. You must then estimate the corresponding BCF value from the dietary test

data according to Annex 8 of the OECD 305 TG and OECD Guidance Document on Aspects of OECD TG 305 on Fish Bioaccumulation (ENV/JM/MONO(2017)16).

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.

The information requirements for simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.) and for soil simulation testing (Annex IX, Section 9.2.1.3) are not addressed in this decision. They may be addressed in a separate decision once the information from the ready biodegradability (Request 2) and sediment simulation testing (Request 6) requested in the present decision is provided.

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

The compliance check was initiated on 07 December 2021.

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: Addressees 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]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.

Appendix 4: Conducting and reporting new tests for REACH purposes

1. Requirements when conducting and reporting new tests for REACH purposes

1.1. Test methods, GLP requirements and reporting

(1) Under Article 13(3) of REACH, all new data generated as a result of this decision must be conducted according to the test methods laid down in a European Commission Regulation or to international test methods recognised by the Commission or ECHA as being appropriate.

(2) Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses must be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.

(3) Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries[2].

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

1.2. Test material

Before generating new data, you must agree within the joint submission on the chemical composition of the material to be tested (Test Material) which must be relevant for all the registrants of the Substance.

(1) Selection of the Test material(s)
The Test Material used to generate the new data must be selected taking into account the following:
- the variation in compositions reported by all members of the joint submission,
- the boundary composition(s) of the Substance,
- the impact of each constituent/ impurity on the test results for the endpoint to be assessed. For example, if a constituent/ impurity of the Substance is known to have an impact on (eco)toxicity, the selected Test Material must contain that constituent/ impurity.

(2) Information on the Test Material needed in the updated dossier
- You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
- The reported composition must include all constituents of each Test Material and their concentration values and other parameters relevant for the property to be tested.

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

This information is needed to assess whether the Test Material is relevant for the Substance and whether it is suitable for use by all members of the joint submission.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[3].

2. General recommendations for conducting and reporting new tests

2.1. Strategy for the PBT/vPvB assessment

Under Annex XIII, the information must be based on data obtained under conditions relevant for the PBT/vPvB assessment. You must assess the PBT properties of each relevant constituent of the Substance present in concentrations at or above 0.1% (w/w) and of all relevant transformation/degradation products. Alternatively, you would have to justify why you consider these not relevant for the PBT/vPvB assessment.

You are advised to consult Guidance on IRs & CSA, Sections R.7.9, R.7.10 and R.11 on PBT assessment to determine the sequence of the tests needed to reach the conclusion on PBT/vPvB. The guidance provides advice on 1) integrated testing strategies (ITS) for the P, B and T assessments and 2) the interpretation of results in concluding whether the Substance fulfils the PBT/vPvB criteria of Annex XIII.

In particular, you are advised to first conclude whether the Substance fulfils the Annex XIII criteria for P and vP, and then continue with the assessment for bioaccumulation. When determining the sequence of simulation degradation testing you are advised to consider the intrinsic properties of the Substance, its identified uses and release patterns as these could significantly influence the environmental fate of the Substance. You must revise your PBT assessment when the new information is available.

[3] https://echa.europa.eu/manuals