ECHA
EUROPEAN CHEMICALS AGENCY

Helsinki, 27 July 2017

Addressee: [redacted]

Decision number: CCH-D-2114366662-44-01/F
Substance name: benzyl 3-(isobutyryloxy)-1-isopropyl-2,2-dimethylpropyl phthalate
EC number: 701-008-3
CAS number: 16883-83-3
Registration number: [redacted]
Submission number: [redacted]
Submission date: 03.12.2015
Registered tonnage band: 1000+T

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (the REACH Regulation), ECHA requests you to submit information on:

1. **In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: Bacterial reverse mutation test, EU B.13/14. / OECD TG 471) using one of the following strains: *E. coli* WP2 uvrA, or *E. coli* WP2 uvrA (pKM101), or *S. typhimurium* TA102 with the registered substance;**

2. **In vitro cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2., test method: OECD TG 473) or in vitro micronucleus study (Annex VIII, Section 8.4.2, test method: OECD TG 487) with the registered substance;**

3. **In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method: OECD TG 476 or TG 490) with the registered substance, provided that both studies requested under 1. and 2. have negative results;**

4. **Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method: EU B.26./OECD TG 408) in rats with the registered substance;**

5. **Pre-natal developmental toxicity study (Annex X, Section 8.7.2.; test method: EU B.31./OECD TG 414) in a second species (rabbit), oral route with the registered substance;**

6. **Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: CO2 evolution test, OECD TG 301B) or**

Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: MITI test (I), OECD TG 301C) or
Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: Closed bottle test, OECD TG 301D) or

Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: Manometric respirometry test, OECD TG 301F) or

Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: Ready biodegradability – CO2 in sealed vessels (headspace test), OECD TG 310)

with the registered substance;

7. **Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: Daphnia magna reproduction test, EU C.20./OECD TG 211) with the registered substance;**

8. **Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method: Fish, early-life stage (FELS) toxicity test, OECD TG 210) with the registered substance;**

9. **Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method: Aerobic mineralisation in surface water – simulation biodegradation test, EU C.25./OECD TG 309) at a temperature of 12 °C with the registered substance. The biodegradation of each relevant constituent present in concentration at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable shall be assessed;**

10. **Soil simulation testing (Annex IX, Section 9.2.1.3.; test method: Aerobic and anaerobic transformation in soil, EU C.23./OECD TG 307) at a temperature of 12 °C with the registered substance. The biodegradation of each relevant constituent present in concentration at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable shall be assessed;**

11. **Sediment simulation testing (Annex IX, Section 9.2.1.4.; test method: Aerobic and anaerobic transformation in aquatic sediment systems, EU C.24./OECD TG 308) at a temperature of 12 °C with the registered substance. The biodegradation of each relevant constituent present in concentration at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable shall be assessed;**

12. **Identification of degradation products (Annex IX, 9.2.3.), using an appropriate test method, with the registered substance;**

13. **Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.; test method: Bioaccumulation in fish: aqueous and dietary exposure, OECD TG 305, aqueous exposure/dietary exposure) with the registered substance; The bioaccumulation potential of each relevant constituent present in concentration at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable shall be assessed;**

14. **Long-term toxicity to terrestrial invertebrates (Annex X, Section 9.4.4.; test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) OECD 222 or Enchytraeid reproduction test OECD 220) with the registered substance;**

15. **Long-term toxicity testing on plants (Annex X, Section 9.4.6.; test method: Terrestrial plants, growth test, OECD 208, with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species) or test method: Soil Quality – Biological Methods – Chronic toxicity in higher plants, ISO 22030) with the registered substance; and**

16. **Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD 216) with the registered substance.**

You may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI to the REACH Regulation. To ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring and conforming to the appropriate rules in the respective annex, and adequate and reliable documentation.

You have to submit the requested information in an updated registration dossier by **5 August 2019. You also have to update the chemical safety report, where** relevant. The timeline has been set to allow for sequential testing.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2 and advice and further observations are provided in Appendix 3.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, has to be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under: http://echa.europa.eu/regulations/appeals.

Authorised[1] by Kevin Pollard, Head of Unit, Evaluation E1

[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

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to X to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

SUBSTANCE PROPERTIES RELATED TO HUMAN HEALTH

You have sought to adapt the information requirements for:

- *In vitro* gene mutation study in bacteria (Annex VII, Section 8.4.1);
- *In vitro* cytogenicity study in mammalian cells or in vitro micronucleus study (Annex VIII, Section 8.4.2.);
- *In vitro* gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.)
- Sub-chronic toxicity (90-day) study (Annex IX, 8.6.2.);
- Pre-natal developmental toxicity study (Annex X, Section 8.7.2.) in a second species; and
- Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.)

by applying a read-across adaptation following REACH Annex XI, Section 1.5.

ECHA notes that a testing proposal has been made for the reproductive toxicity study. The decision on this testing proposal is still pending. Therefore this information requirement is not further discussed in this decision, except to assess the consistency of effects in the data matrix that you provided in support for the read-across hypothesis submitted for other information requirements.

Grouping and read-across approach

Article 13(1) of the REACH Regulation provides that information on intrinsic properties of substances may be generated by means other than tests. Such other means include the use of information from structurally related substances (grouping of substances and read-across), "provided that the conditions set out in Annex XI are met".

Annex XI, Section 1.5. requires a structural similarity among the substances within a group or category such that relevant properties of a substance within the group can be predicted from the data on reference substance(s) within the group by interpolation. The following analysis presents your justification for the proposed grouping approach and read-across hypothesis, together with ECHA's analysis concerning the justification in both a generic and an property-specific context.

Description of the grouping and read-across approach proposed by you

You consider to achieve compliance with the REACH information requirements for the registered substance benzyl 3-(isobutyryloxy)-1-isopropyl-2,2-dimethylpropyl phthalate, CAS No 16883-83-3 (EC No 701-008-3; hereafter referred to as the 'target substance Santicizer 278') using data of the substances 1,2-Benzenedicarboxylic acid, benzyl C7-9-branched and linear alkyl esters, CAS No 68515-40-2 (EC No 271-082-5; hereafter referred to as 'Santicizer 261a'); Benzyl butyl phthalate, CAS No 85-68-7 (EC No 201-622-7; hereafter referred to as 'BBP'); and 1,2-Benzenedicarboxylic acid, di-C8-10 branched alkylesters, C9 rich; Di-'iso'nonyl phthalate, CAS No 68515-48-0 (EC No 271-090-9; hereafter referred to as 'DINP-C9').

Although not explicitly stated, ECHA understands that you are using an analogue approach to predict the properties listed above of the target substance Santicizer 278 based on the available data from the source substances (see above). This prediction assumes that the source and target substances have the similar properties related to human health. ECHA understands this as the hypothesis under which you make predictions for the properties listed above.

Support of the grouping and read-across approach

You have provided a read-across documentation as an attachment in IUCLID, Section 13.

In summary, you provide the following arguments to support the read-across approach:

Source and target substance are structural similar and have similar physico-chemical properties:
"The structures of S261a and S278 are similar, in that they are both have benzyl grouping and one non-cyclic side arm. Reading across to S261a was therefore considered suitable because of the structural similarities as well as the toxicological and physico chemical characteristics as detailed [...] below."

Biological targets of the compounds:

"For the majority of endpoints phthalate esters are considered to have similar and low toxicities – low acute toxicity, lack of irritation to skin or eye, non-sensitising and non-genotoxic. For repeat dose toxicity, phthalate esters have been associated with liver growth following the formation of peroxisomes in the rodent liver. The mode of action involving activation of the peroxisome proliferator– activated receptor-α (PPAR-α) is generally considered to be of low relevance to humans."

"When reviewing the available data to fulfill the REACH information requirements, unlike the majority of toxicological endpoints where there is a strong weight of evidence for consistency of effect and or conclusion, for developmental and reproductive toxicity this was less clear. S278® has differing side chains [...] and consequently it was not considered appropriate to read-across to either the transitional or the high molecular weight phthalate esters, especially as the two closest analogues, BBP and DINP, have given different outcomes in developmental and 2 generation studies [...].

At the time of submission (2010), developmental and reproductive studies had started in the US on the analogue S261a. For S261a [...] the obvious read-across for reproductive

toxicity would be to other well characterised analogues with similar structure, molecular weight, physical properties and metabolites. With regard to reproductive toxicity, existing BBP and DINP data are the most relevant to S261a because of the common hydrolysis products shared by these compounds [...]. However, as noted above, results from the rodent reproductive and developmental studies on BBP and DINP provide dissimilar results."

"The read-across to S261a for developmental and reproductive endpoints may be considered conservative because the non-cyclic side chain on S278 has a higher carbon number and, in general, this has been associated with reduced reproductive and development effects. In addition, because S278 has a significantly higher molecular weight than S261a (454 versus 368), any tolerable S261a dose on a mg/kg bw basis is equimolar with a 20% higher S278 dose expressed in mg/kg bw.
It is concluded that Santicizer® 261a is a suitable read-across surrogate for reproductive and developmental testing of Santicizer® 278."

Data matrix: You have provided a data matrix that lists some of the available studies on the source and target substances. You justify the selection of studies with *"As there is a great deal of information on potential analogues, the following tables do not present all of the available data on the various read-across candidates, but those that are comparable in terms of dose and protocol. In addition there is a very large body of information generally on phthalate esters with many papers on mechanisms of toxicity and the subsequent academic and regulatory reviews."*

In the technical dossier you have provided the following endpoint study records:

Genetic toxicity

i. Key study; experimental results; Reliability 2; GLP; 1982; similar to OECD 471 (Deviations: *"Study did not utilise strains to detect cross-linking agents"*); Strains used: *S. typhimurium* TA 98, TA 100, TA 1535, TA 1537 and TA 1538; Test material: target substance Sanitizer 278 tested up to 10 mg/plate; Conclusion: Negative.
ii. Key study; Read-across from supporting substance (structural analogue or surrogate); Reliability 2; GLP; 2000; according to OECD 471; Strains used: *S. typhimurium* TA 1535, TA 1537 TA 1538, TA 98 and TA 100; Test material: DINP-C9 tested up to 5 mg/plate; Conclusion: Negative.
iii. Key study; Read-across from supporting substance (structural analogue or surrogate); Reliability 2; GLP; 1997; similar to OECD 471 (Deviations: Only 4 strains tested); Strains used: *S. typhimurium* TA 1535, TA 1537, TA 98 and TA 100; Test material: BBP tested up to 11.6 mg/plate; Conclusion: Negative.
iv. Key study; Read-across from supporting substance (structural analogue or surrogate); Reliability 2; non-GLP; 1976; similar to OECD 471 (Deviations: Only 4 strains tested); Strains used: *S. typhimurium* TA 1535, TA 1537, TA 1538 and TA 98; Test material: BBP tested up to 10 mg/plate; Conclusion: Negative.
v. Key study; Read-across from supporting substance (structural analogue or surrogate); Reliability 2; non-GLP; 1977; similar to OECD 476; Test material: BBP up to 5 mg/ml; Conclusion: Negative.

vi. Key study; Read-across from supporting substance (structural analogue or surrogate); Reliability 2; GLP; 1997; similar to EPA OPPTS 870.5300 - In vitro Mammalian Cell Gene Mutation Test; Test material: BBP up to 100 nl/ml; Conclusion: Negative.

vii. Key study; Read-across from supporting substance (structural analogue or surrogate); Reliability 2; non-GLP; 2000; according to Analysis of data from in vitro cytogenetics assays, UKEMS Sub-committee on guidelines for mutagenicity testing, Report Part III. (1989)); Test material: DINP-C9 up to 160 µg/ml; Conclusion: Negative.

viii. Key study; Read-across from supporting substance (structural analogue or surrogate); Reliability 2; GLP; 1997; guideline EPA OPPTS 870.5375 - In vitro Mammalian Chromosome Aberration Test; Test material: BBP up to 1250 µg/ml; Conclusion: Negative.

ix. Key study; Read-across from supporting substance (structural analogue or surrogate); Reliability 2; GLP; 1997; guideline EPA OPPTS 870.5900 - In vitro Sister Chromatid Exchange Assay; Test material: BBP up to 1250 µg/ml; Conclusion: Negative.

Repeated dose toxicity

x. Key study; Read-across from supporting substance (structural analogue or surrogate); Reliability 2 (reliable with restrictions); non-GLP; 1981; similar to OECD 408 (Deviations: "*no ophthalmology examination; no functional observations; limited clinical chemistry examination*"); conducted in rats via oral route (diet) using BBP; doses day corresponding to 0, 2000, 5000 and 12000 ppm, corresponding to 0, 151/171, 381/422, an 960/1069 mg/kg/day for male/female, respectively; the study established a NOAEL at 151 mg/kg/day for systemic toxicity in males.

xi. Key study; Read-across from supporting substance (structural analogue or surrogate); Reliability 2 (reliable with restrictions); non-GLP; 1997; non-guideline (Principle of the test: "*Groups of rats were fed DINP in the diet at up to 0.6% for up to 2 years, and assessed for toxicity and carcinogenicity at 6, 12, 18 and 24 months*"); conducted in rats via oral route (diet) using DINP-C9; doses equivalent to about 0, 17, 175 or 350 mg/kg/day; the study establish a NOAEL at 17 mg/kg/day for systemic toxicity.

xii. Supporting study; Read-across from supporting substance (structural analogue or surrogate); Reliability 2 (reliable with restrictions); GLP; 1999; non-guideline (Principles of the test: "*In male rats, the systemic toxicity (including to the liver and reproductive organs) was assessed following three weeks dietary exposure to the US or EU versions of the phthalate ester, Santicizer(R) 261.*"); conducted in rats via oral route (diet) using Santicizer 261; doses day corresponding to 63.3, 593.1 and 1259 mg/kg bw/day; the study establish a NOAEL at ca. 60 mg/kg/day for systemic toxicity in males.

xiii. Key study; Read-across from supporting substance (structural analogue or surrogate); Reliability 2 (reliable with restrictions); GLP; 1982; similar to OECD 413 (Deviations: "*incomplete exposure schedule; no ophthalmology examination; some details missing from report*"); conducted in rats via inhalation route (whole body; 6 hours per day, 5 days per week) using BBP; doses day corresponding to 0, 0.051, 0.218 or 0.789 mg/l; the study establish a NOAEC at 0.218 mg/l for systemic toxicity.

xiv. Supporting study; Read-across from supporting substance (structural analogue or surrogate); Reliability 2 (reliable with restrictions); GLP; 1982; similar to OECD 412 (Deviations: *"no urinalysis, haematology, clinical chemistry, organ weights or microscopic examination"*); conducted in rats via inhalation route (whole body; 6 hours per day, 5 days per week) using BBP; doses day corresponding to 0, 0.36, 1.0 and 2.1 mg/l; the study establish a NOAEC at 1.0 mg/l for systemic toxicity.

Pre-natal developmental toxicity

xv. Key study; Experimental result; Reliability 1 (reliable without restrictions); GLP; 2014; according to OECD TG 414; conducted in rats via oral route (diet) using the target substance Santicizer 278; Doses: 0, 100, 500, 1000 mg/kg/day; the study established a NOAEL at 500 mg/kg/day for maternal toxicity and 1000 mg/kg/day for teratogenicity.

xvi. No study provided; the endpoint study entry refers to an ongoing developmental toxicity study in rats commissioned by the US producer of Santicizer S261a in 2010.

Toxicity to reproduction

xvii. No study provided; the endpoint study entry refers to an ongoing two-generation study commissioned by the US producer of Santicizer S261a in 2010.

ECHA analysis of the grouping and read-across approach in light of the requirements of Annex XI, 1.5

The source studies listed above include those conducted using BBP and DINP-C9. It is relevant to point out the current regulatory status of these proposed source substances.

ECHA notes that BBP has a harmonised classification (Index No. 607-430-00-3) which includes Repr. Cat. 1B. On this basis the substance was included in the candidate list as a substance of very high concern (SVHC) according to Article 57c. Furthermore, BBP has been grouped together with two other phthalates (Dibutyl phthalate, CAS No 84-74-2 (EC No 201-557-4; hereafter referred to as DBP); and Bis (2-ethylhexyl) phthalate, CAS No 117-81-7 (EC No 204-211-0; hereafter referred to as DEHP)) based on similar concerns and included in Annex XVII of REACH; the uses of the substance are restricted. Moreover; BBP is also included in Annex XIV of REACH (the 'Authorisation List') and the use of the substance requires authorisation before it is used.

ECHA notes that DINP-C9 is grouped together with other phthalates in Annex XVII of REACH in entry 52,[2] which restricts the use of the substances. A recent review[3] concluded in 2013 that DINP has endocrine disrupting properties *("...anti-androgenic potency but may also exhibit its effects through other modes of action")* and affects the fertility. Effects on fertility occur at higher dose levels, with a NOAEL for decreased live birth and survival indices of 622 mg/kg bw/day and a NOAEL of 276 mg/kg bw/day for decreased testicular weights.

With regard to the proposed predictions ECHA has the following observations:

[2] 1,2-Benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich, CAS No 68515-49-1 (EC No 271-091-4; herafter referred to as 'DINP-C10'); Di-"isononyl" phthalate, CAS No 28553-12-0 (EC No 249-079-2; hereafter referred to as 'DINP'); Di-"isodecyl" phthalate CAS No 28553-12-0 (EC No 247-977-1; hereafter referred to as 'DIDP'); and Di-n-octyl phthalate, CAS No 117-84-0 (EC No 204-214-7; hereafter referred to as 'DNOP')

[3] Evaluation of new scientific evidence concerning DINP and DIDP. In relation to entry 52 of Annex XVII to REACH Regulation (EC) No 1907/2006

(i) Bias in the selection of source substances and/or source studies

Annex I, Section 1.1.4 requires "...*that the study or studies giving rise to the highest concern shall be used to establish the DNELs";* In the context of a read-across approach this has two aspects: the selection of the source substance and the selection of the source study.

As you have pointed out yourself there are ("...*great deal of information on potential analogues*..."). ECHA notes that there are numerous potential analogues and numerous other potential source studies. You have not provided justified criteria as to why the analogues selected by you are the most appropriate ones or why such analogues are used to predict some properties but not other properties. You indicate a selection of studies in the matrix based on the comparability of dose and protocol but you have not demonstrated that the source studies used are those which give rise to the highest concern in accordance with Annex I, Section 1.1.4 despite the fact that you are arguing a conservative approach.

ECHA concludes that it is not possible to verify that a) you have selected the source substances which are the most appropriate and b) that the source studies selected are those giving rise to the highest concern as required in Annex I, section 1.1.4.

(ii) Classification and Labelling

Annex IX, Section 1.5. requires that '*If the group concept is applied, substances shall be classified and labeled on this basis*'.

ECHA notes that BBP has a harmonised classification (Index No. 607-430-00-3) which includes Repr. Cat 1B. Your read-across approach assumes that the source and target substances have similar toxicities and you argue that you are following a conservative approach. Furthermore, ECHA notes that you have not self-classified the target substance as Repr. Cat 1B. Moreover, ECHA notes that you use different source substances to predict different properties related to systemic toxicity, *e.g.* for repeated dose toxicity you use the data from BBP and DINP-C9, whereas for toxicity to reproduction you use data to be generated on Santicizer 261a and ignore the available data from the source substances BBP and DINP-9. You state that these source substances cause different effects in reproductive toxicity studies ("... *results from the rodent reproductive and developmental studies on BBP and DINP provide dissimilar results")* but you do not explain why this is a reason to ignore the results or what is the reason why in the absence of data on the registered substance the classification of BBP is not used to classify the registered substance in a conservative approach.

ECHA concludes that the requirements in Annex XI, Section 1.5. with regard to classification and labelling are not met.

(iii) Support of a similar or regular pattern as a result of structural similarity

Annex XI, Section 1.5. provides that "substances whose physicochemical, toxicological and eco-toxicological properties are likely to be similar or follow a regular pattern as result of structural similarity may be considered as a group or 'category' of substances. One prerequisite for a prediction based on read-across therefore is that the substances involved are structurally similar and are likely to have similar properties. One important aspect in this regard is the analysis of the data matrix to compare the properties of source and target substances and to establish whether indeed they are similar or follow a regular pattern.

You argue that the source and target substances are structurally similar and have similar toxicological properties. ECHA acknowledges that the substances have some similarities in that they are 'phthalates'. However, the substances also have structural differences. In respect of these differences, ECHA considers that you have not demonstrated how the properties of the target substance can be predicted from the source substances.

You argue that the source and target substances have similar physico-chemical properties. However, no information has been provided to support this notion. Further, physico-chemical similarity is a prerequisite for applying the grouping and read-across approach, but ECHA does not accept in general or in this specific case that physico-chemical similarity *per se* is sufficient to enable the prediction of properties of a substance.

You assume that source and target substances have similar toxicities and affect the same biological targets. Supporting evidence that this is indeed the case for the target substance Santicizer 278 is not provided. In particular, ECHA notes that there is no study available on the target substance Santicizer 278 that would allow a side by side comparison of the *in vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study; *in vitro* gene mutation; repeated-dose toxicity; or reproductive toxicity. There is an Ames test and a pre-developmental toxicity study available on the target substance, however, no comparison of the results from these studies with the corresponding results available for BBP and DINP-C9 has been provided. In addition, you state that your selected source substances DINP-9 and BBP have different results in reproductive toxicity studies, thereby indicating that the structural analogues you have selected do not have similar toxicities. ECHA notes that you also use different source substances to predict different properties without explaining why a specific source substance is preferred for one property but not for another property. Moreover, ECHA notes that there are repeated dose and toxicity to reproduction studies available for BBP and DINP-C9 (and ongoing for Santicizer 261a) which would allow a side-by-side comparison of the toxicity profiles of the source substances. However, this information, or an explanation for not using this information, is not provided in the dossier.

ECHA concludes that the presented evidence does not support a similar or regular pattern of toxicity as a result of structural similarity. Therefore it cannot be verified that the proposed group/analogue substance(s) can be used to predict properties of the registered substance.

Conclusion on the read-across approach

The adaptation of the standard information requirements for the endpoints: *In vitro* gene mutation study in bacteria (Annex VII, Section 8.4.1.); *In vitro* cytogenicity study in mammalian cells or *in vitro* micronucleus study (Annex VIII, Section 8.4.2.); *In vitro* gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.); Sub-chronic toxicity study (90-day; Annex IX, Section 8.6.2.); and Pre-natal developmental toxicity study in a second species (Annex X, Section 8.7.2.) in the technical dossier is based on the proposed read-across approach examined above. ECHA does not consider the read-across justification to be a reliable basis to predict the properties of the registered substance for the reasons set out above. Thus, the adaptation does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5. Therefore, ECHA rejects the adaptations in the technical dossier for the endpoints higlighted above that are based on Annex XI, Section 1.5.

1. In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.)

An "*in vitro* gene mutation study in bacteria" is a standard information requirement as laid down in Annex VII, Section 8.4.1. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

According to Article 13(3) of the REACH Regulation, tests required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods recognised by the Commission or ECHA.
Other tests may be used if the conditions of Annex XI are met. More specifically, Section 1.1.2 of Annex XI provides that existing data on human health properties from experiments not carried out according to GLP or the test methods referred to in Article 13(3) may be used if the following conditions are met:

(1) Adequacy for the purpose of classification and labelling and/or risk assessment;
(2) Adequate and reliable coverage of the key parameters foreseen to be investigated in the corresponding test methods referred to in Article 13(3);
(3) Exposure duration comparable to or longer than the corresponding test methods referred to in Article 13(3) if exposure duration is a relevant parameter; and
(4) adequate and reliable documentation of the study is provided.

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing four study records for *in vitro* gene mutation studies in bacteria (similar OECD TG 471) with the target substance Santicizer 278 and the source substances BBP and DINP-C9 (see information to support the read-across, Section "Grouping and read-across approach", points i-v above). However, as explained above, your adaptation of the information requirement is rejected. Therefore, the remaining information on this endpoint is the study (see information to support the read-across point i above) which was conducted with the target substance Santicizer 278.

According to paragraph 13 of the current OECD TG 471 test guideline (updated 1997) at least five strains of bacteria should be used: S. typhimurium TA1535; TA1537 or TA97a or TA97; TA98; TA100; S. typhimurium TA102 or E. coli WP2 uvrA or E. coli WP2 uvrA (pKM101). This includes four strains of *S. typhimurium* (TA1535; TA1537 or TA97a or TA97; TA98; and TA100) that have been shown to be reliable and reproducibly responsive between laboratories. These four *S. typhimurium* strains have GC base pairs at the primary reversion site and it is known that they may not detect certain oxidising mutagens, cross-linking agents and hydrazines. Such substances may be detected by E.coli WP2 strains or *S. typhimurium* TA102 which have an AT base pair at the primary reversion site.

You have provided a test from the year 1982 similar to OECD TG 471 and GLP with an assigned reliability score of 2. The test used five different strains of *S. typhimurium* TA TA 98, TA 100, TA 1535, TA 1537 and TA 1538 and it did not include tests with strains S. *typhimurium* TA102 or E. *coli* WP2 uvrA or E. *coli* WP2 uvrA (pKM101). However, since the test was conducted, significant changes have been made to OECD TG guideline 471 so that additionally testing with S. typhimurium TA102 or E. coli WP2 uvrA or E. coli WP2 uvrA (pKM101) is now required. Therefore, the provided study does not meet the current guidelines, nor can it be considered as providing equivalent data according to the criteria in Annex XI, 1.1.2. of the REACH Regulation.

ECHA concludes that a test using *E. coli* WP2 uvrA, or *E. coli* WP2 uvrA (pKM101), or *S. typhimurium* TA102 has not been submitted and that the test using one of these is required to conclude on *in vitro* gene mutation in bacteria.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

ECHA considers that the bacterial reverse mutation test (test method EU B.13/14. / OECD TG 471) is appropriate to address the standard information requirement of Annex VII, Section 8.4.1. of the REACH Regulation.

In your comments on the draft decision you acknowledged that the existing study did not use any of the strains *E. coli* WP2 uvrA, or *E. coli* WP2 uvrA (pKM101), or *S. typhimurium* TA102. You also acknowledged that this information is a standard infromation requirement. However, given what is known about other phtalate esters, you do not believe that the requested data will provide any useful data for hazard evaluation. Therefore, you intend to provide an alternative adaptation, a weight of evidence adaptation for this endpoint.

ECHA Secretariat acknowledges your intention to adapt the standard infromation requirement for this endpoint by means of weight of evidence. A weight of evidence adaptation is considered adequate if the conditions of Annex XI, Section 1.2. are met. ECHA will assess the provided information in light of the standard information requirement once the deadline for providing the requested information has expired.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Bacterial reverse mutation test (test method: EU B.13/14. / OECD TG 471) using one of the following strains: *E. coli* WP2 uvrA, or *E. coli* WP2 uvrA (pKM101), or *S. typhimurium* TA102.

2. In vitro cytogenicity study in mammalian cells or in vitro micronucleus study (Annex VIII, Section 8.4.2.)

An "*in vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study" is a standard information requirement as laid down in Annex VIII, Section 8.4.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing study records using the EPA OPPTS 870.5900 - *In vitro* Sister Chromatid Exchange Assay; EPA OPPTS 870.5375 - In vitro Mammalian Chromosome Aberration Test; and *in vitro* cytogenetics assays, UKEMS Sub-committee on guidelines for mutagenicity testing, Report Part III guidelines (see information to support the read-across, Section "Grouping and read-across approach", points vii-ix above). The studies were conducted using the source substances BBP and DINP-C9. However, as explained above, your adaptation of the information requirement is rejected.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

ECHA considers that the *in vitro* mammalian chromosome aberration test (test method OECD TG 473) and the *in vitro* mammalian cell micronucleus test (OECD TG 487) are appropriate to address the standard information requirement of Annex VIII, Section 8.4.2. of the REACH Regulation.

In your comments on the draft decision you agreed to perform the requested study on the registered substance.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: *In vitro* mammalian chromosome aberration test (test method: OECD TG 473) or *in vitro* mammalian cell micronucleus study (test method: OECD TG 487).

3. In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.)

An "*in vitro* gene mutation study in mammalian cells" is an information requirement as laid down in Annex VIII, Section 8.4.3. of the REACH Regulation, "if a negative result in Annex VII, Section 8.4.1. and Annex VIII, Section 8.4.2." is obtained.
ECHA notes that the registration dossier does not contain appropriate study records for these information requirements. Therefore, adequate information *on in vitro* gene mutation in mammalian cells needs to be present in the technical dossier for the registered substance

to meet this information requirement provided that both studies requested under 1. and 2. (above) have negative results.

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing study records using the OECD TG 476 and EPA OPPTS 870.5300 - *In vitro* Mammalian Cell Gene Mutation Test (see information to support the read-across points v-vi above). The studies were conducted using the source substance BBP. However, as explained above, your adaptation of the information requirement is rejected.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

ECHA considers that the *in vitro* mammalian cell gene mutation tests using the *Hprt* and *xprt* genes (OECD TG 476) and the *in vitro* mammalian cell gene mutation tests using the thymidine kinase gene (OECD TG 490) are appropriate to address the standard information requirement of Annex VIII, Section 8.4.3.

In your comments on the draft decision you agreed to perform the requested study on the registered substance.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: *In vitro* mammalian cell gene mutation test (test method: OECD TG 476 *or* OECD TG 490) provided that both studies requested under 1. and 2. have negative results.

4. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.)

A "sub-chronic toxicity study (90 day)" is a standard information requirement as laid down in Annex IX, Section 8.6.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing study records for a repeated dose toxicity studies with the source substances BBP, DINP-C9, and Santicizer 261 (see supporting information for the read-across, Section "Grouping and read-across approach", points x-xiv above). However, as explained above in this Appendix, your adaptation of the information requirement is rejected.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

ECHA has evaluated the most appropriate route of administration for the study. Based on the information provided in the technical dossier and/or in the chemical safety report, ECHA considers that the oral route - which is the preferred one as indicated in ECHA *Guidance on*

information requirements and chemical safety assessment (version 6.0, July 2017) Chapter R.7a, section R.7.5.4.3 - is the most appropriate route of administration. More specifically, the substance is a liquid of very low vapour pressure and no uses with spray application are reported that could potentially lead to aerosols of inhalable size. Hence, the test shall be performed by the oral route using the test method EU B.26./OECD TG 408.

According to the test method EU B.26./OECD TG 408 the rat is the preferred species. ECHA considers this species as being appropriate and testing should be performed with the rat.

In your comments on the draft decision you agreed to perform the requested study on the registered substance. You also agree that the oral route of exposure is the most suitable for the registered substance.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Repeated dose 90-day oral toxicity study (test method: EU B.26./OECD TG 408) in rats.

5. Pre-natal developmental toxicity study (Annex X, Section 8.7.2.) in a second species

Pre-natal developmental toxicity studies (test method EU B.31./OECD TG 414) on two species are part of the standard information requirements for a substance registered for 1000 tonnes or more per year (Annex IX, Section 8.7.2., column 1, Annex X, Section 8.7.2., column 1, and sentence 2 of introductory paragraph 2 of Annex X of the REACH Regulation).

The technical dossier contains information on a pre-natal developmental toxicity study in rats by the oral route using the target substance Santicizer 278 as test material. This study was conducted based on a testing proposal decision (TPE-D-0000003056-80-05/F). ECHA notes that the study results were not provided by the deadline set and that the enforcement process resulted in a subsequent update (subject also to this decision). This update however, did not contain a robust study summary. Therefore an independent assessment of the results by ECHA could not be performed and the enforcement process is still ongoing.

You have sought to adapt the information requirement for a pre-natal developmental toxicity study in a second species according to Annex XI, Section 1.5. of the REACH Regulation by referring to a pre-natal developmental toxicity study in rat to be conducted with the source substance Santicizer 261a (see supporting information for the read-across Section "Grouping and read-across approach", point xvi above).
ECHA notes that this study is currently not available. In any case, as explained above, your read-across adaptation of the information requirement is rejected.

Furthermore, this read-across proposal was already rejected in the testing proposal decision (TPE-D-0000003056-80-05/F) for the first species. In addition, a pre-natal developmental study in rats has already been conducted on the target substance Santicizer 278. The study with Santicizer 261a is to be conducted in rats. ECHA notes that to meet the information requirement for a pre-natal developmental toxicity study in a second species the test need to be conducted in a species other that rat.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

The test in the first species was carried out by using a rodent species (rat). According to the test method EU B.31./OECD 414, the rabbit is the preferred non-rodent species. On the basis of this default assumption, ECHA considers that the test should be performed with rabbit as a second species.

ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 6.0, July 2017) R.7a, chapter R.7.6.2.3.2. Since the substance to be tested is a liquid, ECHA concludes that testing should be performed by the oral route.
In your comments on the draft decision you agreed to perform the requested study on the registered substance. You also agree that the oral route of exposure is the most suitable for the registered substance.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Pre-natal developmental toxicity study (test method: EU B.31./OECD TG 414) in a second species (rabbit) by the oral route.

SUBSTANCE PROPERTIES RELATED TO THE ENVIRONMENT

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to X to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

Your registration dossier contains for the endpoints of Ready biodegradability (Annex VII, Section 9.2.1.1.); and Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.) adaptation arguments in form of a grouping and read-across approach under Annex XI, Section 1.5. of the REACH Regulation. ECHA has considered first the scientific and regulatory validity of your read-across approach in general before assessing the individual endpoints (see below).

Grouping of substances and read-across approach

You have sought to adapt the information requirements for Ready biodegradability (Annex VII, Section 9.2.1.1.); and Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.) by applying a read-across approach in accordance with Annex XI, Section 1.5. According to Annex XI, Section 1.5. there needs to be structural similarity among the substances within a group or category and furthermore, 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 (read-across approach). Furthermore, Annex XI, Section 1.5. lists several additional requirements, including that adequate and reliable documentation of the applied method have to be provided. You consider to achieve compliance with the REACH information requirements for the registered substance Santicizer 278 (target substance) using data of structurally similar substances bis(2-ethylhexyl) phthalate, CAS No 117-81-7 (EC No 204-

211-0; hereafter referred to as DEHP); bis(8-methylnonyl) phthalate, CAS No 68515-49-1 (EC no 271-091-4; hereafter referred to as DIDP); DINP-C9; and Santicizer 261a (ECHA notes that this last substance is not mentioned in the read-across hypothesis for environmental endpoints).

You have provided read-across documentation "1,2-Benzenedicarboxylic acid, 1-(2,2-dimethyl-1-(1-methylethyl)-3-(2-methyl-1-oxopropoxy)propyl) 2-(phenylmethyl) ester (CAS 16883-83-3) Rationale for the Read-Across Analogue for Mammalian Toxicity Including Developmental and Reproductive Endpoints" ([redacted]) as a separate attachment in section 13 of IUCLID technical dossier. ECHA notes that as indicated in the title the document covers "Mammalian Toxicity Including Developmental and Reproductive Endpoints" and includes data matrices for human health and physicochemical endpoints. In the document neither data nor discussion is provided for environmental endpoints, including those of ready biodegradation and bioaccumulation which you have adapted using a read-across approach.

However, for the endpoints of ready biodegradation and bioaccumulation you have provided a short discussion on the read-across in the technical dossier in the Endpoint summary of Environmental fate and pathways (section 5 of IUCLID), in the Endpoint summary of Biodegradation in water: screening tests (IUCLID section 5.2.1.), in the endpoint summary of Bioaccumulation aquatic/sediment (IUCLID section 5.3.1.) and in the PBT assessment (section 3.2). Some discussion has also been provided in the respective sections of your Chemical Safety Report (CSR).

For the endpoint of ready biodegradation you use the following arguments to support the prediction of properties of the registered substance from data for source substances within the group: *"Due to the structural similarities of other high molecular weight phthalate esters, it is considered appropriate to read-across to DEHP (CAS RN: 117-81-7), DINP (CAS RN: 68515-48-0) and DIDP (CAS RN: 68515-49-1)"* and *"Since the molecular weight and the structure of S278 are similar to these substances, S278 is expected to exhibit similar behaviour and degradation patterns and to therefore be readily biodegradable".*

Under the PBT section in IUCLID you note that *"the structure and physico-chemical properties of Santicizer 278 are such that it would not be expected to behave significantly differently to these related substances."*

For the endpoint of bioaccumulation you consider likewise that *"The molecular weight, structure, and physico-chemical properties of Santicizer 278 are comparable that read-across from these substances is considered appropriate".*

You propose that the source and registered substances are expected to exhibit similar behaviour and degradation patterns and that read-across is considered appropriate for the above-mentioned information requirements.

ECHA considers that this information is your read-across hypothesis.

In the technical dossier you have provided the following endpoint study records:

Ready biodegradability

i. Key study: *"Biodegradation of Phthalic Acid Esters in River Water and Activated*

Sludge", Saeger VW and Tucker ES (1976); Reliability 2; GLP not specified; 'Modified Sturm' procedure, similar to OECD 301B; Test material: DEHP; Result: 86.16 % degradation (CO2 evolution) in 28 days.

ii. Supporting study: "*Shake Flask Biodegradation of 14 Commercial Phthalate Esters*", [redacted] (1984); Reliability 2; GLP not specified; Shake flask method, similar to OECD 301B; Test material: DEHP; Result: >99 % primary degradation (CO2 evolution) in 28 days.

iii. Supporting study: "*Activated sludge biodegradation of 12 commercial phthalate esters*", [redacted] (1985); Reliability 2; GLP not specified; EPA OTS 795.45 (Inherent Biodegradability: Modified SCAS Test for Chemical Substances that are Water Insoluble or Water Insoluble and Volatile), "*equivalent to OECD tests 302A and 302B*"; Test material: DEHP; Result: inherently biodegradable.

iv. Supporting study: "*Shake Flask Biodegradation of 14 Commercial Phthalate Esters*" [redacted] (1984); Reliability 2; GLP not specified; Shake flask method, similar to OECD 301B; Test material: DINP-C9; Result: >99 % primary degradation (CO2 evolution) in 28 days.

v. Supporting study: "*Activated sludge biodegradation of 12 commercial phthalate esters*", O'Grady DP, Howard PH and Werner AF (1985); Reliability 2; GLP not specified; "*equivalent to OECD tests 302A and 302B*"; Test material: DINP-C9; Result: inherently biodegradable.

vi. Supporting study: "*Shake Flask Biodegradation of 14 Commercial Phthalate Esters*", [redacted] (1984); Reliability 2; GLP not specified; Shake flask method, similar to OECD 301B; Test material: DIDP; Result: >99 % primary degradation (CO2 evolution) in 28 days.

vii. Supporting study: "*Activated sludge biodegradation of 12 commercial phthalate esters*", O'Grady DP, Howard PH and Werner AF (1985); Reliability 2; GLP not specified; "*equivalent to OECD tests 302A and 302B*"; Test material: DIDP; Result: inherently biodegradable.

viii. Other information: Report no. ES-79-SS2, 1981 ("*unclear if "Year of test guideline" or "Year of study completion".*"); Reliability not reported; GLP not specified; OECD 302 A (Inherent Biodegradability: Modified SCAS Test); Test material: Santicizer 261a; Result: inherently biodegradable.

ix. Other information: Report no. ES-80-SS6, 1981 ("*unclear if "Year of test guideline" or "Year of study completion".*"); Reliability not reported; GLP not specified; OECD 302 A (Inherent Biodegradability: Modified SCAS Test); Test material: Santicizer 261a; Result: inherently biodegradable.

x. Other information: Report no. ES-80-SS6, 1979 ("*unclear if "Year of test guideline" or "Year of study completion".*"); Reliability not reported; GLP not specified; ASTM shake flask procedure; Test material: Santicizer 261a; Result: 83.31 % degradation after 28 day(s).

These last three studies were conducted with a substance that is not mentioned in the read-across justification. They are listed here for completeness but, since they are marked as 'other information' and no reliability is reported, ECHA could not assess them and/or consider their relevance for the read-across approach.

Bioaccumulation

i. Key study: "*Di-2ethylhexyl phthalate: Residue dynamics and biological effects in Rainbow trout and Fathead minnows*", [redacted] (1976); Reliability 2;

non GLP; similar to OECD TG 305 E; Test material: DEHP; Result: BCF 155 – 886 L/kg (whole body w.w.)

ii. Supporting study; "*Distribution of phthalate esters in a marine aquatic food web: comparison to polychlorinated biphenyls.*", [redacted] (2004); Reliability 1; GLP not specified; marine field study; Test material: DEHP; Result: food-web magnification factor 0.32.

ECHA's evaluation and conclusion

Your proposed adaptation argument is that the similarity in structure and physico-chemical properties between the source and target substances is a sufficient basis for predicting the properties of the substance. This argument is limited and is in principle not capable of being sufficient. You have not provided any other basis for predicting the properties of the target substance. Similarity in structure and physico-chemical properties is a prerequisite for applying the grouping and read-across approach, but ECHA does not accept in general or this specific case that similarity in structure and physico-chemical properties *per se* is sufficient to enable the prediction of environmental (fate) properties of a substance.

This is because similarity in structure and physico-chemical properties does not always lead to predictable or similar environmental (fate) properties. Further elements are needed[4], such as a well-founded hypothesis of (bio)transformation to a common compound(s), or that different compounds have the same type of effect(s) or properties, to allow a prediction of environmental (fate) properties that does not underestimate risks.

Additionally, ECHA has taken into account all of your arguments together. ECHA firstly notes that you have not provided a reasoning as to why these arguments add to one another to provide sufficient basis for read-across. Secondly, ECHA considers that the arguments when taken all together do not provide a basis for predicting the properties of the registered substance. ECHA considers that this grouping and read-across approach does not provide a robust basis whereby the environmental fate may be predicted from data for reference substance(s) within the group, and hence does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5. of the REACH Regulation. Although ECHA did not assess all source studies in detail, ECHA notes that there are specific considerations for key studies of the individual endpoints which also result in a failure to meet the requirement of Annex XI, 1.5, and these are set out under the endpoint concerned below.

Therefore, ECHA rejects all adaptations in the technical dossier that are based on Annex XI, Section 1.5 for the environmental endpoints.

6. Ready biodegradability (Annex VII, Section 9.2.1.1.)

"Ready biodegradability" is a standard information requirement as laid down in Annex IX, section 9.2.1.1. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

[4] Please see for further information ECHA *Guidance on information requirements and chemical safety assessment* (version 1, May 2008), Chapter R.6: QSARs and grouping of chemicals and ECHA's Read-Across Assessment Framework (https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across).

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing study records for ready biodegradation studies on analogue substances DEHP, DINP-C9, Santicizer 261a and DIDP. However, as explained above in this Appendix, your adaptation of the information requirement is rejected.Since ECHA rejects your adaptation, ECHA provides the following general comment on the study summaries of the key study on the source substance you have provided in the technical dossier. For this study ECHA notes that no details on the test material are given apart from "*Commercial grade DEHP (lot QL-1000) prepared by Monsanto Co. PA.*" Further, no information is reported on the 10-day window. Therefore, this source study does not meet the information requirement.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.
Regarding the test method, depending on the substance profile, you may conclude on ready biodegradability, by applying the most appropriate and suitable test guideline among those listed in the ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) and in the paragraph below. The test guidelines include the description of their applicability domain.

In your comments on the draft decision you agreed to perform an OECD TG 301 or OECD 310 study according to a method suitable for the registered substance considering its low water solubility. Depending on the outcome of the ready biodegradation study you propose a tiered testing strategy for the other environmental fate related endpoints requested in this decision. The strategy has been addressed by ECHA under the specific endpoint requests 9.-13., below.
Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to perform one of the following tests with the registered substance subject to the present decision:

Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: CO2 evolution test, OECD TG 301B)
or
Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: MITI test (I), OECD TG 301C)
or
Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: Closed bottle test, OECD TG 301D)
or
Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: Manometric respirometry test, OECD TG 301F)
or
Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: Ready biodegradability – CO2 in sealed vessels (headspace test), OECD TG 310) with the registered substance

7. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)

"Long-term toxicity testing on aquatic invertebrates" is a standard information requirement as laid down in Annex IX, Section 9.1.5. of the REACH Regulation. Adequate information on

this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex IX, Section 9.1.5., column 2. You provided the following justification for the adaptation: "*In accordance with column 2 of REACH Annex IX, the long term testing on fish does not need to be conducted as the chemical safety assessment according to Annex I has not indicated a need to investigate further the effects on aquatic organisms.*"

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.1.5., column 2 because the Chemical Safety Report (CSR) submitted by you as part of the technical dossier does not contain the Exposure Assessment (EA) and the subsequent Risk Characterisation (RC) sections. In absence of this information ECHA considers it not justified to state that the Chemical Safety Assessment (CSA) has not indicated the need to investigate further the effects of the substance on aquatic organisms.

Furthermore, the ECHA Guidance on information requirements and chemical safety assessment (version 4.0, June 2017), Chapter R.7b, page 37, indicates that the need to conduct further testing according to column 2 of Annex IX, section 9.1., may be triggered e.g. when due to low water solubility of a substance, short term toxicity tests do not reveal any toxicity. Therefore, ECHA notes that as no effects were observed in any of the short-term aquatic studies submitted as part of the technical dossier and the substance has a low water solubility (QSAR estimate 0.0015 mg/L), the available data does not allow to conclude on aquatic toxicity. You have not demonstrated that a column 2 adaptation (Annex IX, 9.1.) would be justified.

ECHA acknowledges that in your comments on the draft decision you agreed to perform the OECD TG 211 *Daphnia* reproduction study on the registered substance as a first step of an aquatic testing strategy proposed by you. ECHA has addressed the proposed testing strategy under request 8. below.

Therefore, your adaptation of the information requirement cannot be accepted.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) *Daphnia magna* reproduction test (test method EU C.20. / OECD TG 211) is the preferred test to cover the standard information requirement of Annex IX, Section 9.1.5.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Daphnia magna reproduction test (test method: EU C.20./OECD TG 211).

Notes for your consideration

Once results of the test on long-term toxicity to aquatic invertebrates are available, you shall revise the chemical safety assessment as necessary according to Annex I of the REACH

Regulation.

Due to the low solubility of the substance in water you should consult OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), Chapter R.7b, Table R.7.8-3 summarising aquatic toxicity testing of difficult substances for choosing the design of the requested ecotoxicity test(s) and for calculation and expression of the result of the test(s).

8. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.)

"Long-term toxicity testing on fish" is a standard information requirement as laid down in Annex IX, Section 9.1.6. of the REACH Regulation. Adequate information on Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1.), or Fish, short-term toxicity test on embryo and sac-fry stages (Annex IX, 9.1.6.2.), or Fish, juvenile growth test (Annex IX, 9.1.6.3.) needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex IX, Section 9.1.6., column 2. You provided the following justification for the adaptation: "*In accordance with column 2 of REACH Annex IX, the long term testing on fish does not need to be conducted as the chemical safety assessment according to Annex I has not indicated a need to investigate further the effects on aquatic organisms.*"

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.1.6., column 2 because the Chemical Safety Report (CSR) submitted by you as part of the technical dossier does not contain the Exposure Assessment (EA) and the subsequent Risk Characterisation (RC) sections. In absence of this information ECHA considers it not justified to state that the Chemical Safety Assessment (CSA) has not indicated the need to investigate further the effects of the substance on aquatic organisms.

Furthermore, the ECHA Guidance on information requirements and chemical safety assessment (version 4.0, June 2017), Chapter R.7b, page 37, indicates that the need to conduct further testing according to column 2 of Annex IX, section 9.1., may be triggered e.g. when due to low water solubility of a substance, short term toxicity tests do not reveal any toxicity. Therefore, ECHA notes that as no effects were observed in any of the short-term aquatic studies submitted as part of the technical dossier and the substance has a low water solubility (QSAR estimate 0.0015 mg/L) the available data does not allow to conclude on aquatic toxicity. You have not demonstrated that a column 2 adaptation (Annex IX, 9.1.) would be justified.

In your comments on the draft decision you discuss that as per literature on phthalates, the registered substance has been shown not to be acutely toxic in OECD guideline studies. You consider that based on fugacity modelling the aqueous phase is not a target compartment and hence you intend to follow a sequential testing approach for aquatic testing. As already addressed under request 7. above, you intend to start with the OECD 211 *Daphnia* reproduction study.

Depending on the outcome of the *Daphnia* study and the ready biodegradation study also requested in this decision, you propose the following: You consider that the chronic fish study is not needed if 1) no effects are observed in the *Daphnia* study and the registered substance is readily biodegradable (with/without fulfilling the 10-d window requirement), and 2) if based on a NOEC/LOEC an RCR of below 0.2 is derived. You consider that it is necessary to conduct the long-term fish study if 1) no effects are observed in the *Daphnia* study and the substance is not readily biodegradable (with/without fulfilling the 10-d window requirement), and 2) if based on a NOEC/LOEC an RCR of above 0.2 is derived. You consider the RCR cut-off value of 0.2 to arise from the "*assessment factor difference between two and three chronic NOEC values*".

ECHA acknowledges your testing strategy for aquatic testing and notes the following. As discussed in the paragraphs above, already included in the draft decision submitted to you, absence of toxicity in acute studies for a low water solubility substance cannot be used to conclude on aquatic toxicity. This is further emphasised for a substance with adsorptive properties, such as the registered substance, as the time taken for an equilibrium to be reached and toxic effects to be shown for a low water solubility and adsorptive substance is too long for an effect to be revealed in acute studies. As already outlined in the *Notes for your consideration* section at the end of this request, the Integrated Testing Strategy (ITS) outlined in ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), Chapter R.7b (Section R.7.8.5 including Figure R.7.8-4), is hence not applicable in this case and the long-term studies on both invertebrates and fish need to be conducted.

In your comments you also indicate that based on EPI suite 4.1 fugacity modelling the aqueous compartment is not the compartment of concern as the model indicates that the registered substance partitions to mainly soil and sediment, 44.3 and 55.3 % respectively. According to ECHA *Guidance on information requirements and chemical safety assessment Chapter R.11* (version 3.0, June 2017) and *Chapter R.7b* (version 4.0, June 2017) while distribution modelling may be used to evaluate environmental exposure and compartments of concern, results of such models should be used with care, as the results are strongly dependent of the relative size of the environmental compartments, and the emission parameters employed in the modelling. ECHA notes that you have not provided any further information on the model used and have not indicated whether default or substance specific values were used in deriving the estimates. It is therefore not possible for ECHA to check the validity and applicability of the distribution modelling used. Nevertheless ECHA notes that by default, and also based on the modelled percentages provided, the water compartment receives a significant amount of emissions, either directly or indirectly, and transports/distributes substances through e.g. deposition and run-off. In addition, as no exposure assessment has been submitted as part of the CSA it is not possible for ECHA to assess the expected level of water exposure. ECHA hence considers that multi-media modelling alone cannot be used to conclude that the aquatic compartment is not a compartment of concern and to adapt the present standard information requirement for long-term toxicity testing on fish.

ECHA therefore considers that chronic testing of fish as per Annex VIII section 9.1.3., column 2 and Annex IX section 9.1.6.1. is indicated for the registered substance. Furthermore, ECHA considers that for PNEC derivation data on three trophic levels, on aquatic invertebrates, plants and fish, is needed. This further emphasises that as the acute data cannot be considered as suitable to conclude on the aquatic toxicity of the registered

substance, it is necessary to assess the chronic toxicity on both aquatic invertebrates and fish. For the PNEC derivation you may use a relevant assessment factor as described ECHA *Guidance on information requirements and chemical safety assessment Chapter R.10* (May 2008).

Lastly, ECHA notes that substance being readily biodegradable is not an acceptable adaptation according to Annex IX, section 9.1.6.1. and currently the biodegradation status of the registered substance is unknown.
Therefore, your adaptation of the information requirement cannot be accepted.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017)fish early-life stage (FELS) toxicity test (test method OECD TG 210), fish short-term toxicity test on embryo and sac-fry stages (test method EU C.15. / OECD TG 212) and fish juvenile growth test (test method EU C.14. / OECD TG 215) are the preferred tests to cover the standard information requirement of Annex IX, Section 9.1.6.

However, the FELS toxicity test according to OECD TG 210 is more sensitive than the fish, short-term toxicity test on embryo and sac-fry stages (test method EU C.15 / OECD TG 212), or the fish, juvenile growth test (test method EU C.14. / OECD TG 215), as it covers several life stages of the fish from the newly fertilized egg, through hatch to early stages of growth (see ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), *Chapter R.7b, Figure R.7.8-4).*

Moreover, the FELS toxicity test is preferable for examining the potential toxic effects of substances which are expected to cause effects over a longer exposure period, or which require a longer exposure period of time to reach steady state (ECHA *Guidance Chapter R.7b,* version 4.0, June 2017).

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Fish, early-life stage (FELS) toxicity test (test method: OECD TG 210).

Notes for your consideration

Once results of the test on long-term toxicity to fish are available, you shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation.

ECHA notes that due to low water solubility and lack of effects in short-term studies it is not possible to determine the sensitivity of species. Therefore, the Integrated testing strategy (ITS) outlined in ECHA *Guidance on information requirements and chemical safety assessment* version 4.0, June 2017, Chapter R.7b (Section R.7.8.5 including Figure R.7.8-4), is not applicable in this case and the long-term studies on both invertebrates and fish are requested to be conducted.

Due to the low solubility of the substance in water you should consult OECD Guidance

Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA *Guidance on information requirements and chemical safety assessment* version 4.0, June 2017, Chapter R.7b, Table R.7.8-3 summarising aquatic toxicity testing of difficult substances for choosing the design of the requested ecotoxicity test(s) and for calculation and expression of the result of the test(s).

9. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.)

"Simulation testing on ultimate degradation in water" is a standard information requirement as laid down in Annex IX, section 9.2.1.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have not provided any study record for simulation testing on ultimate degradation in water that would meet the information requirement of Annex IX, Sections 9.2.1.2

Instead, you have sought to adapt this information requirement according to Annex IX, Section 9.2.1.2., column 2. You provided the following justification for the adaptation: "*In accordance with column 2 of REACH Annex IX, the simulation testing on ultimate degradation in surface waters does not need to be conducted as the substance is readily biodegradable.*"

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Column 2 of Annex IX, Sections 9.2 and 9.2.1.2. ECHA notes that you have sought to adapt this information requirement on the basis of ready biodegradability. However, as described in section 6. of this decision, your proposed prediction based on read-across for ready biodegradability (REACH Annex VII, 9.2.1.1) has been evaluated not to meet Annex VII and REACH Annex XI, 1.5 adaptation criteria. Therefore, information compliant with Annex VII Section 9.2.1.1 on ready biodegradability is not present in the dossier and consequently cannot be used for adaptation purposes.

Furthermore, the substance is not highly insoluble in water (QSAR estimate for water solubility is 0.0015 mg/L) whilst the substance uses (wide dispersive uses by consumers and professionals) do not exclude direct and/or indirect exposure of the aquatic compartment.

ECHA notes further that due to lack of information on the degradation of the substance you have not in your Chemical Safety Assessment (CSA) or the technical dossier justified that there is no need to investigate further the degradation of the substance or its degradation products. ECHA considers that the information is needed for the PBT/vPvB assessment and for the identification of the degradation products in relation to the PBT/vPvB assessment.

In your comments on the draft decision you indicate that you intend to undertake a sequential testing programme starting with a ready biodegradation study. You indicate that if the substance is shown to be "*readily biodegradable or biodegradable by more than 60% (based on CO2 evolution) but failing 10-day window*" no further biodegradation testing will be undertaken. ECHA considers this approach acceptable for the purpose of the PBT/vPvB assessment, as outlined in *ECHA Guidance on information requirements and chemical safety assessment*, Chapter R.11, Section R.11.4.1.1 (version 3.0, June 2017). However, ECHA

notes further that if you intend to adapt the current information requirement a scientifically valid justification will need to be provided as to why the CSA (including the PBT assessment) does not indicate the need to study the degradation of the registered substance further.

If the registered substance is not shown to be readily biodegradable, you intend to initiate either a soil simulation (OECD 307) or a sediment simulation (OECD 308) study, and if there is a need to identify the degradation products you intend to use an aromatic ring radio labelled test item. You consider that based on an EPI Suite 4.1 Fugacity model the registered substance partitions to the soil and sediment compartments, 44.3 and 55.3 % respectively, surface water is not a relevant compartment and a test on ultimate degradation in surface water (OECD 309) is therefore not applicable. However, as fully discussed under request 8. above, ECHA considers that distribution modelling alone cannot be used to adapt standard information requirements relating to testing the surface water compartment. ECHA considers that as by default the surface water compartment receives a significant amount of emission, a testing strategy on simulation testing should always start with the OECD 309 simulation study specifically for simulation testing ECHA notes that as long as it is technically feasible to conduct the simulation surface water study. Also, the potential for formation of non-extractable residues (NERs) is minimised in a water simulation study, while especially for an adsorptive substance, NER formation in soil and sediment studies may be difficult to interpret.

Nevertheless, ECHA notes that if it is considered that assessing the persistency of the substance in water is not relevant and soil and/or sediment simulation studies are more applicable, you shall provide a full scientific justification as to why based on the registered substance properties, fate and use patterns and any other relevant information water testing is not technically feasible and/or not relevant for the registered substance.

While you indicate that you will conduct either a soil or sediment simulation study you do not indicate when you consider both may be needed. ECHA notes that once it is possible to conclude on P for all compartments, including assessing P for all constituents and any potential transformation and/or degradation products, no further testing is needed. On the contrary, if based on a simulation study conducted it is not possible to conclude the P assessment for all compartments, further simulation testing may be needed.

Concerning the timeline, in your comments on the draft decision, ECHA notes that you have commented on the timeline given in this decision. You indicate that you would need 24 months to undertake the sequential environmental fate testing, but you have not demonstrated its inappropriateness or required (with any justification) an extension. ECHA considers that a deadline of 24 months is a reasonable time period for providing the required information in the form of an updated registration from the date of the adoption of the decision.

Therefore, your adaptation of the information requirement cannot be accepted.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017)Aerobic mineralisation in surface water – simulation

biodegradation (test method EU C.25. / OECD TG 309) is the preferred test to cover the standard information requirement of Annex IX, Section 9.2.1.2.

One of the purposes of the simulation test is to provide the information that must be considered for assessing the P/vP properties of the registered substance in accordance with Annex XIII of the REACH Regulation to decide whether it is persistent in the environment. Annex XIII also indicates that "*the information used for the purposes of assessment of the PBT/vPvB properties shall be based on data obtained under relevant conditions*". The Guidance on information requirements and chemical safety assessment R.7b (version 4.0, June 2017) specifies that simulation tests "attempt to simulate degradation in a specific environment by use of indigenous biomass, media, relevant solids [...], and a typical temperature that represents the particular environment". The Guidance on information requirements and chemical safety assessment Chapter R.16 on Environmental Exposure Estimation, Table R.16-8 (version 3.0 February 2016) indicates 12°C (285K) as the average environmental temperature for the EU to be used in the chemical safety assessment. Performing the test at the temperature of 12°C is within the applicable test conditions of the Test Guideline OECD TG 309. Therefore, the test should be performed at the temperature of 12°C.

In the OECD TG 309 Guideline two test options, the "pelagic test" and the "suspended sediment test", are described. ECHA considers that the pelagic test option should be followed as that is the recommended option for P assessment. The amount of suspended solids in the pelagic test should be representative of the level of suspended solids in EU surface water. The concentration of suspended solids in the surface water sample used should therefore be approximately 15 mg dw/L. Testing natural surface water containing between 10 and 20 mg SPM dw/L is considered acceptable. Furthermore, when reporting the non-extractable residues (NER) in your test results you are requested to explain and scientifically justify the extraction procedure and solvent used obtaining a quantitative measure of NER.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Aerobic mineralisation in surface water – simulation biodegradation test (test method: EU C.25./OECD TG 309); The biodegradation of each relevant constituent present in concentration at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable shall be assessed. This can be done simultaneously during the same study.

10. Soil simulation testing (Annex IX, Section 9.2.1.3.)

"Soil simulation testing" is a standard information requirement as laid down in Annex IX, section 9.2.1.3. of the REACH Regulation for substances with a high potential for adsorption to soil. The registered substance has low water solubility (0.0015 mg/L), high partition coefficient (calculated log Kow 7) and high adsorption coefficient (calculated log Koc,soil 5.383), indicating high adsorptive properties. Therefore, adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have not provided any study record of soil simulation testing of the registered substance in the registration dossier.

You have sought to adapt this information requirement according to Annex IX, Section 9.2. You provided the following justification for the adaptation: "*In accordance with column 2 of REACH Annex IX, the soil simulation testing does not need to be conducted as the substance is readily biodegradable.*"

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Column 2 of Annex IX, Sections 9.2 and 9.2.1.3 due to the following.

ECHA notes that you have sought to adapt this information requirement on the basis of ready biodegradability. However, as described in section 6. of this decision, your proposed prediction based on read-across for ready biodegradability (REACH Annex VII, 9.2.1.1) has been evaluated not to meet Annex VII and REACH Annex XI, 1.5 adaptation criteria. Therefore, information compliant with Annex VII Section 9.2.1.1 on ready biodegradability is not present in the dossier and consequently cannot be used for adaptation purposes. Regarding the exposure to soil, the substance has a low water solubility of (0.0015 mg/L), high partition coefficient (calculated log Kow 7) and high adsorption coefficient (calculated log Koc,soil 5.383) indicating adsorptive properties. Furthermore, based on the uses reported in the technical dossier, ECHA considers that such uses are reported for which soil exposure cannot be excluded (wide dispersive outdoor uses by consumers (ERCs 8f and 10a) and wide dispersive indoor uses by professional users (ERCs 8a, 8b) and consumers (ERCs 8c and 11a)). ECHA therefore considers that you have not demonstrated that soil exposure is unlikely.

ECHA notes further that due to lack of information on the degradation of the substance you have not in your Chemical Safety Assessment (CSA) or the technical dossier justified that there is no need to investigate further the degradation of the substance or its degradation products. ECHA considers that the information is needed for the PBT/vPvB assessment and for the identification of the degradation products in relation to the PBT/vPvB assessment.

Therefore, your adaptation of the information requirement cannot be accepted.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) Aerobic and anaerobic transformation in soil (test method EU C.23. / OECD TG 307) is the preferred test to cover the standard information requirement of Annex IX, Section 9.2.1.3.

One of the purposes of the simulation test is to provide the information that must be considered for assessing the P/vP properties of the registered substance in accordance with Annex XIII of REACH Regulation to decide whether it is persistent in the environment. Annex XIII also indicates that "*the information used for the purposes of assessment of the PBT/vPvB properties shall be based on data obtained under relevant conditions*". The Guidance on information requirements and chemical safety assessment R.7b (version 4.0, June 2017) specifies that simulation tests "attempt to simulate degradation in a specific environment by use of indigenous biomass, media, relevant solids [...], and a typical temperature that represents the particular environment". The Guidance on information requirements and chemical safety assessment Chapter R.16 on Environmental Exposure

Estimation, Table R.16-8 (version 3.0 February 2016) indicates 12°C (285K) as the average environmental temperature for the EU to be used in the chemical safety assessment. Performing the test at the temperature of 12°C is within the applicable test conditions of the Test Guideline OECD TG 307. Therefore, the test should be performed at the temperature of 12°C.

Simulation tests performed in sediment or in soil possibly imply the formation of non-extractable residues (NER). These residues (of the parent substance and/or transformation products) are bound to the soil or to the sediment particles. NERs may potentially be re-mobilised as parent substance or transformation product unless they are irreversibly bound by covalent bonds or incorporated into the biomass. When reporting the non-extractable residues (NER) in your test results you are requested to explain and scientifically justify the extraction procedure and solvent used obtaining a quantitative measure of NER.

In your comments on the draft decision (DD) you indicate that you intend to undertake a sequential testing programme starting with a ready biodegradation study and continuing with soil and/or sediment simulation testing if necessary. ECHA has addressed your sequential testing strategy fully under section 9. above. Furthermore, ECHA notes that if you intend to adapt the current information requirement a scientifically valid justification will need to be provided as to why the CSA does not indicate the need to study the degradation of the substance further.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Aerobic and anaerobic transformation in soil (test method: EU C.23./OECD TG 307). The biodegradation of each relevant constituent present in concentration at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable shall be assessed. This can be done simultaneously during the same study,

11. Sediment simulation testing (Annex IX, Section 9.2.1.4.)

"Sediment simulation testing" is a standard information requirement as laid down in Annex IX, section 9.2.1.4. of the REACH Regulation for substances with a high potential for adsorption to sediment. The registered substance has low water solubility (0.0015 mg/L), high partition coefficient (calculated log Kow 7) and high adsorption coefficient (calculated log Koc 5.383), indicating high adsorptive properties. Therefore, adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have not provided any study record of sediment simulation testing of the registered substance in the registration dossier.

Whilst the biodegradation section of the technical dossier does not contain a specific adaptation in accordance with column 2 of Annex IX, Section 9.2 or 9.2.1.4. or with the general rules of Annex XI for this standard information requirement, you have provided an adaptation based on ready biodegradation for the other standard information requirements of Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.) and 1. Soil simulation testing (Annex IX, Section 9.2.1.3.). As discussed above in sections 9. and 10., this adaptation cannot be accepted as the registered substance cannot be considered readily biodegradable. For the same reason, ECHA considers that there is also an

information gap for the present endpoint of Sediment simulation testing (Annex IX, Section 9.2.1.4.).
Regarding exposure of sediment, the substance has a low water solubility of (0.0015 mg/L), high partition coefficient (calculated log Kow 7) and high adsorption coefficient (calculated log Koc 5.383) indicating adsorptive properties. Furthermore, based on the uses reported in the technical dossier, ECHA considers that such uses are reported for which sediment exposure cannot be excluded (wide dispersive outdoor uses by consumers (ERCs 8f and 10a) and wide dispersive indoor uses by professional users (ERCs 8a, 8b) and consumers (ERCs 8c and 11a)) and also that the exposure estimations that you provided in the Chemical Safety Report (CSR) indicate that there is exposure to sediment in number of your exposure scenarios. ECHA therefore considers that you have not demonstrated that sediment exposure is unlikely.

ECHA notes further that due to lack of information on the degradation of the substance you have not in your Chemical Safety Assessment (CSA) or the technical dossier justified that there is no need to investigate further the degradation of the substance or its degradation products. ECHA considers that the information is needed for the PBT/vPvB assessment and for the identification of the degradation products in relation to the PBT/vPvB assessment.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) Aerobic and anaerobic transformation in aquatic sediment systems (test method EU C.24. / OECD TG 308) is the preferred test to cover the standard information requirement of Annex IX, Section 9.2.1.4.

One of the purposes of the simulation test is to provide the information that must be considered for assessing the P/vP properties of the registered substance in accordance with Annex XIII of REACH Regulation to decide whether it is persistent in the environment. Annex XIII also indicates that "*the information used for the purposes of assessment of the PBT/vPvB properties shall be based on data obtained under relevant conditions*". The Guidance on information requirements and chemical safety assessment R.7b (version 4.0, June 2017) specifies that simulation tests "attempt to simulate degradation in a specific environment by use of indigenous biomass, media, relevant solids [...], and a typical temperature that represents the particular environment". The Guidance on information requirements and chemical safety assessment Chapter R.16 on Environmental Exposure Estimation, Table R.16-8 (version 3.0 February 2016) indicates 12°C (285K) as the average environmental temperature for the EU to be used in the chemical safety assessment. Performing the test at the temperature of 12°C is within the applicable test conditions of the Test Guideline OECD TG 308. Therefore, the test should be performed at the temperature of 12°C.

Simulation tests performed in sediment or in soil possibly imply the formation of non-extractable residues (NER). These residues (of the parent substance and/or transformation products) are bound to the soil or to the sediment particles. NERs may potentially be re-mobilised as parent substance or transformation product unless they are irreversibly bound by covalent bonds or incorporated into the biomass. When reporting the non-extractable

residues (NER) in your test results you are requested to explain and scientifically justify the extraction procedure and solvent used obtaining a quantitative measure of NER.

In your comments on the draft decision (DD) you indicate that you intend to undertake a sequential testing programme starting with a ready biodegradation study and continuing with soil and/or sediment simulation testing if necessary. ECHA has addressed your sequential testing strategy fully under section 9. above. Furthermore, ECHA notes that if you intend to adapt the current information requirement a scientifically valid justification will need to be provided as to why the CSA does not indicate the need to study the degradation of the substance further.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Aerobic and anaerobic transformation in aquatic sediment systems (test method: EU C.24./OECD TG 308). The biodegradation of each relevant constituent present in concentration at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable shall be assessed. This can be done simultaneously during the same study.

Notes for your consideration concerning requests 9, 10, 11.

Before conducting the requested tests you are advised to consult the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.7b, Sections R.7.9.4 and R.7.9.6 (version 4.0, June 2017) and Chapter R.11, Section R.11.4.1.1 (version 3.0, June 2017) on PBT assessment to determine the sequence in which the simulation tests are to be conducted and the necessity to conduct all of them. The order in which the simulation biodegradation tests are performed needs to take into account the intrinsic properties of the registered substance and the identified use and release patterns which could significantly influence the environmental fate of the registered substance.

In accordance with Annex I, Section 4, of the REACH Regulation you should revise the PBT assessment when results of the tests detailed above is available. You are also advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 3.0, June 2017), Chapter R.11, Section R.11.4.1.1. and Figure R.11-3 on PBT assessment for the integrated testing strategy for persistency assessment in particular taking into account the degradation products of the registered substance.

12. Identification of degradation products (Annex IX, 9.2.3.)

The identification of the degradation products is a standard information requirement according to column 1, Section 9.2.3. of Annex IX of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

The biodegradation section in the technical dossier does not contain any information in relation to the identification of degradation products, nor an adaptation in accordance with column 2 of Annex IX, Sections 9.2 or 9.2.3. or with the general rules of Annex XI for this standard information requirement. "

As explained fully in sections 9., 10. and 11. above, ECHA considers that with the current information gaps the Chemical Safety Assessment cannot be used to justify that there is no need to investigate further the degradation of the substance and its degradation products. ECHA notes further that the information requested here is needed for the PBT/vPvB assessment and for the identification of the degradation products in relation to the PBT/vPvB assessment.

Regarding appropriate and suitable test method, the methods will have to be substance-specific. When analytically possible, identification, stability, behaviour, molar quantity of metabolites relative to the parent compound should be evaluated. In addition, degradation half-life, log Kow and potential toxicity of the metabolite may be investigated. You may obtain this information from the simulation study also requested in this decision, or by some other measure. You will need to provide a scientifically valid justification for the chosen method.

ECHA notes that as briefly addressed in request 9. above, in your comments on the draft decision you indicate that if the registered substance is not shown to be readily biodegradable and there is a need to identify the degradation products, you intend to potentially use an aromatic ring radio labelled test item in the simulation study(ies) to be conducted. ECHA notes that any approach used to identify the transformation and/or degradation products will need to be scientifically justified. ECHA notes further that if you intend to adapt the current information requirement a scientifically valid justification will likewise need to be provided as to why the CSA does not indicate the need to identify the transformation and/or degradation products of the registered substance.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision:

Identification of the degradation products (Annex IX, Section 9.2.3.) by using an appropriate and suitable test method, as explained above in this section.

Notes for your consideration

Before providing the above information you are advised to consult the ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), Chapter R.7b., Sections R.7.9.2.3 and R.7.9.4. These guidance documents explain that the data on degradation products is only required if information on the degradation products following primary degradation is required in order to complete the chemical safety assessment. Section R.7.9.4. further states that when substance is not fully degraded or mineralised, degradation products may be determined by chemical analysis.

13. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.)

"Bioaccumulation in aquatic species, preferably fish" is a standard information requirement as laid down in Annex IX, Section 9.3.2.of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex XI, Section 1.5.

of the REACH Regulation by providing study records for ready biodegradation studies on analogue substances DEHP. However, as explained above in this Appendix, your adaptation of the information requirement is rejected.
Since ECHA rejects your adaptation, ECHA did not assess in detail the study summaries of the source studies you have provided in the technical dossier. However, ECHA does note that for the key source study you have not provided details on the test material other than "*carbonyl-14C-labelled DEHP*". Further, you have not provided information on parameters such as pre-treatment, acclimation of test species, duration of uptake and depuration phase, feeding, photoperiod, light intensity, dissolved oxygen concentrations, number of animals per concentration, loading rate. Therefore, this source study does not meet the information requirement.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7c* (version 3.0, June 2017) bioaccumulation in fish: aqueous and dietary exposure (test method EU C.13. / OECD TG 305) is the preferred test to cover the standard information requirement of Annex IX, Section 9.3.2. ECHA Guidance defines further that results obtained from a test with aqueous exposure can be used directly for comparison with the B and vB criteria of Annex XIII of REACH Regulation and can be used for hazard classification and risk assessment. Comparing the results of a dietary study with the REACH Annex XIII B and vB criteria is more complex and has higher uncertainty. Therefore, the aqueous route of exposure is the preferred route and shall be used whenever technically feasible. If you decide to conduct the study using the dietary exposure route, you shall provide scientifically valid justification for your decision.

You shall also attempt to estimate the corresponding BCF value from the dietary test data by using the approaches given in Annex 8 of the OECD 305 TG. In any case you shall report all data derived from the dietary test as listed in the OECD 305 TG.
In your comments on the draft decision you indicate that you intend to undertake a sequential testing programme for the environment fate related information requirements requested in this decision.You state that you consider the biaoccumulation study is needed only in the case the degradation studies would show the registered substance and/or its degradation products to be P. ECHA acknowledges that if the registered substance and/or its degradation products is not P, there is no need to study further the PBT properties of the substance.ECHA notes further that if you intend to adapt the current information requirement a scientifically valid justification will need to be provided as to why the CSA does not indicate the need to study the bioaccumulation of the substance.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision Bioaccumulation in fish: aqueous or dietary bioaccumulation fish test (test method: OECD TG 305); The bioaccumulation potential of each relevant constituent present in concentration at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable shall be assessed. This can be done simultaneously during the same study.

Notes for your consideration

Before conducting the above test you are advised to consult the ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, June 2017), Chapter R.11.4. and Figure R.11-4 on the PBT assessment for further information on the integrated testing strategy for the bioaccumulation assessment of the registered substance. You should revise the PBT assessment when information on bioaccumulation is available.

14. Long-term toxicity to terrestrial invertebrates (Annex X, Section 9.4.4.)

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annexes IX and X, section 9.4., of the REACH Regulation. Adequate information on effects on soil micro-organisms (Annex IX, section 9.4.2.), short-term toxicity testing on invertebrates (Annex IX, section 9.4.1.), long-term toxicity testing on invertebrates (Annex X, section 9.4.4.), short-term toxicity testing on plants (Annex IX, section 9.4.3.) and long-term toxicity testing on plants (Annex X, section 9.4.6.) needs to be present in the technical dossier for the registered substance to meet the information requirements.

You have sought to adapt the standard information requirement of Annex IX section 9.4.1. by providing the following justification for an adaptation: "*No data is available for this endpoint. In the absence of such studies the guidance states that the PNEC soil may be calculated using the equilibrium partitioning method. However, as the aquatic PNEC is greater than the water solubility of the test substance toxicity is not expected, and a PNEC soil is not calculated.*"

ECHA notes that as identified in ECHA Guidance on information requirements and chemical safety assessment Chapter R.7c (version 3.0, June 2017) particularly for poorly soluble substances it is not normally possible to derive a robust PNEC for the purposes of a soil screening assessment from acute aquatic toxicity testing showing no effect. Therefore, as no predicted aquatic no effect concentration (PNECaqua) has been derived for this substance the Equilibrium Partitioning Method cannot be used to derive screening PNEC terrestrial. Furthermore, according to ECHA Guidance R.7c (version 3.0, June 2017) as the water solubility of the substance is less than 1 mg/l, the absence of acute aquatic toxicity is not a reliable indicator for potential effects on soil organism due to the low exposure in the aquatic test. Therefore ECHA concludes that lack of effects in an acute aquatic study alone cannot be used to adapt the standard information requirement for terrestrial testing.

Therefore, your adaptation of the information requirement cannot be accepted.

You have furthermore sought to adapt the standard information requirement of Annex X section 9.4.4. by providing the following justification for an adaptation: "*In accordance with column 2 of REACH Annex X, the long term toxicity testing on invertebrates study does not need to be conducted as the chemical safety assessment according to Annex I has not indicated a need to investigate further the effects of the substance and/or degradation products on terrestrial organisms.*"

ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex X section 9.4.4. because of the following. You have not provided an exposure assessment (EA) and risk characterisation (RC) for the environment in your Chemical Safety Report, whilst in section 3.5 of the IUCLID technical dossier it is indicated that the substance has

wide dispersive outdoor uses by consumers (ERCs 8f and 10a) and wide dispersive indoor uses by professional users (ERCs 8a, 8b) and consumers (ERCs 8c and 11a). On this basis ECHA considers it not justified to state that the Chemical Safety Assessment has not indicated the need to investigate further the effects of the substance and/or its degradation products on terrestrial organisms.

In your comments on the draft decision you indicate that you intend to undertake a sequential testing programme starting with the soil microorganisms study (OECD 216) and continuing with the earthworm reproduction test (OECD 220) if toxicity is observed in the OPECD 216 study. ECHA notes that as discussed in the *Notes for your consideration* section at the end of request 17. below, the soil microorganisms study is not considered to be part of the integrated terrestrial testing strategy outlined in section R.7.11.6., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, June 2017). Therefore, ECHA notes that the outcome of the soil microorganisms study cannot be used to adapt the present information requirement of Long-term toxicity to terrestrial invertebrates (Annex X, Section 9.4.4.). As fully outlined in the *Notes for your consideration* section depending on the results obtained from the aquatic long-term studies requested above you may apply the terrestrial ITS given in ECHA *Guidance on information requirements and chemical safety assessment* (Chapter R.7c, version 3.0, June 2017). However, due to substance being adsoprtive at least one long-term terrestrial study needs to be conducted. ECHA considers it appropriate to start with the soil invertebrate study as according to ECHA *Guidance on information requirements and chemical safety assessment* (Chapter R.7c, version 3.0, June 2017) if only one chronic study is conducted, in absence of selective toxicity an invertebrate study is preferred.

Concerning the timeline, in your comments on the draft decision, ECHA notes that you have commented on the timeline given in this decision. You indicate that 24 months is required to undertake all three aquaitc tests in a sequential manner, but you have not demonstrated its inappropriateness or required (with any justification) an extension. ECHA considers that a deadline of 24 months is a reasonable time period for providing the required information in the form of an updated registration from the date of the adoption of the decision.

Therefore, your adaptation of the information requirement cannot be accepted.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

The earthworm reproduction test (OECD TG 222), Enchytraeid reproduction test (OECD TG 220), and Collembolan reproduction test (OECD TG 232) are each considered capable of generating information appropriate for the fulfilment of the information requirements for long-term toxicity testing to terrestrial invertebrates. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity and substance properties. You are to apply the most appropriate and suitable test guideline among those listed above. However ECHA notes that when log Kow >5 and log Koc >4, as in this case, the test OECD 232 is not appropriate as the dominant route of exposure for Collembolans is via pore water.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision:
Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) (test method: OECD TG 222), or
Enchytraeid reproduction test (test method: OECD TG 220).

15. Long-term toxicity to plants (Annex X, Section 9.4.6.)

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annexes IX and X, section 9.4., of the REACH Regulation. Adequate information on effects on soil micro-organisms (Annex IX, section 9.4.2.), short-term toxicity testing on invertebrates (Annex IX, section 9.4.1.), long-term toxicity testing on invertebrates (Annex X, section 9.4.4.), short-term toxicity testing on plants (Annex IX, section 9.4.3.) and long-term toxicity testing on plants (Annex X, section 9.4.6.) needs to be present in the technical dossier for the registered substance to meet the information requirements.

You have sought to adapt the standard information requirement of Annex IX section 9.4.3. by providing the following justification for an adaptation: "*In accordance with column 2 of REACH Annex IX, the short term toxicity to plants study does not need to be conducted as the Equilibrium Partitioning Method may be applied from the available aquatic data to assess the hazard to terrestrial plants.*"

ECHA notes that no predicted aquatic no effect concentration (PNECaqua) has been derived for this substance. Therefore, as already stated above in section 14. above, the EPM cannot be used to assess the hazard to terrestrial organisms. Therefore, the adaptation proposed by you cannot be accepted.

You have furthermore sought to adapt the standard information requirement of Annex X section 9.4.6. by providing the following justification for an adaptation: "*In accordance with column 2 of REACH Annex X, the long term toxicity testing on plants study does not need to be conducted as the chemical safety assessment according to Annex I has not indicated a need to investigate further the effects of the substance and/or degradation products on terrestrial organisms.*"

ECHA points out that as fully explained in section 15 above whilst wide dispersive outdoor/indoor uses have been identified in IUCLUID section 3.5 and no EA or RC sections have been submitted as part of the Chemical Safety Assessment, it is not justified to state that the CSA has not indicated the need to investigate further the effects of the substance and/or its degradation products on terrestrial organisms.

In your comments on the draft decision you indicate that you intend to undertake a sequential testing programme starting with the soil microorganisms study (OECD 216) and continuing with the earthworm reproduction test (OECD 220) if toxicity is observed. ECHA has addressed your proposed strategy fully under request 14. above. In summary, the soil microorganisms study is not considered to be part of the integrated terrestrial testing strategy outlined in section R.7.11.6., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, June 2017). Therefore, ECHA notes that the outcome of the soil microorganisms study cannot be used to adapt the present information requirement. The adaptation possibilities that may be used by you for

the present endpoint pending the outcome of other studies requested in this decision have been outlined in the *Notes for your consideration* section at the end of request 17. below.

Therefore, the adaptations proposed by you to cover the information requirements of Annex IX, 9.4.3 and Annex X, 9.4.6 cannot be accepted.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

The Terrestrial plants growth test (OECD 208), (subject to the conditions outlined below) and the Soil Quality – Biological Methods – Chronic toxicity in higher plants test (ISO 22030) are each considered capable of generating information appropriate for the fulfilment of the information requirements for long-term toxicity testing on plants (Annex X, 9.4.6.) and at the same time to fulfil the information requirement of Annex IX, 9.4.3.

OECD guideline 208 (Terrestrial plants, growth test) considers the need to select the number of test species according to relevant regulatory requirements, and the need for a reasonably broad selection of species to account for interspecies sensitivity distribution. For long-term toxicity testing, ECHA considers six species as the minimum to achieve a reasonably broad selection. The long-term toxicity testing shall be conducted with species from different families, as a minimum with two monocotyledonous species and four dicotyledonous species, selected according to the criteria indicated in the OECD 208 guideline. You should consider if testing on additional species is required to cover the information requirement.

Therefore, pursuant to Article 41(3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance:
Long-term toxicity to plants (Annex X, 9.4.6.): test method: Terrestrial plants, growth test (OECD 208), with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species) or test method: Soil Quality – Biological Methods – Chronic toxicity in higher plants (ISO 22030).

16. Effects on soil micro-organisms (Annex IX, Section 9.4.2.)

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annexes IX and X, section 9.4., of the REACH Regulation. Adequate information on effects on soil micro-organisms (Annex IX, section 9.4.2.), short-term toxicity testing on invertebrates (Annex IX, section 9.4.1.), long-term toxicity testing on invertebrates (Annex X, section 9.4.4.), short-term toxicity testing on plants (Annex IX, section 9.4.3.) and long-term toxicity testing on plants (Annex X, section 9.4.6.) needs to be present in the technical dossier for the registered substance to meet the information requirements.

You have sought to adapt the standard information requirement of Annex IX section 9.4.2. by providing the following justification for an adaptation: *"In accordance with column 2 of REACH Annex IX, the effects on soil microorganisms study does not need to be conducted as the Equilibrium Partitioning Method may be applied from the available aquatic data to assess the hazard to soil microorganisms."*

ECHA notes that no predicted aquatic no effect concentration (PNECaqua) has been derived for this substance. Therefore, as already stated above in sections 14. and 15. above the EPM cannot be used to assess the hazard to terrestrial organisms. Furthermore, ECHA emphasises that the intrinsic properties of soil microbial communities are not addressed through the EPM extrapolation method and therefore the potential adaptation possibility outlined for the information requirement of Annex IX, Section 9.4. does not apply for the present endpoint.

Therefore, the adaptation proposed by you to cover the information requirement of Annex IX, 9.4.2 cannot be accepted.

In your comments on the draft decision you indicate that you intend to undertake a sequential testing programme to fulfil the terrestrial information requirements starting with the soil microorganisms study (OECD 216) and continuing with the earthworm reproduction test (OECD 220) if toxicity is observed. ECHA has addressed your proposed strategy fully under request 14. above. In summary, and as also indicated in this section above, the soil microorganisms study is not considered to be part of the integrated terrestrial testing strategy outlined in section R.7.11.6., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, June 2017) and it is in any case necessary to provide data on this endpoint.

As explained above, the information requirement is not met. Consequently there is an information gap and it is necessary to provide information for this endpoint.

Therefore, pursuant to Article 41(3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance: Effects on soil micro-organisms (Annex IX, 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD 216).

Notes for your consideration in relation to sections 15., 16. and 17. above

ECHA notes that the results obtained from the toxicity tests on fish and aquatic invertebrates also requested in this decision may subsequently allow the derivation of PNECwater. If the results of the proposed toxicity test on fish and aquatic invertebrates allow the subsequent derivation of a PNECwater, you may consider the ITS as recommended in section R.7.11.6., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, June 2017), and determine the need for further testing on terrestrial organisms. Nevertheless ECHA notes that since the substance has high partitioning in soil it would fall into Hazard Category 3 (R.7.11.6., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, June 2017)) and at least one long-term study is in any case needed.

ECHA emphasises that the intrinsic properties of soil microbial communities are not addressed through the EPM extrapolation method and the study on soil mircoorganisms is in any case required.

Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

The compliance check was initiated on 24 November 2016.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

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) and the deadline.

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

As no amendments were proposed, ECHA took the decision according to Article 51(3) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

2. Failure to comply with the requests in this decision, or to otherwise fulfil the information requirements with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State.

3. In relation to the information required by the present decision, the sample of the substance used for the new tests must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is suitable to fulfil the information requirement for the range of substance compositions manufactured or imported by the joint registrants.

   It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition. In addition, it is important to ensure that the particular sample of the substance tested in the new tests is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured or imported by each registrant.

   If the registration of the substance by any registrant covers different grades, the sample used for the new tests must be suitable to assess these grades. Finally there must be adequate information on substance identity for the sample tested and the grades registered to enable the relevance of the tests to be assessed.