EUROPEAN CHEMICALS AGENCY

Helsinki, 9 July 2018

Addressee: [redacted]

Decision number: CCH-D-2114432929-37-01/F
Substance name: Dibenzylbenzene, ar-methyl derivative
EC number: 258-649-2
CAS number: 53585-53-8
Registration number: [redacted]
Submission number: [redacted]
Submission date: 27/06/2017
Registered tonnage band: Over 1000

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) ;**

2. **In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method: OECD TG 476 or TG 490) ;**

3. **Pre-natal developmental toxicity study (Annex IX, Section 8.7.2., column 2; test method: EU B.31./OECD TG 414) in a second species (rabbit), oral route;**

4. **Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.; test method: EU B.56./OECD TG 443) in rats, oral route with the registered substance specified as follows:**
   - **Ten weeks premating exposure duration for the parental (P0) generation;**
   - **Dose level setting shall aim to induce some toxicity at the highest dose level;**
   - **Cohort 1A (Reproductive toxicity);**

   Cohort 1B (Reproductive toxicity) with extension to mate the Cohort 1B animals to produce the F2 generation;

5. **Robust study summaries for key study [redacted] and disregarded studies "[redacted]Marlotherm S, neu; #2" and "[redacted]Marlotherm SH; #1" (Annex VII, Section 9.1.2. in conjunction with Annex I, Section 3.1.5);**

6. **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;**

7. **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;**

8. **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. This can be done simultaneously during the same study;**

9. **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. This can be done simultaneously during the same study;**

10. **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. This can be done simultaneously during the same study;**

11. **Identification of degradation products (Annex IX, 9.2.3.) using an appropriate test method with the registered substance, including each relevant constituent present in concentrations at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable;**

12. **Effects on terrestrial organisms – Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21./OECD TG 216).**

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 **17 January 2022**. You also have to update the chemical safety report, where relevant.

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 Ofelia Bercaru, Head of Unit, Evaluation E3

[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

0. Test material used to generate (eco-)toxicology information

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.

In order to meet several information requirements you have provided in your dossier (submission number [redacted], submission date 10 June 2016) information from studies conducted with a test material identified by you as the registered substance (hereinafter substance subject to this decision) and referred to as "dibenzyltoluene" in the Chemical Safety Report and as "*Marlotherm S*" in the technical dossier. You have further specified, in the technical dossier, that the test material is composed of [redacted] and "[redacted] as an impurity, for the following information requirements:

- *In vitro* gene mutation study in bacteria (Annex VII, 8.4.1);
- *In vitro* gene mutation in mammalian cells (Annex VII, 8.4.3);
- Pre-natal developmental toxicity study (Annex X, 8.7.2);
- One-generation reproduction toxicity study;
- Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.).
- Ready biodegradability (Annex VII, Section 9.2.1.1.)

According to the recommendations of the ECHA Guidance on identification and naming of substances under REACH and CLP (version 2.1, May 2017) "*For a UVCB substance, all known constituents and all constituents present at concentrations ≥ 10% should be specified by at least an English-language IUPAC name and preferably a CAS number*". ECHA observes that tetratoluene isomers, constituting [redacted] of the test material, are not listed in the composition of the substance subject to this decision. ECHA also notes, that you have confirmed this discrepancy in your dossier by indicating in the description of this test material that "*The purity of the material used for the test was lower than the purity of the actual material*". In the light of this considerable difference between the compositions of the substance subject to this decision and the test material used by you for fulfilling several information requirements and consistent with your statements regarding the registered substance and the test material cited above, ECHA considers that the data generated from this test material (hereafter referred to as the "source substance") and reported in the technical dossier corresponds to information obtained from a different substance than the substance subject to this decision.

Annex XI, Section 1.5 of the REACH Regulation sets out the provisions under which human health effects and environmental effects or environmental fate of a substance may be predicted from data obtained on a different substance and defines such an adaptation as grouping of substances and read-across.

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 one of which is that adequate and reliable documentation of the applied method have to be provided.

Even though you have not unambiguously claimed a read-across adaptation in the type of study field in IUCLID, ECHA understands that you have provided documentation of such an adaptation in the description of the composition of the test material where you indicated that "*based on comparable basic structure of the impurities and the assumption that any toxic effects would increase with higher molecular weight and lipophilicity, we regard that the studies conducted with the lower purity material being "worst case" and can be used for the evaluation of the actual product*".

However the documentation that you provided in your dossier does not contain any specific justification whereby relevant human health and environmental properties of the registered substance may be predicted from data on the source substance. Specifically, whilst you refer to "*comparable structures of the impurities*" (as mentioned above), no information was provided on the identity of the constituents in the test material "*Marlotherm S*" that you consider as being structurally related to impurities in the reported compositions of the substance subject to this decision.

ECHA further points out that no details were provided on the identity and respective concentrations of the different isomers covered by the "[redacted]" reported in the test material "*Marlotherm S*". In the absence of this information, ECHA cannot assess the relevance of the information obtained from this test material for predicting the properties of the substance subject to this decision.

ECHA also stresses that no scientific information was included in the dossier to establish and support your assumption that higher toxicity is correlated with higher molecular weight and lipophilicity for the different endpoints under consideration.

Whilst you did not provide any comment on the draft decision on this aspect, in summary ECHA wishes to note that you have not established that relevant properties of the registered substance can be predicted from data on the source substance. In the absence of this information, ECHA cannot verify that the properties of the registered substance can be predicted from the data on the source substance. Since your adaptation does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5., it is rejected.

ECHA
EUROPEAN CHEMICALS AGENCY

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

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.

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.

In order to fulfil this information requirement you have provided study records for four *in vitro* gene mutation study in bacteria (OECD TG 471):

- *AMES,* [redacted] *Marlotherm S, neu, #1*
- *AMES,* [redacted] *Marlotherm S, #2*
- *AMES,* [redacted] *Marlotherm S, #3*
- [redacted] *KsKK/ Ames test*

According to the information provided in the technical dossier, the study *AMES,* [redacted] *Marlotherm S neu, #1* has been conducted with a test material referred to as "Marlotherm S, neu". There is no information on the composition of this test material reported in the study summary and the information on the possible composition provided for other studies is inadequate (see requests 5 and 8 below, for example). In the absence of this information ECHA is not in a position to assess the relevance of the data obtained from this test to fulfil the information requirement of Annex VII, Section 8.4.1 for the registered substance.

According to the information provided in the technical dossier, the studies *AMES* [redacted] *Marlotherm S, #2* and *AMES,* [redacted] *Marlotherm S, #3* have been conducted with a test material referred to as "Marlotherm S". The composition of this test material is described as "*about:* [redacted]". As explained above in Section 0 of this decision, ECHA considers that this approach constitutes a read-across adaptation according to the provisions of Annex XI, Section 1.5 of the REACH regulation and concludes that your adaptation of the information requirement is rejected.

You have also provided an endpoint study record reporting on an *in vitro* gene mutation study in bacteria conducted according to a protocol equivalent to the OECD TG 471 and allegedly with the registered substance ([redacted] 1981). You have assigned a Klimisch score of 2 to this study indicating that the information was "*Comparable to guideline study with acceptable restrictions (incubation time and temperature are not mentioned)*" and reported the following deviations from the test guideline "*E. coli WP2 or S. typhimurium TA102 was not tested; conditions of testing are not sufficiently described (test medium, incubation time and temperature were not described); Only 4 concentrations instead of at least 5 were* tested".

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.

As outlined above, you have provided a test ([redacted] 1981)from the year 1981 according to OECD TG 471 and GLP with an assigned reliability score of 2. While the test used five different strains of S. *typhimurium* (TA 1535, TA 1537, TA 1538, TA 98 and TA 100), 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.

In addition to these deviations, ECHA notes that no information is provided on the composition and purity of the test material used in this test (above) other than a batch number and characterisation of the physical state of the test substance. In the absence of this information, ECHA cannot assess the relevance of the information obtained from this test material for determining the properties of the substance subject to this decision.

On the basis of the information provided, and due to the above mentioned deviations from the test guideline in the study of [redacted] 1981, ECHA concludes that the provided studies, as currently reported, are not adequate to fulfil the information requirement of Annex VII, Section 8.4.1.

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.

ECHA notes that in your comments on the draft decision you agree to conduct the study requested.
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).

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

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.

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 you have provided a key study, *in vivo* mammalian erythrocyte micronucleus test (OECD TG 474), conducted with the registered substance to cover information requirement with regard to Annex VII, 8.4.2. However, ECHA notes that the registration dossier does not contain appropriate study records for the information requirement of Annex VII, Section 8.4.1.
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 the study requested under 1 has negative results.

In order to fulfil this information requirement you have provided study records for an *in vitro* mammalian cell gene mutation test (OECD TG 476), *HPRT,* [redacted] *Marlotherm S, #1.*

According to the information provided in the technical dossier, this study has been conducted with a test material referred to as "Marlotherm S". The composition of this test material is described as "*about:* [redacted]". As explained above in Appendix 1 of this decision, ECHA considers that this approach constitutes a read-across adaptation according to the provisions of Annex XI, Section 1.5 of the REACH regulation and concludes that your adaptation of the information requirement is rejected. 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.

ECHA notes that in your comments on the draft decision you agree to conduct the study requested.

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 the study requested under 1 has negative results.

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

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.

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 registered substance as test material, (DT; Kurosaki (1988)). The technical dossier also contains information on another pre-natal developmental

toxicity study in rats by the oral route conducted with a test material referred to as "Marlotherm S" (*DT,* [redacted] *Marlotherm S, #1*). According to the information provided in the technical dossier, this study has been conducted with a test material referred to as "Marlotherm S". The composition of this test material is described as "*about:* [redacted].
As explained above in Section 0 of Appendix 1 of this decision, ECHA considers that this information is read-across across from the substance Marlotherm S to the substance subject to this decision, according to the provisions of Annex XI, Section 1.5 of the REACH regulation. For the reasons presented above in Section 0, this adaptation is rejected and the results from the study DT; [redacted], Marlotherm S, #1 are not considered relevant for assessing information on prenatal developmental toxicity of the registered substance. Nevertheless, the study *DT; Kurosaki (1988)* fulfils the standard information requirement for a pre-natal developmental toxicity study in a first species (Annex IX, Section 8.7.2.).

However, there is no information provided for a pre-natal developmental toxicity study in a second species.

You have sought to adapt the information requirement for a pre-natal developmental toxicity study in a second species. You provided the following justification for the adaptation "*study scientifically unjustified/other information available*"~~:~~:
"The registrant understands that according to Annex X, 8.7.2, column 1 of the REACH Regulation, the pre-natal developmental toxicity study shall be initially performed on one species. A decision on the need to perform a study at this tonnage level or the next on a second species should be based on the outcome of the first test and all other relevant available data according to Annex IX, 8.7.2, column 2 of the REACH Regulation.
Two pre-natal developmental studies on rodents are available to fulfil the required information for a substance registered for 1000 tonnes or more per year. In the studies, no treatment related specific effects on the development of fetuses were observed. Findings observed in the studies were either slight and/or can be related to the maternal toxicity caused by treatment.

The rat is one of the rodent species that has proven to be extremely useful in pharmacological and toxicological research because there are many similarities between rat and human metabolic pathways, and many anatomical and physiological characteristics are similar, allowing for comparisons in absorption, excretion, and distribution. The rat is also a convenient size, is relatively docile, has a short life span and gestation period, and there is a large database of its characteristics, which is invaluable in the interpretation of the relevance of animal data for humans (Kacew and Festing, 1996). In the absence of any indications of the substance affecting rat development in the pre-natal study, there is no reason to suggest that any effects on development are likely in other species.

A pre-natal developmental toxicity in a second species is scientifically unjustified based on the adequate available data and in terms of animal welfare, noting testing on vertebrate animals for the purposes of Article 25 of the REACH regulation shall be undertaken only as a last resort. This finding is consistent with moves to reduce, refine or replace the use of vertebrates in toxicity tests on ethical grounds, and would avoid testing on more than 500 rabbits including offspring (Oberg, 2010).

Literature:

Kacew S, and Festing MFW. Role of Rat Strain in the Differential Sensitivity to Pharmaceutical Agents and Naturally Occurring Substances. J. Toxicol. Environ. Health, 1996; 47:1–30.
Oberg M. Benchmark dose approaches in chemical health risk assessment in relation to number and distress of laboratory animals. Reg Toxicol Pharmacol. 2010; 58: 451-4."

The arguments brought forward by you seem to indicate that your intend to adapt by referring to Annex X, Section 8.7.2, column 1 and Annex IX, Section 8.7.2., column 2 of the REACH Regulation. However, these provisions do not allow adapting the second species at Annex X because the column 1 at Annex X is cumulative to Annex IX requiring one prenatal developmental toxicity study more in addition to that required Annex IX. The column two specifies that the needed study must be on a second species. Thus, at Annex level information on two species is required and that information requirement cannot be adapted as proposed.

In addition, while you have not explicitly referred to any specific Annex XI adaptation mentioned in the REACH Regulation, you have provided information that could be interpreted as an attempt to adapt the information requirement in accordance with Annex XI, Section 1.2 of the REACH Regulation. Therefore ECHA has analysed this adaptation possibility for the registered substance as follows.

Weight of evidence approach according to Annex XI, Section 1.2:

According to the provisions of Annex XI, Section 1.2, in a weight of evidence approach there has to be sufficient evidence from several independent sources of information leading to the assumption/conclusion that a substance has or has not a particular dangerous (hazardous) property, while the information from each single source alone is regarding insufficient to support this notion. However, ECHA notes that this adaptation, with your justification as cited above, does not meet general rules for adaptation of Annex XI, Section 1.2 for the reasons outlined below.

You have referred to the following sources of individual information to justify the adaptation:

1. Key study: pre-natal developmental toxicity study in rats (OECD Guideline 414). (*DT, [redacted], Marlotherm S, #1*). GLP. Rel. 1. Study conducted with the analogue substance Marlotherm S;
2. Key study: Effects of dibenzyltoluene on fetal developments of rats. Kurosaki T et al. (1988). Equivalent or similar to OECD Guideline 414. GLP compliance not specified. Rel. 1. Study conducted with the registered substance;
3. Reference to a scientific publication "Kacew S, and Festing MFW. Role of Rat Strain in the Differential Sensitivity to Pharmaceutical Agents and Naturally Occurring Substances. *J. Toxicol. Environ. Health*, 1996; 47:1–30."; and
4. Reference to a scientific publication "Oberg M. Benchmark dose approaches in chemical health risk assessment in relation to number and distress of laboratory animals. Reg Toxicol Pharmacol. 2010; 58: 451-4."

ECHA has evaluated the information provided individually and together and assessed whether you provided "sufficient weight of evidence from several independent sources of information leading to the assumption/conclusion that the substance has or has not a particular dangerous property" according to REACH Annex XI, Section 1.2. with respect to the information requirement of Section 8.7.2. for a pre-natal developmental toxicity study.

1. As explained in Section 0 above, the first pre-natal developmental toxicity study in rats by the oral route conducted with a test material referred to as "Marlotherm S" (DT, [redacted] Marlotherm S, #1) is not considered appropriate to fulfil the information requirement for pre-natal developmental toxicity study, as the test material does not represent the registered substance. Thus, the results from this study do not contribute in the weight of evidence assessment of the hazardous properties of the registered substance regarding to prenatal developmental toxicity.
2. ECHA considers that the study of Kurosaki T et al. (1988) you provided is appropriate to cover standard information requirement of Annex IX, 8.7.2 for a pre-natal developmental toxicity in a first species. However, this study does not provide information on prenatal developmental toxicity in a second species or information on species differences. Thus, information on one species is covered with this piece of information. ECHA points out that you have not provided any substance-specific scientific argument to support your statement whereby "In the absence of any indications of the substance affecting rat development in the pre-natal study, there is no reason to suggest that any effects on development are likely in other species". The scientific references you provided (Kacew and Festing, 1996; Oberg, 2010) do not inform on the prenatal developmental toxicity of the registered substance on second species. General considerations on strain differences and sensitivity to various toxicants (Kacew and Festing 1996) do not support you claim that lack of effects in the rat equals with no species differences. Furthermore, you have not justified how the information from article from Oberg (2010) on benchmark dose approaches informs on prenatal developmental toxicity on second species for the registered substance.
3. In conclusion, the available information on prenatal developmental toxicity indicates that the registered substance is not a developmental toxicant in the rat. However, the information considered individually or together does not provide information prenatal developmental toxicity on a second species and does not allow to conclude that species differences do not exist. Thus, it is not possible to conclude whether the registered substance has or has not hazardous properties related to (prenatal) developmental toxicity.

Therefore ECHA concludes that the studies and information specified above do not provide scientific evidence, which can contribute to meeting the relevant information requirement according to pre-natal developmental toxicity on a second species.

Adaptation according to Annex IX, Section 8.7.2, column 2:
ECHA notes that you refer in your adaptation argument to the provisions of Annex IX, 8.7.2, column 2 of the REACH Regulation specifying that a decision on the need to perform a study on a second species at the Annex IX tonnage level should be based on the outcome of the first test and all other relevant available data. ECHA points out that you have registered the substance subject to this decision for 1000 tonnes or more per year. As indicated above, a pre-natal developmental toxicity study in a second species (test method EU B.31./OECD TG 414) is part of the standard information requirements for a substance registered for 1000 tonnes or more per year (Annex X, Section 8.7.2., column 1, and sentence 2 of introductory paragraph 2 of Annex X of the REACH Regulation).

Further, according to Column 2 of Annex X, 8.7, reproductive toxicity studies do not need to be conducted if

- the substance is known to be a genotoxic carcinogen and appropriate risk management measures are implemented, or

- the substance is known to be a germ cell mutagen and appropriate risk management measures are implemented, or

- the substance is of a low toxicological activity (no evidence of toxicity seen in any of the test available), it can be proven from toxicokinetics data that no systemic absorption occurs via relevant routes of exposure (e.g. plasma/blood concentrations below detection limit using a sensitive method and absence of the substance and of metabolites of the substance in urine, bile or exhaled air) and there is no or no significant human exposure.

ECHA notes that two first conditions are not met, as based on data available in the registration dossier, the substance is not known to be either a genotoxic carcinogen or germ cell mutagen.

Regarding the third condition of low toxicological activity, you did not provide measured data on toxicokinetics but claimed that "*based on the chemical structure and the physico-chemical properties of the material basic toxicokinetic properties can be estimated. The water solubility of DBT is low. The logPow is > 6. Since only dissolved material is likely to be absorbed in the gastrointestinal tract, water solubility might be the limiting factor. Due to the higher low Pow the material might absorb to proteins. Nevertheless, based on structural considerations, as well as systemic effects observed in animal experiments with oral application it can reasonably be assumed that absorption via the gastrointestinal tract does occur.*" ECHA therefore concludes that systemic absorption occurs via oral exposure. Additionally ECHA notes, that based on the information provided in the joint submission it cannot be concluded that there is no or no significant human exposure. In particular, the use of the registered substance, in the joint submission is leading to significant exposure of workers because the registered substance is used by professionals as dielectric fluids (*PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)).* Furthermore, the registered substance is also used by professionals *(PROC 19: Hand-mixing with intimate contact and only PPE available)* and consumers as dental paste (*PC0:*); hence it cannot be considered there is no or no significant human exposure.

At REACH Annex X level, a prenatal developmental toxicity study conducted on a second species is a standard information requirement in addition to a prenatal developmental toxicity in a first species that is required at REACH Annex IX level. Availability of information on two species allows a more comprehensive evaluation of pre-natal developmental toxicity. The pre-natal developmental toxicity study in a second species can be omitted if, taking into account the outcome of the first test and all other relevant available data, an adaptation pursuant to REACH Annex X, Section 8.7, Column 2 or pursuant to REACH Annex XI can be justified.

However, for the reasons described above, your adaptations 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.

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) Chapter R.7a, Section 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.

ECHA notes that in your comments on the draft decision you agree to conduct the study requested.

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.

Notes for your consideration

ECHA notes that a revised version of OECD TG 414 was adopted this year by the OECD. This revised version contains enhancements of certain endocrine disrupting relevant parameters. You should test in accordance with the revised version of the guideline as published on the OECD website for adopted test guidelines (https://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals-section-4-health-effects_20745788).

4. Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.)

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.

An extended one-generation reproductive toxicity study (test method EU B.56/OECD TG 443) for a first species is a standard information requirement as laid down in Annex IX, Section 8.7.2. 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.

The basic test design of an extended one-generation reproductive toxicity study (test method EU B.56./OECD TG 443 with Cohorts 1A and 1B, without extension of Cohort 1B to include a F2 generation, and without Cohorts 2A, 2B and 3) is a standard information requirement as laid down in column 1 of 8.7.3., Annex X. If the conditions described in column 2 of Annex X are met, the study design needs to be expanded to include the extension of Cohort 1B, Cohorts 2A/2B, and/or Cohort 3. Further detailed guidance on study

design and triggers is provided in the ECHA *Guidance on information requirements and chemical safety assessment* Chapter R.7a, Section R.7.6 (version 6.0, July 2017).

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

a) The information provided

In order to fulfil this information requirement you have provided study records for a one-generation reproductive toxicity study (OECD TG 415; [redacted], 1993).

According to ECHA's Guidance on information requirements (version 6.0, July 2017, R.7a, section R.7.6.4.2.5.), the one-generation reproductive toxicity study (EU B.34, OECD 415) is not an appropriate study to fulfil the information requirement for an extended one-generation reproductive toxicity study because of limited postnatal exposure duration and inadequate coverage of key aspects/parameters (REACH Annex XI, 1.1.2).

Furthermore, ECHA notes that according to the information provided in the technical dossier, this study has been conducted with a test material referred to as "Marlotherm S". The composition of this test material is described as "*about:* [redacted]. As explained above in Section 0 of this decision, ECHA considers that this approach constitutes a read-across adaptation according to the provisions of Annex XI, Section 1.5 of the REACH regulation and concludes that your adaptation of the information requirement is rejected.

You have also sought to adapt this information requirement. You provided the following justification for the adaptation: *"A high quality one-generation study is available for dibenzyltoluene. No effects on reproductive parameters were observed in that study. Mating performance and fertility were unaffected up to a dose level of 720 mg/kg. In the high dose group litter size, pup weight, pup survival and organ weights were affected, but these effects are secondary to maternal toxicity. In 2 subchronic toxicity studies in rats (90d and 120d) no effects on reproductive organs have been observed. Based on the available data – and considering the use of the material with low potential to exposure to the general population, as well as animal welfare aspects - the performance of a multigeneration study is not justified."*

While you have not explicitly claimed an adaptation, you have provided information that could be interpreted as an attempt to adapt the information requirement according to Annex X, Section 8.7., column 2. However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex X, Section 8.7, column 2., regarding reproductive toxicity studies. ECHA has already explained that in the Section 3 of this draft decision, as the same rules of adaptation, as outlined in Annex X, Section 8.7, column 2, are also applicable for the pre-natal developmental toxicity study.

Therefore, 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. Thus, an

extended one-generation reproductive toxicity study according Annex X, Section 8.7.3. is required. The following refers to the specifications of this required study.

b) The specifications for the study design

Ten weeks premating exposure duration is required if there is no substance specific information in the dossier supporting shorter premating exposure duration as advised in the ECHA *Guidance on information requirements and chemical safety assessment* Chapter R.7a, Section R.7.6 (version 6.0, July 2017). In this specific case ten weeks exposure duration is supported by the lipophilicity of the substance (log Kow > 6) to ensure that the steady state in parental animals has been reached before mating.

The highest dose level shall aim to induce some toxicity to allow comparison of effect levels and effects of reproductive toxicity with those of systemic toxicity. The dose level selection should be based upon the fertility effects with the other cohorts being tested at the same dose levels.

If there is no existing relevant data to be used for dose level setting, it is recommended that results from a conducted range-finding study (or range finding studies) are reported with the main study. This will support the justifications of the dose level selections and interpretation of the results.

Extension of Cohort 1B

If the column 2 conditions of 8.7.3., Annex X are met, Cohort 1B must be extended, which means that the F2 generation is produced by mating the Cohort 1B animals. This extension provides information also on the sexual function and fertility of the F1 animals. The extension is inter alia required, if the use of the registered substance is leading to significant exposure of consumers and professionals (column 2, first paragraph, lit. (a) of section 8.7.3., Annex X) and/or if there are indications that the internal dose for the registered substance will reach a steady state in the test animals only after an extended exposure (column 2, first paragraph, lit. (b), second indent of section 8.7.3., Annex X)".

In particular, the use of the registered substance, in the joint submission is leading to significant exposure of workers because the registered substance is used by professionals as dielectric fluids (*PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)).* Furthermore, the registered substance is also used by professionals *(PROC 19: Hand-mixing with intimate contact and only PPE available)* and consumers as dental paste (*PC0:*); hence the human exposure cannot be considered not significant.

In addition, there are indications that the internal dose for the registered substance and/or its metabolites will reach a steady state in the test animals only after an extended exposure. The registered substance has low water solubility and the logPow is > 6. You also claim that "*Once absorbed via the gastrointestinal tract it is likely that the material will be distributed systemically. No high first pass effect in the liver is expected due to lack of functional groups, which are only introduced by enzymatic reactions*".

Therefore, ECHA concludes that Cohort 1B must be extended to include mating of the animals and production of the F2 generation because the uses of the registered substance is leading to significant exposure of professionals and consumers and there are indications

that the internal dose for the registered substance and/or any of its metabolites will reach a steady state in the test animals only after an extended exposure.

Species and route selection

According to the test method EU B.56./ OECD TG 443, the rat is the preferred species. On the basis of this default assumption, ECHA considers that testing should be performed in rats.

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) Chapter R.7a, Section 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.

ECHA notes that in your comments on the draft decision you agree to conduct the study requested.

c) Outcome

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: Extended one-generation reproductive toxicity study (test method EU B.56./OECD TG 443), in rats, oral route, according to the following study-design specifications:

- Ten weeks premating exposure duration for the parental (P0) generation;
- Dose level setting shall aim to induce some toxicity at the highest dose level;
- Cohort 1A (Reproductive toxicity);
- Cohort 1B (Reproductive toxicity) with extension to mate the Cohort 1B animals to produce the F2 generation; and

Notes for your consideration

No triggers for the inclusion of Cohorts 2A and 2B (developmental neurotoxicity) and Cohort 3 (developmental immunotoxicity) were identified. However, you may expand the study by including the extension of Cohorts 2A and 2B and/or Cohort 3 if new information becomes available after this decision is issued to justify such an inclusion. Inclusion is justified if the new information shows triggers which are described in column 2 of Section 8.7.3., Annex X and further elaborated in ECHA *Guidance on information requirements and chemical safety assessment* Chapter R.7a, Section R.7.6 (version 6.0, July 2017). You may also expand the study to address a concern identified during the conduct of the extended one-generation reproduction toxicity study and also due to other scientific reasons in order to avoid a conduct of a new study. The justification for the expansion must be documented. The study design must be justified in the dossier and, thus, the existence/non-existence of the conditions/triggers must be documented.

5. Robust study summaries for key study "[redacted]" and disregarded studies "[redacted] Marlotherm S, neu; #2" and "[redacted] Marlotherm SH; #1" (Annex VII, Section 9.1.2. in conjunction with Annex I, Section 3.1.5)

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.

Pursuant to Articles 10(a)(vii) of the REACH Regulation, the information set out in Annex VII to XI must be provided in the form of robust study summary, if required under Annex I. Article 3(28) defines a robust study summary as a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report. Guidance on the preparation of the robust study summaries is provided in the ECHA Practical Guide 3: 'How to report robust study summaries'.

"Growth inhibition study aquatic plants" is a standard information requirement as laid down in Annex VII, Section 9.1.2. 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. Furthermore, pursuant to Article 10 (a)(vii) and Annex I, Section 3.1.5. if there are several studies addressing the same effect, then, the study or studies giving rise to the highest concern shall be used to draw the conclusion and a robust study summary shall be prepared for that study or studies and included as part of the technical dossier. Robust study summaries (RSS) will be required of all key data used in the hazard assessment. More specifically, Sections 1.1.4 and 3.1.5 of Annex I to the REACH Regulation requires Registrants to provide robust study summaries also for studies that are not used as a key study but that give rise to a higher concern than the study used as a key study.

In the technical dossier you have provided a study record for a key study "[redacted]", for which you conclude that "*No significant inhibition was observed at the highest soluble (measured) concentration, which was 16.0 µg/L*". Furthermore, in the technical dossier you have provided two disregarded studies of higher concern, where effects on growth inhibition have been observed: "[redacted] *Marlotherm SH; #1" and "*[redacted] *Marlotherm S, Neu; #2"*.

However, ECHA notes that you have not provided sufficient information in the technical dossier to allow verification of reliability of these three studies, as explained below.

The key study conducted with *1,2-dibenzyl-3-methylbenzene; dibenzyltoluene / 26898-17-9 / 248-097-0)*(the registered substance) [redacted] is performed according to ISO nr. 10253 and GLP with measured concentrations.

ECHA acknowledges that the test guideline used in this study can be an acceptable alternative to the standard OECD TG to investigate the endpoint "Growth inhibition study aquatic plants" (OECD TG 201), as indicated in the Appendix R.7.8-3 of ECHA Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017). However, ECHA notes that, based on the current information in the robust study summary, ECHA cannot fully assess the validity of the study and its results because of the following shortcomings:

1. Measured initial concentration has been used to express the results, rather than for

instance the more commonly used time weighted mean measured concentration. In this regard, the standard OECD TG 201, paragraph 37, recommends: "If the deviation from the nominal or measured initial concentration is not within the range of ± 20 %, analysis of the results should be based on geometric mean concentration during exposure or on models describing the decline of the concentration of the test substance." You report: "*For limit test initial measured concentration was 16 µg/L. After 72h exposure, concentrations measured in the 6 test flasks ranged from 4.2 to 6.0 µg/L with an average of 5.3 µg/L*". Without a justification it is not clear why you have selected the (higher) measured initial concentration rather than for instance the (lower) time weighted mean measured concentration. This would lower the concentration up to which no effects had been observed in the key study.

2. You also report: "*The deviation between µ(ave) gave results over 0-72 h for the cultures incubated with [14C]-DBT at its maximum solubility and the corresponding controls was very small (<2%). This achieved statistical significance, a result which is judged to reflect low variability between replicates within these treatment groups. No other statistically significant differences were found and it was concluded that the No Observed Effect Concentration (NOEC) and the EC50 value exceed the measured values found in the limit test.*" ECHA understands from this text that you conclude that no effects have been observed in the study due to the small difference (<2%) between the growth rate (µ) in the control and in the treatment group. However, the tables with results and the statistical test have not been presented in your RSS. Thus, ECHA cannot verify your conclusions.

3. The study has been indicated as being conducted with the registered substance but the test material you have used in this study is not clearly defined. ("*[14C]-DBT, Batch No. 0595, 500 µCi of stated specific activity 15 mCi/mmol (55.1.µCi/mg) was provided by the* [redacted] *and stored at ca -20°C in the dark. Non-radiolabelled DBT (*[redacted]*), Product Code* [redacted]*, 100 ml was supplied by the Sponsor and stored at ambient temperature in the dark.*"). In addition, ECHA notes that no information is provided on the composition and purity of the test material used in this test other than the batch number/product code. In the absence of this information, ECHA cannot assess the relevance of the information obtained from this test material for determining the properties of the substance subject to this decision.

Therefore, based on the shortcomings listed above, ECHA cannot fully assess the validity of the key study and its results (72h EC50growth rate and 72h NOEC growth rate > 16 µg/L (initial measured)).

For the disregarded study conducted with a test material referred to as "*Marlotherm S, neu*" "[redacted] *Marlotherm S, Neu; #2*" (reliability 3 "*not reliable*") you give as reason to disregard the study as: "*Guideline study, but unclear description of solution preparation. Uncertainty about real exposure concentrations.*" This is a study conducted according to EU method C.3/OECD TG 201 and GLP. However, based on the current information in the RSS, ECHA cannot consider the study as reliable. A number of issues should be clarified in this RSS for ECHA to be able to fully assess the quality of this study and the reasons why the study is disregarded by you:

1. The measured concentrations are expressed and used in a non-standard way as follows: "*Nominal concentrations: 0 / 8.4 / 17 / 28 / 48 / 84 / 140 / 252 µg/L. The geometrical mean of the measured values deviated about -43 % from the nominal*

concentrations. For the biological evaluation the nominal concentrations minus 43 % were used: [redacted] *Marlotherm S, neu; #2. Concentrations used for evaluation: 0 / 4.8 / 9.7 / 16 / 27 / 48 / 80 / 144 µg/L."* Normally, the geometric mean of each test concentration should be used, as recommended in paragraph 37 of OECD TG 201. Further, ECHA notes that it is not clear whether the reported EC50growth rate (0.046 mg/L) is based on measured concentrations or nominal concentrations. ECHA notes that measured vs. nominal concentrations are not reported in the study summary and these values would be needed for a sufficient assessment of the study quality and to determine the impact of the non-standard use of measured concentrations. In particular, measured concentrations are needed in order for ECHA to verify your statement that this study is not reliable due to "*unclear description of solution preparation. Uncertainty about real exposure concentrations.*"

2. You have indicated that the validity criteria have been fulfilled for this study. The OECD TG 201, paragraph 11, lists three validity criteria that need to be fulfilled in order for a study to be considered valid. Two of these criteria define that the mean coefficient of variation for section-by-section specific growth rates (days 0-1, 1-2 and 2-3, for 72-hour tests) in the control cultures must not exceed 35 and that the coefficient of variation of average specific growth rates during the whole test period in replicate control cultures must not exceed 7% in tests with *Desmodesmus subspicatus*. However, you have not reported this information, thus ECHA cannot assess the validity of this study. ECHA notes that test material you have used in this study is not clearly defined ("*Composition of test material, percentage of components:* [redacted]"). No information on the components of this test material is reported in the robust study summary other than the generic names. For instance, you have not indicated which isomers of dibenzyltoluene and in which concentration are present in the test material. In the absence of this information, ECHA cannot assess the relevance of the information obtained from this test material for determining the properties of the substance subject to this decision.

Similarly, for the study conducted with a test material referred to as the registered substance, "[redacted] *Marlotherm SH; #1*" (reliability 3 "*not reliable*") you give as reason to disregard the study: "*GLP guideline study, but much uncertainty on real exposure concentrations.*"

This is a study conducted according to OECD TG 201 and GLP. However, based on the current information in the robust study summary, ECHA cannot consider the study as reliable. A number of issues should be clarified in this study summary for ECHA to be able to fully assess the quality of this study and the reasons why the study is disregarded by you:

1. The measured concentrations have not been reported although you indicate that the concentrations have been analytically monitored. The OECD TG 201, paragraph 37, recommends: "If the deviation from the nominal or measured initial concentration is not within the range of ± 20 %, analysis of the results should be based on geometric mean concentration during exposure or on models describing the decline of the concentration of the test substance." You report that "*The results of the in-life portion of the present study were based on the nominal treatment concentrations because the concentrations found in the samples at t(0) and t(72h) were in the same (extreme low) concentration range.*" However, you have not reported the measured

concentrations nor indicated whether the deviation was within ± 20 %. These values would be needed for a sufficient assessment of the study quality and the impact of the use of nominal concentrations to express the results. In particular, you indicate that the test material is poorly water soluble (*"Absolute EbC10 and EbC50 values were difficult to determine because of the poor water solubility of the test substance."*) and that nominal test concentrations up to 10mg/L (1st main test) and 8mg/L (2nd main test) have been used. These nominal test concentrations cannot be considered as *"extreme low"* and might be above the water solubility of the poorly water soluble test material. Hence, measured concentrations are needed in order to determine to which concentrations the test organisms have been actually exposed and to verify your statement that this study is not reliable due to *"much uncertainty on real exposure concentrations."*

2. You have indicated that the validity criteria have been fulfilled for this study. The OECD TG 201, paragraph 11, lists three validity criteria that need to be fulfilled in order for a study to be considered valid. Two of these criteria define that the mean coefficient of variation for section-by-section specific growth rates (days 0-1, 1-2 and 2-3, for 72-hour tests) in the control cultures must not exceed 35 and that the coefficient of variation of average specific growth rates during the whole test period in replicate control cultures must not exceed 7% in tests with *Desmodesmus subspicatus*. However, you have not reported this information, thus ECHA cannot assess the validity of this study.

3. You have reported a pH value of 7.11 - 10.51, but you have not reported the pH values at the beginning and at the end of the test at all treatments, as indicated in paragraph 61 of OECD TG 201. In the absence of details on the pH in the controls, ECHA cannot verify whether the pH of the control medium did not increase by more than 1.5 units during the test, as required by paragraph 30 of OECD TG 201. If the increase of the pH in the controls is above the value given in the TG, an explanation should be provided on how this would influence the reliability of the results.

4. ECHA notes that test material you have used in this study is not clearly defined (*"Analytical purity: approx. 99 %, Composition of test material, percentage of components: Dibenzyltoluene, no further detials mentioned"*). No information on the components of this test material is reported in the robust study summary other than the generic name. For instance, you have not indicated which isomers of Dibenzyltoluene and in which concentration are present in the test material. In the absence of this information, ECHA cannot assess the relevance of the information obtained from this test material for determining the properties of the registered substance subject to this decision.

Considering all above mentioned deficiencies in reporting these two disregarded studies, ECHA cannot verify their validity. Furthermore, considering the lack of reported measured concentrations, ECHA cannot verify your claim of the studies being "not reliable", as explained above. This is of importance since effects have been observed in these two disregarded studies, which are hence showing the highest concern for the endpoint under consideration.

If after re-assessing the studies, you come to the conclusion that the reliability and adequacy of the key and disregarded studies should be changed, you should update your dossier accordingly, including any potential changes to for instance PNEC derivation,

classification and risk characterisation. As stated in the notification letter, this update will be assessed by ECHA in the follow up phase.

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 notes that in your comments on the draft decision you agree to provide improved robust study summaries (RSSs) for the three algae growth inhibition studies discussed above. You further include comments on all the three algae studies subject to this decision, which are addressed below.

Regarding the key study, in your comments on the draft decision you maintain that results should be expressed as measured initial concentration based on the following reasons.

You consider that "*the best possible exposure took place in this test considering the nominal loading rate, the pre-conditioning of test vessels and the properties of the test material.*" ECHA notes that the registered substance has a high adsorption potential and a low water solubility. ECHA acknowledges that, based on the information provided in your comments and on the information in the RSS (dossier submission number [redacted], submission date 10 June 2016), for this limit test the coating of the test vessels with a silicon agent may have reduced the loss of test material due to limited adsorption to the test vessels. ECHA further acknowledges that the registered substance was dissolved in the test solution at a measured concentration (16µg/L) below its water solubility (0.018 mg/L as reported in your technical dossier) before algae exposure took place.

However, ECHA notes that, based on the available information, it is not possible to verify whether the test material was lost from the test system in the course of the 72h exposure. As explained above, in the test solutions with algae, the concentrations measured after 72h exposure did not stay within the range ± 20% of the measured initial concentration. In this regard, in your comments on the draft decision you consider that, based on "*analytical determination in flasks incubated without algae*", the loss of test material from the test solutions is due to adsorption to algal biomass. However, since the tables with results and the analytical measurements in the test solutions without algae after 72h are neither available in the RSS (dossier submission number [redacted], submission date 10 June 2016) nor have they been included in your comments on the draft decision, ECHA cannot currently assess your claim. Hence, ECHA considers based on the available information that you have not demonstrated whether it is appropriate to express the results of the key study based on measured initial concentration.

ECHA finally notes that for the key study, in your comments on the draft decision you indicate that you will provide a "*table with the results and data regarding the statistics*", as well as information on "*The purity of the substance (>99%) along with information regarding the composition of the tested material*" in a future dossier update. As these details on the key study are not yet provided in the technical dossier, ECHA cannot currently fully assess the validity of the key study and its results.

Regarding the two disregarded studies, in your comments on the draft decision you indicate that you will provide additional details to the RSSs but you still consider that the studies are unreliable. As the details on these two studies are not yet provided ECHA cannot currently assess your claim.

Therefore, pursuant to Article 10(a)(vii) and Section 3.1.5 of Annex I to the REACH Regulation of the REACH regulations, you are required to provide robust study summaries for key study "[redacted]" and the disregarded studies "[redacted] *Marlotherm S, Neu; #2*" and "[redacted] *Marlotherm SH; #1*" in the IUCLID format. Further guidance can be found in ECHA Practical Guide 3: 'How to report robust study summaries'.

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

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.

"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.

In the technical dossier you have provided a study record for long-term toxicity testing on aquatic invertebrates ("*DR*[redacted] *Marlotherm S; #1*"). You provided a robust study summary for this GLP study with analytical monitoring according to OECD TG 202, part II (1984 version) with the source substance *Marlotherm S*.

Firstly, as explained above in Section 0 of this decision, ECHA considers that this approach constitutes a read-across adaptation according to the provisions of Annex XI, Section 1.5 of the REACH regulation and concludes that your adaptation of the information requirement is rejected.

Secondly, this study does not provide the information required by Annex IX, Section 9.1.5., because based on the current information in the robust study summary, ECHA cannot consider the study as reliable because of the following shortcoming. Regarding the stability of the test material you report: "*The test substance concentrations were not stable during the course of the study. The test substance seemed to be adsorptive to surfaces (glass, algae) so that the analytically available amount was reduced. All values were calculated on the basis of the nominal concentrations.*" As explained in both the current OECD TG 211 and 1984 version of OECD TG 202, in the section on the conditions of validity, measured concentrations instead of nominal concentrations should be used in such situations: "*The results should be based on measured concentrations if the deviation from the nominal concentration is greater than 20 per cent.*" ECHA further notes that you have not reported measured concentrations in the robust study summary and that it is not clear whether the samples for analytical measurements were taken from the stock solution or test solution and at which times. In the absence of this information, it is not possible to determine to which concentrations the test organisms have been actually exposed.

Thirdly, ECHA notes that the conclusion you derive from the results of this study is incorrect. In the endpoint summary of IUCLID you conclude "*No significant effect on daphnia reproduction was observed up to solubility limit*". You have reported a water solubility of 0.018 mg/L in your dossier for the registered substance. ECHA notes that a

clear dose-response relationship was observed and that you report a 21d LOECreproduction = 0.1 mg/L (nominal) and a 21d NOECreproduction = 0.03 mg/L (nominal). Since you reported that the measured concentrations are much lower than the nominal concentrations, ECHA concludes that the observed effects have very likely been observed below the limit of water solubility of the test substance and disagrees with your conclusion. 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.

ECHA acknowledges that in your comments on the draft decision you agree to conduct the OECD TG 211 *Daphnia* reproduction study on the registered substance as a first step of an integrated testing strategy. ECHA has addressed the proposed testing strategy under request 7. below.

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).

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

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.

"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. You provided the following justification for the adaptation: "*Lack of significant exposure of aquatic media, expected difficulty of testing and animal welfare consideration lead to recommend waiving chronic fish testing.*"While you have not explicitly claimed an adaptation, you have provided information that could be interpreted as an attempt to adapt the information requirement according to Annex XI, Sections 2 ("*expected diffulty of testing*") and 3 ("*Lack of significant exposure of aquatic media*").

However, ECHA notes that your adaptation does not meet the general rule for adaptation of Annex XI, Section 3. because the lack of significant exposure of aquatic media has not been substantiated in your dossier.

Firstly, Annex XI, Section 3.1 allows the testing to be omitted "based on the exposure scenario(s) developed in the Chemical Safety Report." However, in your adaptation you do not make any reference to the exposure scenarios.

Secondly, Annex XI, Section 3.2(a)(i) requires you to "demonstrate the absence of or no significant exposure in all scenarios...". However, there are uses of the registered substance, as demonstrated in your dossier, that suggest exposure to the aquatic environment is likely (e.g. ERC 10a). Further, you have shown in your PEC calculations in the Chemical Safety Report that $PEC_{regional,\ freshwater}$ value for water for instance is 7 ng/L. Similarly the $PEC_{freshwater}$ concentrations resulting from the different exposure scenarios is around 6 ng/L. You have not demonstrated why this would constitute "no significant exposure in all scenarios".

Thirdly and importantly, Annex XI, Sections 3.2(a)(ii) and Section 3.2(a)(iii) require that "a DNEL or a PNEC can be derived from the results of available test data..." and that "the comparison of the derived DNEL or PNEC with the result of the exposure assessment shows that exposurs are always well below the derived DNEL or PNEC. Since you have incorrectly (see issues 5 and 6 above and the note for consideration below) not derived a $PNEC_{aquatic}$, you have not demonstrated that the calculated PEC concentrations are well below the derived PNEC.

Furthermore, ECHA notes that your adaptation does not meet the general rule for adaptation of Annex XI, Section 2. Because the fact that the substance is difficult to test (adsorptive, low water solubility) does not exclude testing is possible. As apparent from your disregarded Growth inhibition study aquatic plants conducted with "*Marlotherm S, neu*" "[redacted] *Marlotherm S, Neu; #2*", a substance with a low water solubility and high adsorptive potential can still show effects. Hence, ECHA considers that it has not been sufficiently shown why aquatic toxicity testing is difficult or why it is not possible to modify some conditions of the test design according to the guidelines to enable the performance of a valid test. In particular, you have not adequately considered the guidance in sections 3.1 and 3.6 of the OECD *Guidance document on aquatic toxicity testing of difficult substances and mixtures* (Environmental health and safety publications, Series on testing and assessment No. 23; ENV/JM/MONO(2000)6, pages 26 to 28), which deals with poorly water-soluble and adsorptive substances such as the registered substance.

ECHA acknowledges that, if your assumption of technical difficulties materialise during the study, the test may prove unfeasible to continue because of the physicochemical properties of the substance. In such a case, you may decide, based on preliminary test results or laboratory assessment, that the test is technically not possible and then stop testing. The information as to why the test is stopped and the reasons for not being technically possible should be explicitly included in the registration dossier.

Guidance is available for difficult to test substances, e.g. 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 R7b, 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).

Therefore, your adaptations for the information requirement cannot be accepted.

ECHA notes that in your comments on the draft decision you agree that for the registered substance it cannot be concluded if fish or invertebrates are shown to be substantially more sensitive based on acute data, as ECHA explained in the *Notes for your consideration* section at the end of this request. You hence consider that long-term studies might be required on fish and aquatic invertebrates and you propose to follow the Integrated testing strategy (ITS) outlined in ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017). As already addressed under request 6. above, you intend to perform first the OECD 211 *Daphnia* reproduction study. You propose to perform the long-term fish study only if, based on the results of the long-term *Daphnia* study and the application of a relevant assessment factor, a risk from the chemical safety assessment (CSA) is indicated. However, as already outlined in the *Notes for your consideration* section at the end of this request, ECHA considers that the ITS is not applicable in this case. In particular, with regards to conclusions on the CSA (PNEC Derivation), ECHA notes that due to low water solubility of the substance and lack of a valid /relevant dose-response effects in short-term studies, it is not possible to determine the interspecies variation in sensitivity to the registered substance. Therefore, ECHA considers that in the absence of compelling evidence from short-term toxicity studies to predict relative differences (or lack of) in species sensitivity, information on long-term toxicity to both invertebrates and fish are required as outlined in section R.7.8.5.3 of the above-mentioned Guidance document.

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 also for PNEC derivation data on three trophic levels (aquatic invertebrates, plants and fish) is needed. 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 in ECHA *Guidance on information requirements and chemical safety assessment Chapter R.10* (May 2008).

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 R7b, 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 R7b,* 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

As further explained in Appendix 3 of the draft decision, it is important to ensure that the particular sample of substance selected to be tested in the study is appropriate to assess the properties of the registered substance. Hence, it is critical that those constituents which are most relevant should be present at appropriate concentrations in any sample tested.

Before conducting the above test you are advised to consult the ECHA Guidance on information requirements and chemical safety assessment, Chapters R.4 (v.1.1, December 2011), R.5 (v.2.1, December 2011), R.6 (May 2008), R.7b (v 4.0, June 2017) and R.7c (v 3.0, June 2017). If you decide to adapt the testing requested according to the specific rules outlined in Annexes VI to X and/or according to general rules contained in Annex XI of the REACH Regulation, you are referred to the advice provided in practical guides on "How to use alternatives to animal testing to fulfil your information requirements for REACH registration".

In particular, before conducting the above test you are adviced to consult Section R.7.8.5 of ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017) which outlines the Integrated testing strategy / Weight of evidence considerations which may be used to conclude aquatic pelagic toxicity.

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

ECHA notes that due to a lack of a valid /relevant dose-response effects in short-term fish and *Daphnia* 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 R7b (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. As the registered substance has a reported low water solubility, long-term studies are indicated.

Due to the low solubility of the substance in water (0.018 mg/L) and the high adsorption potential 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 R7b, 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. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.)

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.

"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 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 "*According to column 2 of regulation Annex IX: substance is highly insoluble in water and sediment exposure is unlikely*".

ECHA has assessed this adaptation and concludes that based on the information in the technical dossier your adaptation does not meet the specific rules for adaptation of Column 2 of Annex IX, Sections 9.2 and 9.2.1.2 due to the following.

According to Annex IX, Section 9.2.1.2, column 2 of the REACH Regulation, simulation testing on ultimate degradation in surface water does not need to be conducted if the substance is highly insoluble in water or is readily biodegradable.

Firstly, ECHA notes that the statement in your adaptation "*sediment exposure is unlikely*" is not a valid adaptation for simulation testing on ultimate degradation in surface water.

Secondly, ECHA notes that in the technical dossier (IUCLID section 4.8) you provide a water solubility study indicated as being conducted with the registered substance "*dibenzyltoluene / 26898-17-9 / 248-097-0*", where you conclude that "*Interpretation of results (migrated information): insoluble (< 0.1 mg/L). The substance was found to be practically insoluble in water. The water solubility was found to be 18 µg/L.*" However, ECHA considers that the registered substance is poorly water soluble (water solubility = 0.018 mg/L) and you have not provided evidence to support your claim that it is highly insoluble. As apparent from your disregarded Growth inhibition study aquatic plants conducted with "*Marlotherm S, neu*" "[redacted] *Marlotherm S, Neu; #2*", substances with a low water solubility can still show effects below the limit of their solubility and thus they cannot be considered overall as highly insoluble.

Finally, ECHA notes that based on the information in the technical dossier the registered substance is not readily biodegradable, as explained below. You have provided five studies under IUCLID section 5.2.1, Biodegradation in water: screening tests, in the technical dossier:

- Three ready biodegradability studies showing very low or no degradation:
  1) "*RB 301B;* [redacted] *Marlotherm S, neu; #1*": 1% degradation (CO_2 evolution) after 29d, test substance: Marlotherm S neu ([redacted]), EU method C.4-C/OECD TG 301B. for this study you conclude: "*under test conditions no biodegradation observed*"
  2) "*RB 301B;* [redacted] *Marlotherm S; #2*": 2.3% degradation (CO_2 evolution) after 28d, test substance: Marlotherm S, OECD TG 301B. For this study you conclude: "*Marlotherm S was tested for biodegradability according to 'modified Sturm-Test' (OECD Guideline 301 B). Calculated from the organic carbon content of the test substance and the measured CO2 generation 2.3%*

of the theoretical CO2 (ThCO2) had been generated by the test substance within 28 d in the case of the 10 mg test substance/L - culture. 28.5% of the theoretical CO2 (ThCO2) had been generated by the test substance within 43 d in the case of the 20 mg test substance/L - culture. This culture was prolonged as biodegradability had started before day 28 and a plateau was not reached until that day.
From these data obtained Marlotherm S may be regarded as "inherently biodegradable" though biodegradability of this test material seemed to be not fast." However, ECHA notes that based on the results from this study (28% degradation after 43 days) the registered substance would fulfil the P criterion (degradation half-life in freshwater or estuarine water >40 days) and potentially the vP criterion (degradation half-life in freshwater or estuarine water >60 days).

3) "*RB 301D;* [redacted] *Marlotherm S; #1*": 0.5% degradation (O2 consumption) after 28d, test substance: Marlotherm S ([redacted]), OECD TG 301D. For this study you conclude: "*under test conditions no biodegradation observed*".

- One inherent biodegradability study "*IB 302C;* [redacted] *Marlotherm S; #1*" according to OECD TG 302C with the test substance Marlotherm S ([redacted]) showing negligent degradation of 0.2% (O2 consumption) after 28d.

- One non-standard study "[redacted] *1990 /K2 KS/Biodegradation in water: screening tests.001*", conducted "*in conditions similar to a ready biodegradability test*" (no guideline followed) indicated as being conducted with the registered substance (dibenzyltoluene, EC No 248-097-0, CAS No 26898-17-9) showing that "*dibenzyltoluene is degraded by 65% in 62 days and almost completely (94%) in 149 days.*". According to your conclusions "*It is shown that ready biodegradability criteria are not met but, under prolonged incubation conditions, primary and ultimate biodegradation occur. Therefore the substance can be considered as inherently biodegradable.*"

Concerning these studies, ECHA notes that the study "*RB 301B;* [redacted] *Marlotherm S, neu; #1*" has been conducted with Marlotherm S neu ([redacted]) as the test material. You further report in the Details on test material: "*Composition of test material, percentage of components:* [redacted]" However, no information on the components of this test material is reported in the robust study summary other than the generic names. For instance, you have not indicated which isomers of dibenzylbenzene, ar-methyl derivative and in which concentration are present in the test material. In the absence of this information, ECHA cannot assess the relevance of the information obtained from this test material for determining the ready biodegradability of the registered substance. ECHA notes further that three of the studies listed above have been conducted with Marlotherm S as the test material, namely "*RB 301B;* [redacted] *Marlotherm S; #2*", "*RB 301D;* [redacted] *Marlotherm S; #1*" and "*IB 302C;* [redacted] *Marlotherm S; #1*"

As explained above in Section 0 of this decision, ECHA considers that this approach constitutes a read-across adaptation according to the provisions of Annex XI, Section 1.5 of the REACH regulation and concludes that your adaptation of the information requirement is

rejected.

With regard to the latter study performed according to OECD TG 302C, IB 302C; [redacted] Marlotherm S; #1, ECHA further notes that inherent biodegradability tests cannot anyway be used to assess the ready biodegradability of substances because of the optimum conditions in these tests.

Thus, based on the current information in the technical dossier, the conclusion on the ready biodegradability of the registered substance cannot be based on these four studies i.e. RB 301B; [redacted] Marlotherm S, neu; #1; RB 301B; [redacted] Marlotherm S; #2; RB 301D; [redacted] Marlotherm S; #1; IB 302C; [redacted] Marlotherm S; #1.

However, ECHA notes that the study "[redacted] *1990 /K2 KS/Biodegradation in water: screening tests.001*" indicated as being conducted with the registered substance dibenzyltoluene, shows that "*ready biodegradability criteria are not met*".

Hence, ECHA concludes that based on the provided combined screening level information on biodegradation, the registered substance cannot be considered as ready biodegradable.

ECHA notes further that column 2 of Annex IX, Section 9.2. requires that the simulation study shall be conducted if indicated by the chemical safety assessment (CSA) according to Annex I, including PBT assessment.

In your PBT assessment you indicate that "*Dibenzyltoluene is not considered to be a PBT substance. It does not meet the P/vP criterion based on screening data.*". However, ECHA notes that - in contrast to your conclusions drawn from the available information on ready bioavailability ("*inherently biodegradable, not fulfilling specific criteria*") - the available data in the technical dossier indicates that the substance could be (very) persistent and that there is a PBT/vPvB concern.

First, as explained above, based on submitted information, the registered substance is not ready biodegradable and thus fulfils the P/vP screening criterion.

Secondly, ECHA notes the following on the study "[redacted] *1990 /K2 KS/Biodegradation in water: screening tests.001*" indicated as being conducted with the registered substance dibenzyltoluene. Based on the Tables you provide in your dossier, the half-life based on UV measurements, the predicted half-life of the parent compound would not be below 40 days or 60 days. Notably, the % degradation you report after 62 and 105 days is 58% and 50% respectively. Also, plotting all degradation results against the test duration leads to the conclusion that the half-life is >40 days. Therefore, based on the results on this study the registered substance would fulfil the P criterion (degradation half-life in freshwater or estuarine water >40 days) and potentially the vP criterion (degradation half-life in freshwater or estuarine water >60 days).

ECHA acknowledges the opinion by the ECB PBT working group attached to your technical dossier and referred to in the biodegradation endpoint summary (IUCLID section 5.2.1) and in the PBT assessment (IUCLID section 2.3) that the registered substance is not persistent. However, ECHA notes the following:

- Not all studies cited in the ECB PBT working group report are reported in your dossier and *vice versa*.

- Based on the current REACH legislation and the available ECHA Guidance on information requirements and chemical safety assessment (version 3.0, June 2017), Chapters R.11., PBT/vPvB assessment, ECHA comes to a different conclusion than the ECB PBT working group. Especially the experimental data (as explained above) do not support a conclusion that the substance is "not P/not vP".

In summary, ECHA notes that based on the provided combined screening level information on biodegradation, in the technical dossier, there is no sufficient evidence that the registered substance would not be P or vP. In the technical dossier, there is also no experimental data on the identity of the biodegradation products and their fate. In addition, the substance is potentially B/vB based on measured Log Kow > 6 (above the screening criterion for B of 4.5) and information on aquatic toxicity is missing and has been requested in this decision. ECHA hence considers that the current information in the chemical safety assessment (CSA) including the PBT/vPvB assessment is not complete. ECHA notes further that you have not provided adequate justification in your CSA or in the technical dossier for why there is no need to investigate further the degradation of the substance and its degradation products. On this basis, you have not demonstrated that there is no need to investigate further the degradation of the substance and its degradation products.

In conclusion, ECHA considers that as explained above 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.

In your comments on the draft decision you have not agreed to conduct the currently required study.

While you agree to provide additional information on the degradation of the registered substance, in your comments on the draft decision you have indicated your intention to perform only the soil simulation testing according to OECD TG 307 (request 9 below). ECHA notes that, regarding the three simulation test requests subject to this decision (8-10), you have provided in your comments information on the choice of compartment for simulation testing relevant to all three simulation test requests. Therefore, ECHA addresses them all here, and refers to it under points 9 and 10 below, as necessary.

Concerning the choice of compartment for simulation testing, ECHA notes that in your justification you have considered fate and physico-chemical properties only, as described below.

Regarding simulation testing in water, you consider that, based on the physico-chemical properties of the registered substance (mixture of isomers having low water solubility and high adsorption potential), a test on ultimate degradation in surface water (OECD TG 309) does not need to be conducted since it will bring "*no new information on the ultimate environmental fate of the substance*". Based on the fate and physico-chemical properties of the registered substance, you consider soil to be the environmental compartment of concern because a lower degradation rate is expected in soil rather than in water due to partly immobilisation caused by sorption.

Regarding simulation testing in sediment, you consider that the registered substance has similar fate in soil and sediment: based on its physico-chemical properties (mixture of

isomers having low water solubility and high adsorption potential), the isomers will be tightly bound to organic material in soil and sediment and hence will have little, if any, bioavailability. As a consequence, you consider that sediment simulation study (OECD TG 308) does not need to be additionally conducted since the results of soil simulation testing (OECD TG 307) will also predict the fate of the registered substance in sediments.

While you justify your choice to study simulation only in the soil compartment based on the fate and physico-chemical properties of the substance, ECHA considers that these properties alone cannot be used to adapt standard information requirements relating to testing the surface water and sediment compartments. According to the integrated testing strategy for persistency assessment described in Section R.11.4.1.1. of *ECHA Guidance on information requirements and chemical safety assessment*, Chapter R.11 (version 3.0, June 2017), ECHA considers that also the influence of the relevant environmental compartment(s) in terms of the identified uses and release patterns should be taken into consideration when choosing the most relevant environmental compartment to be tested first. .

ECHA considers also that since by default the surface water compartment receives a significant amount of emission, testing should start with the OECD TG 309 simulation study, 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, based on the fate and release(s) of the substance, it is considered that water compartment is not a relevant environmental compartment at all, this should also be taken into account in the testing strategy (ECHA guidance Chapter R. 11. version 3.0, June 2017). In such a case you shall provide a full scientific justification as to why based on the registered substance properties, fate and use and release patterns and any other relevant information water testing is not technically feasible and/or not relevant for the registered substance.

Furthermore, while you indicate that you intend to conduct only a soil simulation study, you do not indicate in which circumstances further simulation studies in other compartments may be needed. ECHA notes that the P/vP assessment should cover all environmental compartments and, for the purpose of reducing efforts of testing, testing should be started with the compartment which is foreseen to provide with the best possibility to use the results for concluding the P/vP assessment. ECHA notes that once it is possible to conclude that the P and/or vP criteria are fulfilled in one environmental compartment, including assessing P/vP for all constituents and any potential transformation and/or degradation products, no further testing is needed for the other compartments. In such case, a scientifically valid justification for adapting simulation studies in other compartments will need to be provided as to why there is no concern in the remaining compartments. On the contrary, if based on a simulation study conducted it is not possible to conclude the P/vP assessment for all compartments, further simulation testing may be needed. ECHA notes that, if needed, the timeline of this decision allows sequencial simulation testing of all environmental compartments.

In conclusion, ECHA considers that the justifications you provided in your comments to the draft decision to adapt standard information requirements relating to testing the surface water compartment discussed above cannot be accepted. ECHA notes that if you should encounter technical difficulties to perform the requested test, for example related to

sensitivity of the analytical method, such difficulties and attempted solutions should be clearly demonstrated in the relevant technical dossier section.

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.

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

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.

"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 a relatively low water solubility (18 µg/L), high partition coefficient (log Kow >6) and high adsorption coefficient (log Koc "calculated to be between 3.548 and 5.578"), 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 sought to adapt this information requirement Annex IX, Section 9.2.1.3., column 2. You provided the following justification for the adaptation: "*According to column 2 of regulation Annex IX: substance is highly insoluble in water and soil exposure is unlikely*".

ECHA has assessed this adaptation and concludes based on the information in the technical dossier 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.

According to Annex IX, Section 9.2.1.3, column 2 of the REACH Regulation, simulation testing on soil does not need to be conducted if the substance is readily biodegradable or if direct or indirect exposure of soil is unlikely. However:

- ECHA notes that the substance is not readily biodegradable, as fully explained in request 8 above.

- ECHA further notes that contrary to your adaptation statement, direct and indirect exposure of the soil compartment cannot be excluded based on the reported uses of the substance (e.g. Environmental Release Category (ERC) 10a). Also the exposure estimations that you provided in the Chemical Safety Report (CSR) indicate that there is exposure to soil in a number of exposure scenarios. Further, the physico-chemical properties (in particular the high sorption coefficient "*between 3.548 and 5.578*" and logKow >6 indicating adsorptive properties) and the potentially high toxicity of the substance do not exclude exposure of the soil compartment at environmentally relevant concentrations. ECHA therefore considers that you have not demonstrated that soil exposure is unlikely.

- ECHA notes that your statement in the adaptation "*substance is highly insoluble*" (to which ECHA disagrees) is not a valid adaptation for soil simulation testing.

Furthermore, column 2 of Annex IX, Section 9.2. requires that the simulation study shall be conducted if indicated by the chemical safety assessment (CSA) according to Annex I, including PBT assessment.

ECHA notes that you have not provided adequate justification in your chemical safety assessment (CSA), including the PBT assessment, nor in the technical dossier for why there is no need to investigate further the degradation of the substance and its degradation products, as fully discussed in request 8 above.

In conclusion, ECHA considers that as explained above and in request 8 of this decision, further information on degradation 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.

ECHA notes that in your comments on the draft decision you agree that "*additional information on the ultimate fate of the registered substance needs to be developed*" and agree to conduct the study requested. ECHA has addressed your comments on the draft decision regarding choice of compartment for simulation testing under request 8. above. In your comments on the draft decision you have further indicated that, based on discussions with contract laboratories, you recommend to conduct soil simulation testing using a radio-labelled surrogate test substance and you provide the following justification for this assessment approach. You indicate that the registered substance is a complex mixture of Dibenzyltoluene and Benzylphenylmethyltoluene isomers, which, based on QSAR modelling, are "*expected to have virtually identical physical/chemical properties (i.e. water solubility and Koc) that determine environment fate.*" You hence recommend to test one labelled dibenzyl toluene isomer such as [redacted].

Regarding the proposed assessment approach, whilst it is your responsibility to ensure you are able to interpret and use the results of the test using the appropriate guideline in order to fulfil the information requirement, ECHA considers that whenever feasible a simulation study should be performed using a radio-labelled test material, as indicated in Section R.11.4.1.1.3 of *ECHA Guidance on information requirements and chemical safety assessment*, Chapter R.11 (version 3.0, June 2017).

ECHA also acknowledges that testing selected constituent(s) is an acceptable approach for the purpose of the PBT/vPvB assessment of UVCBs substances but such approach has to be clearly justified, 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). Regarding your justification, there are several deficiencies that currently do not allow ECHA to assess whether the proposed assessment approach would be adequate for the purpose of the PBT/vPvB assessment. Firstly, you have not provided any information on the QSAR results on physical/chemical properties, hence ECHA is not able to assess the predictions. Secondly, in your justification you have addressed only the fate properties of the isomers, but you have not discussed whether the constituent chosen to be tested represents the worst case of the (v)P, (v)B and T properties of the all constituents present at ≥0.1% w/w concentration in the substance. More specifically, you have not addressed whether you expect all Dibenzyltoluene and Benzylphenylmethyltoluene isomers to have similar P, B and T properties. Thirdly, you have not addressed whether your approach would cover the PBT/vPvB assessment of the whole substance including the unknown constituents, which according to the composition provided in IUCLID Section 1.2, is present at a typical concentration of [redacted]) and comprises "[redacted]". Finally, ECHA notes that in your comments on the draft decision you have not discussed whether the choice of the constituent to be tested would have an impact on the identification of the degradation products needed for the purpose of the PBT/vPvB assessment.

ECHA considers that all issues listed above should be taken into consideration when undertaking the simulation test(s).
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.

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.

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

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.

"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 a relatively low water solubility (18 µg/L), high partition coefficient (log Kow >6) and high adsorption coefficient (log Koc "calculated to be between 3.548 and 5.578"), 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 sought to adapt this information requirement Annex IX, Section 9.2.1.4., column 2. You provided the following justification for the adaptation: "*According to column 2 of regulation Annex IX: substance is highly insoluble in water and sediment exposure is unlikely*".

ECHA has assessed this adaptation and concludes based on the information in the technical dossier that your adaptation does not meet the specific rules for adaptation of Column 2 of Annex IX, Sections 9.2. and 9.2.1.4 due to the following.

According to Annex IX, Section 9.2.1.4, column 2 of the REACH Regulation, simulation testing on sediment does not need to be conducted if the substance is readily biodegradable or if direct or indirect exposure of sediment is unlikely. However:

- ECHA notes that the substance is not readily biodegradable, as fully explained in request 8 above.

- ECHA further notes that contrary your adaptation statement, direct and indirect exposure of the sediment compartment cannot be excluded based on the reported uses of the substance (e.g. Environmental Release Category (ERC) 10a). Also the exposure estimations that you provided in the Chemical Safety Report (CSR) indicate that there is exposure to sediment in a number of exposure scenarios. Further, the physico-chemical properties (in particular the high sorption coefficient "*between 3.548 and 5.578*" and logKow >6 indicating adsorptive properties) and the potentially high toxicity of the substance do not exclude exposure of the sediment compartment at environmentally relevant concentrations. ECHA therefore considers that you have not demonstrated that sediment exposure is unlikely.
- ECHA notes that your statement in the adaptation "*substance is highly insoluble*" (to which ECHA disagrees) is not a valid adaptation for sediment simulation testing.

Furthermore, column 2 of Annex IX, Section 9.2. requires that the simulation study shall be conducted if indicated by the chemical safety assessment (CSA) according to Annex I, including PBT assessment.

ECHA notes that you have not provided adequate justification in your chemical safety assessment (CSA), including the PBT assessment, nor in the technical dossier for why there is no need to investigate further the degradation of the substance and its degradation products, as fully discussed in request 8 above.

In conclusion, ECHA considers that as explained above and in request 8 of this decision, further information on degradation 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 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.

ECHA notes that in your comments on the draft decision you have not agreed to conduct the currently required study. While you agree to provide additional information on the degradation of the registered substance, you intend to perform only soil simulation testing (request 9) since you consider that the results of soil simulation testing will also predict the fate of the registered substance in sediments. ECHA has addressed your comments regarding the choice of compartment for simulation testing under request 8. above. For the reasons explained in request 8, ECHA considers that the justifications provided in your comments on the draft decision cannot be used to adapt standard information requirements relating to testing the sediment compartment. 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.

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.

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

Before conducting the requested tests under sections 8, 9 and 10 above you are advised to consult the ECHA Guidance on information requirements and chemical safety assessment, Chapter R7b, 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 20172014) 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 are 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.

Given the nature of the registered substance as an extract of unknown or variable composition, complex reaction products or biological materials (UVCB), analytical challenges can be expected.

ECHA draws the attention of the Registrant to the ECHA Guidance on information requirements and chemical safety assessment (version 3.0, June 2017), Chapters R.11., PBT/vPvB assessment Section R.11.4.1. which provides further guidance on what should be considered as relevant constituents and for UVCBs (substances of Unknown or Variable composition, Complex reaction products or Biological materials), Section R.11.4.2.2 which provides further guidance on how to carry out a PBT/vPvB assessment.

In addition, you are advised to consult the ECHA Guidance on information requirements and chemical safety assessment, Chapters R.4 (v.1.1, December 2011), R.5 (v.2.1, December 2011), R.6 (May 2008), R.7b (v 4.0, June 2017) and R.7c (v 3.0, June 2017). If you decide to adapt the testing requested according to the specific rules outlined in Annexes VI to X and/or according to general rules contained in Annex XI of the REACH Regulation, you are referred to the advice provided in practical guides on "How to use alternatives to animal testing to fulfil your information requirements for REACH registration" and on "How to use and report (Q)SARs".

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

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.

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.

According to Annex XIII of REACH, the identification of PBT/vPvB substances shall take account of the PBT/vPvB-properties of relevant constituents of the substance. Indeed, Section R.11.4.1 (page 36) of REACH Guidance document R.11 on PBT/vPvB assessment (version 3.0, June 2017) indicates that "*constituents, impurities and additives should normally be consideredrelevant for the PBT/vPvB assessment when they are present in concentration of ≥ 0.1% (w/w). This limit of 0.1% (w/w) is set based on a well-established practice rooted in a principle recognised in European Union legislation*". Therefore degradation products should be identified for each constituent present in the registered substance in concentrations at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable.

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. "

According to Annex IX, Section 9.2.3., column 2 of the REACH Regulation, identification of degradation products is not needed if the substance is readily biodegradable. ECHA notes that based on the information in the technical dossier, the registered substance is not readily biodegradable in as already explained in section 8above.

Furthermore, ECHA notes that you have not provided any justification in your chemical safety assessment (CSA) or in the technical dossier for why there is no need to provide information on the degradation products, as explained fully in sections 8-10 above. ECHA considers that this information is needed in relation to the PBT/vPvB assessment and the risk 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.

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 studies 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 in your comments on the draft decision you agree to perform this request and indicate soil simulation testing (OECD TG 307) as your test method. While ECHA agrees that you may obtain information on the degradation products from the relevant simulation studies requested in this decision, ECHA has addressed your comments regarding the choice

of compartment for simulation testing and your proposed assessment approach under requests 8. and 9., respectively, above.

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, including each constituents present in concentrations at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable following the conditions listed above.

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.

12. 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.

ECHA notes that you have submitted data to cover the standard information requirements of short-term and long-term toxicity testing on invertebrates (Annex IX, section 9.4.1. and Annex X, section 9.4.4.), and short-term and long-term toxicity testing on plants (Annex IX, section 9.4.3. and Annex X, section 9.4.6.), however these data are not sufficient to address the present standard information requirement.

You have waived the standard information requirement of Annex IX, section 9.4.2. using the following justification: "*the study does not need to be conducted because direct and indirect exposure of the soil compartment is unlikely – [exposure considerations]*".

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, section 9.4., column 2 due to the following.

ECHA considers your claim of no direct or indirect exposure as not correct as based on the uses reported in your Chemical Safety Report (CSR) the substance has wide dispersive outdoor uses (ERC 10 a) for which exposure to soil cannot be ruled out. This is supported by exposure calculations indicating exposure to soil for several exposure scenarios. Additionally, the registered substance has a relatively low water solubility (18 µg/L), high partition coefficient (log Kow >6) and high adsorption coefficient (log Koc "calculated to be

between 3.548 and 5.578"), indicating high adsorptive properties. Consequently, also substance properties indicate that soil is a compartment of concern and exposure of soil cannot be ruled out.

ECHA notes also that in the studies on terrestrial invertebrates and on terrestrial plants submitted in the technical dossier effects on terrestrial organisms were observed. Hence, possible effects on terrestrial micro-organisms cannot be ruled out.

Therefore, your justification for waiving does not meet the criteria of either the specific adaptation rules of Column 2 of Annex IX, Section 9.4, or the general adaptation rules of Annex XI. Therefore, the adaptation cannot be accepted.

In your comments on the Member State Competent Authority Proposal for Amendment (PfA) you disagreed with the request to add the soil microorganism study. You concluded that due to lack of effects in available aquatic studies (including aquatic microorganisms), low toxicity observed in available terrestrial studies and terrestrial RCRs of below 1 no testing of terrestrial microorganisms is required. However, ECHA disagrees with your conclusion due to the following. According to *ECHA Guidance on information requirements and chemical safety assessment* Chapter R7c (version 3.0., November 2017) three L(E)C50 values covering three taxonomic groups, plants, invertebrates and micro-organisms as per Annex IX requirements, are normally required. In the Guidance it is further defined that where less than a full soil toxicity data-set is available, both the available soil data and the Equilibrium Partitioning Method (EPM) should be used in deriving the PNECsoil. However, as the substance has a low water solubility and no effects were observed in acute aquatic studies it has not been possible to derive a reliable PNECaquatic to be used as basis of the EPM. Furthermore, the use of the EPM is not acceptable to waive the standard information requirement for soil microorganisms since, as also indicated in the *Notes for your considerations* below, PNECaquatic does not take into consideration any toxicity data on microorganisms. ECHA also considers that absence of toxicity in a single aquatic microorganism study (guideline "other", "O2 consumption test (Huels method)") cannot alone as such be used to waive the need to assess the toxicity of soil microorganisms as per Annex IX section 9.4.2. Aquatic microorganism studies could be used as part of a weight of evidence approach, however as per Annex XI section 1.2. at least two independent lines of evidence would be required. ECHA hence disagrees with the justification for waiving brought forward in your comments.

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* (version 3.0, June 2017), Chapter R.7C, Section R.7.11.3.1., the nitrogen transformation test is considered sufficient for most non-agrochemicals.

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: Soil microorganisms: nitrogen transformation test (test method: EU C.21./OECD TG 216).

Notes for your consideration

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.

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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 20 February 2017.

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

You were notified that the draft decision does not take into account any updates after 19 May 2017. You updated your registration with submission number [redacted] on 27 June 2017 and therein you have completed the adaptation of the substance identifiers. This has resulted in a change of the EC number from the number 248-097-0 to the number 258-649-2, a change of the CAS number from the number 26898-17-9 to the number 53585-53-8 and a change of the substance name from "Dibenzyltoluene" to "Dibenzylbenzene, ar-methyl derivative". This complies to the communication number SUB-C-2114363929-37-01/F (date 13 June 2017), in which ECHA requested you to submit an updated dossier including new identifiers of the registered substance. ECHA has only taken into account the updated substance identifiers (submission number [redacted], date 27 June 2017) and modified the draft decision accordingly. No assessment of the other content of the updated registration dossier has occurred.

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

ECHA received proposal(s) for amendment and modified the draft decision.

ECHA invited you to comment on the proposed amendment(s).

ECHA referred the draft decision to the Member State Committee.

Your comments on the proposed amendment(s) were taken into account by the Member State Committee.

The Member State Committee reached a unanimous agreement on the draft decision in its MSC-60 written procedure and ECHA took the decision according to Article 51(6) of the REACH Regulation.

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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. Hence, it is critical that those constituents which are the most relevant should be present at appropriate concentrations in any sample tested. 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.