~~Confidential~~

Helsinki, 23 July 2021

Addressees
Registrant(s) of Joint_239_816_9 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
14 December 2017

Registered substance subject to this decision ("the Substance")
Substance name: Bis(4-(1,1,3,3-tetramethylbutyl)phenyl)amine
EC number: 239-816-9
CAS number: 15721-78-5

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

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadline of ***28 October 2024***.

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

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

1. Long-term toxicity testing on aquatic invertebrates also requested below (triggered by Annex VII, Section 9.1.1.,Column 2).

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

1. Long-term toxicity testing on fish also requested below (triggered by Annex VIII, Section 9.1.3., Column 2);

2. Soil simulation testing also requested below (triggered by Annex VIII, Section 9.2.);

3. Sediment simulation testing also requested below (triggered by Annex VIII, Section 9.2.);

4. Identification of degradation products also requested below (triggered by Annex VIII, Section 9.2.);

5. Bioaccumulation in aquatic species also requested below (triggered by Annex I, Sections 0.6.1. and 4; Annex XIII, Section 2.1.).

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

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

2. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: OECD TG 210);

3. Soil simulation testing (Annex IX, Section 9.2.1.3.; test method: EU C.23./OECD TG 307) at a temperature of 12 °C;

4. Sediment simulation testing (Annex IX, Section 9.2.1.4.; test method: EU C.24./OECD TG 308) at a temperature of 12 °C;

5. Identification of degradation products (Annex IX, 9.2.3.; test method: using an appropriate test method);

6. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2; test method: OECD TG 305, aqueous exposure);

7. Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: EU C.21./OECD TG 216);

8. Long-term toxicity on terrestrial invertebrates (Annex IX, Section 9.4.1., column 2; test method: Earthworm reproduction test (OECD TG 222) or Enchytraeid reproduction test (OECD TG 220) or Collembolan reproduction test (OECD 232);

9. Long-term toxicity to terrestrial plants (Annex IX, Section 9.4.3. column 2.; test method: Terrestrial plant test: seedling emergence and seedling growth test, OECD TG 208 with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species) *or* Soil Quality – Biological Methods – Chronic toxicity in higher plants, ISO 22030).

Reasons for the request(s) are explained in the following appendices:

- Appendix/Appendices entitled "Reasons to request information required under Annexes VII to IX of REACH", respectively.

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you, and in accordance with Articles 10(a) and 12(1) of REACH:

- the information specified in Annex VII to REACH, for registration at 1-10 tonnes per year (tpa), or as a transported isolated intermediate in quantity above 1000 tpa;
- the information specified in Annexes VII and VIII to REACH, for registration at 10-100 tpa;
- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa.

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

For certain endpoints, ECHA requests the same study from registrants at different tonnages. In such cases, only the reasoning why the information is required at lower tonnages is provided in the corresponding Appendices. For the tonnage where the study is a standard information requirement, the full reasoning for the request including study design is given.

Only one study is to be conducted; the registrants concerned must make every effort to reach an agreement as to who is to carry out the study on behalf of the other registrants under Article 53 of REACH.

How to comply with your information requirements

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

You must follow the general testing and reporting requirements provided under the Appendix entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes". In addition, you should follow the general recommendations provided under the Appendix entitled "General recommendations when conducting and reporting new tests for REACH purposes". For references used in this decision, please consult the Appendix entitled "List of references".

The studies relating to biodegradation and bioaccumulation are necessary for the PBT assessment. However, to determine the testing needed to reach the conclusion on the persistency and bioaccumulation of the Substance you should consider the sequence in which these tests are performed and other conditions described in Appendix entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes".

Appeal

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

Failure to comply

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

Authorised[1] under the authority of Christel Schilliger-Musset, Director of Hazard Assessment

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

Appendix A: Reasons to request information required under Annex VII of REACH

1. Long-term toxicity testing on aquatic invertebrates as requested in C.1.

Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.) is a standard information requirement in Annex VII to REACH. However, for poorly soluble substances, a long-term aquatic toxicity study on aquatic invertebrates (Annex IX, Section 9.1.5) must be considered (Annex VII, section 9.1.1, Column 2).

Poorly water soluble substances require longer time to reach steady-state conditions. Hence, short-term tests do not give a true measure of toxicity for this type of substances and long-term test is required. A substance is regarded as poorly water soluble if, for instance, it has a water solubility below 1 mg/L or below the detection limit of the analytical method of the test material (ECHA Guidance R.7b, Section 7.8.5).

Based on the reported water solubility of < 0.1 mg/L, the sample preparation method used in the aquatic toxicity studies and expressing the results as a 100% (v/v) saturated solution, there are indications that the registered substance is poorly water soluble.

Therefore, long-term toxicity testing is needed to accurately define the hazard of the Substance.

The examination of the information provided, as well as the selection of the requested test and the test design are addressed under Section C.1. Your comments on the draft decision are addressed in Section C.1.

Appendix B: Reasons to request information required under Annex VIII of REACH

1. Long-term toxicity testing on fish as requested in C.2

Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.) is a standard information requirement in Annex VIII to REACH. However, for poorly soluble substances, a long-term aquatic toxicity study on fish (Annex IX, Section 9.1.6) must be considered (Annex VIII, section 9.1.3, Column 2).

Poorly water soluble substances require longer time to reach steady-state conditions. As a result, short-term tests do not give a true measure of toxicity for this type of substances and long-term test is required. A substance is regarded as poorly water soluble if, for instance, it has a water solubility below 1 mg/L or below the detection limit of the analytical method of the test material (ECHA Guidance R.7b, Section 7.8.5).

Based on the reported water solubility of < 0.1 mg/L, the sample preparation method used in the aquatic toxicity studies and expressing the results as a 100% (v/v) saturated solution, there are indications that the registered substance is poorly water soluble.

Therefore, long-term toxicity testing is needed to accurately define the hazard of the Substance.

The examination of the information provided in the dossier and in your comments, as well as the selection of the requested test and the test design are addressed under Section C.2.

2. Soil simulation testing as requested in C.3

and

3. Sediment simulation testing as requested in C.4

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

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

- it is potentially persistent or very persistent (P/vP) as:
  - it is not readily biodegradable (*i.e.* <60% degradation in an OECD 301B), and
- it is potentially bioaccumulative or very bioaccumulative (B/vB) as:
  - it has a high potential to partition to lipid storage (*e.g.* log Kow > 4.5);

Your registration dossier provides the following:

- The Substance is not readily biodegradable (20% degradation after 28 days in OECD TG 301B);
- The Substance has a high potential to partition to lipid storage (based on the information on Partition coefficient n-octanol/water, log Kow of 8.8 -[redacted] 2013- and log Kow of 10.82 -Episuite, KOWWIN v1.68, 2012-);

Furthermore, the information in your dossier is currently incomplete and therefore:

- it is not possible to conclude on the bioaccumulation potential of the Substance (see Appendix C, Section 6 of this decision), and
- it is not possible to conclude on the toxicity of the Substance (see Appendix A Section 2 and Appendix C, Sections 1-2 of this decision).

The information above indicates that the Substance is a potential PBT/vPvB substance. The Substance has low water solubility (< 0.1 mg/L), high partition coefficient (log Kow >4.5) and high adsorption coefficient (log $Koc_{,soil}$ of > 5.63), indicating high potential to adsorb to soil and sediment.
Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation. Based on the adsorptive properties of the Substance, soil and sediment represent relevant environmental compartments.

The examination of the available information or adaptations, as well as the selection of the requested tests and the test designs are addressed respectively in Sections C.3 and C.4.

4. Identification of degradation products as requested in C.5

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

As already explained under Sections B.2 and B.3, the Substance is a potential PBT/vPvB substance. Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation.

You have not provided information on the identity of transformation/degradation products for the Substance.

On this basis, the information requirement is not fulfilled.

5. Bioaccumulation in aquatic species as requested in C.6

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

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

- it is potentially persistent or very persistent (P/vP) as:
  - it is not readily biodegradable (*i.e.* <60% degradation in an OECD 301B), and
- it is potentially bioaccumulative or very bioaccumulative (B/vB) as:
  - it has a high potential to partition to lipid storage (*e.g.* log Kow > 4.5);

Your registration dossier provides the following:

- The Substance is not readily biodegradable (20% degradation after 28 days in OECD TG 301B);
- The Substance has a high potential to partition to lipid storage (based on the information on Partition coefficient n-octanol/water, log Kow of 8.8 - [redacted] 2013- and log Kow of 10.82 -Episuite, KOWWIN v1.68, 2012-);

Furthermore, the information in your dossier is currently incomplete and therefore:

- it is not possible to conclude on the persistence of the Substance (see Appendix C, Sections 3 and 4 of this decision), and
- it is not possible to conclude on the toxicity of the Substance (see Appendix C, Sections 1-2 of this decision).

The information above indicates that the Substance is a potential PBT/vPvB substance.

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

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

Appendix C: Reasons to request information required under Annex IX of REACH

1. Long-term toxicity testing on aquatic invertebrates

Long-term toxicity testing on aquatic invertebrates is a standard information requirement in Annex IX to the REACH Regulation.

You have adapted this information requirement according to Annex IX, Section 9.1., Column 2 justifying that based on acute aquatic results for the substance showing no evidence of toxicity reported at the limit of solubility, and the low water solubility, toxicity is not expected in chronic toxicity testing, therefore, chronic testing of invertebrates is waived.

We have assessed this information and identified the following issue(s):

As specified in Annex IX, Section 9.1., Column 2, a long-term toxicity study on aquatic invertebrates must be performed unless the Chemical Safety Assessment (CSA) demonstrates that risks towards the aquatic compartment arising from the manufacture and use of the Substance are controlled (Annex I, Section 0.1). The justification must be documented in the Chemical Safety Report (CSR).

In particular, the CSA must take into account the following elements to support that long-term aquatic toxicity testing is not required:

- all relevant hazard information from your registration dossier,
- the outcome of the risk characterisation in relation to the manufacture and/or uses of the Substance,
- the outcome of the assessment for identification of persistent, bioaccumulative and toxic (PBT) and/or very persistent and very bioaccumulative (vPvB) substances including information on relevant degradation products and constituents (Article 14 (3) in conjunction with Annexes I and XIII) present in concentration at or above 0.1% (w/w) (ECHA Guidance, Chapter R.11).

Poorly water soluble substances require longer time to reach steady-state conditions. As a result, short-term tests do not give a true measure of toxicity for this type of substances and long-term test is required. A substance is regarded as poorly water soluble if, for instance, it has a water solubility below 1 mg/L or below the detection limit of the analytical method of the test material (ECHA Guidance R.7b, Section 7.8.5).

To reach the conclusion that the risks are controlled, we understand that you rely on acute ecotoxicity data for aquatic invertebrates and fish indicating NOEC of 100% v/v saturated solution.

Based on the reported water solubility of < 0.1 mg/L, the sample preparation method used in the aquatic toxicity studies and expressing the results as a 100% (v/v) saturated solution, ECHA considers the Substance poorly water soluble. Short-term aquatic toxicity studies may thus not give a true measure of toxicity for this type of substances and long-term studies are required.

Therefore, without long-term aquatic toxicity studies your CSA does not demonstrate that the risks of the Substance are adequately controlled for the freshwater compartment(s). As a consequence, your adaptation is rejected as it does not meet the specific rules for adaptation of Annex IX, Section 9.1., Column 2.

On this basis, the information requirement is not fulfilled.

In your comments on the draft decision, you continue your attempt to adapt this information requirement based on Column 2 of Annex IX.

We have assessed your comments and identified the following issues.

ECHA notes that following the recent Board of Appeal decision taken for the case A-011-2018, Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term aquatic toxicity under Column 1. This provision must be understood as a trigger for providing further information on long-term aquatic toxicity to fish if the chemical safety assessment according to Annex I indicates the need. A direct consequence of the Board of Appeal's decision in case A-011-2018 is that the standard information requirement for long term toxicity in invertebrates under Section 9.1. of Annex IX can only be adapted on the basis of the general rules for adaptation set out in Annex XI of REACH.

In your comments on the draft decision you present the arguments that the substance is difficult to test and it is not bioavailable based on physico-chemical properties and the results of the human health studies.

However, your dossier does not contain any valid adaptation under Annex XI and none of the arguments refers to Annex XI.

Therefore, the arguments provided with your comments are not relevant reasons to adapt the information requirement.

Study design

The Substance is difficult to test, as already explained above. OECD TG 211 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified and documented. To this end, you must conduct chemical analysis to demonstrate that the selected approach permit to maximize exposure. In addition, due to the properties of Substance, it may be difficult to achieve and maintain the desired exposure concentrations. Therefore, you must monitor the test concentration(s) of the Substance throughout the exposure duration and report the results. Methods capable of identifying gross changes in the composition of WAFs with time are required. If it is not possible to demonstrate the stability of exposure concentrations (i.e. measured concentration(s) not within 80-120% of the nominal concentration(s)), you must express the effect concentration based on measured values as described in OECD TG 211. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solutions.

2. Long-term toxicity testing on fish

Long-term toxicity testing on fish is a standard information requirement in Annex IX to the REACH Regulation.

You have adapted this information requirement according to Annex IX, Section 9.1., Column 2 justifying that based on acute aquatic results for the substance showing no evidence of toxicity reported at the limit of solubility, and the low water solubility, toxicity is not expected

in chronic toxicity testing, therefore, chronic testing of invertebrates is waived.

We have assessed this information and identified the following issue(s):

As specified in Annex IX, Section 9.1., Column 2, a long-term toxicity study on fish must be performed unless the Chemical Safety Assessment (CSA) demonstrates that risks towards the aquatic compartment arising from the manufacture and use of the Substance are controlled (Annex I, Section 0.1). The justification must be documented in the Chemical Safety Report (CSR).

In particular, the CSA must take into account the following elements to support that long-term aquatic toxicity testing is not required:

- all relevant hazard information from your registration dossier,
- the outcome of the risk characterisation in relation to the manufacture and/or uses of the Substance,
- the outcome of the assessment for identification of persistent, bioaccumulative and toxic (PBT) and/or very persistent and very bioaccumulative (vPvB) substances including information on relevant degradation products and constituents (Article 14 (3) in conjunction with Annexes I and XIII) present in concentration at or above 0.1% (w/w) (ECHA Guidance, Chapter R.11).

Poorly water soluble substances require longer time to reach steady-state conditions. As a result, short-term tests do not give a true measure of toxicity for this type of substances and long-term test is required. A substance is regarded as poorly water soluble if, for instance, it has a water solubility below 1 mg/L or below the detection limit of the analytical method of the test material (ECHA Guidance R.7b, Section 7.8.5).

To reach the conclusion that the risks are controlled, we understand that you rely on acute ecotoxicity data for aquatic invertebrates and fish indicating NOEC of 100% v/v saturated solution.

As explained under the last paragraph of Section A.1, based on the sample preparation method used in the aquatic toxicity studies and expressing the results as a 100% (v/v) saturated solution, ECHA considers the Substance poorly water soluble. Short-term aquatic toxicity studies may thus not give a true measure of toxicity for this type of substances and the long-term studies are required.

Therefore, without long-term aquatic toxicity studies your CSA does not demonstrate that the risks of the Substance are adequately controlled for the freshwater water compartment. As a consequence, your adaptation is rejected as it does not meet the specific rules for adaptation of Annex IX, Section 9.1., Column 2.

On this basis, the information requirement is not fulfilled.

In your comments on the draft decision, you continue your attempt to adapt this information requirement based on Column 2 of Annex IX.

As noted in Section C.1. above, a direct consequence of the Board of Appeal's decision in case A-011-2018 is that the standard information requirement for long term toxicity in fish under Section 9.1. of Annex IX cannot be omitted based on Column 2 of this provision, but can only be adapted on the basis of the general rules for adaptation set out in Annex XI of REACH.

In your comments on the draft decision you present the arguments that the substance is difficult to test and it is not bioavailable based on physico-chemical properties and the results of the human health studies.

However, your dossier does not contain any valid adaptation under Annex XI and none of the arguments refer to Annex XI.

Therefore, the arguments provided with your comments are not relevant reasons to adapt the information requirement.

Study design

To fulfil the information requirement for the Substance, Fish, Early-life Stage Toxicity Test (test method OECD TG 210) is considered suitable.

The Substance is difficult to test, as already explained above. OECD TG 210 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified and documented. To this end, you must conduct chemical analysis to demonstrate that the selected approach permit to maximize exposure. In addition, due to the properties of Substance, it may be difficult to achieve and maintain the desired exposure concentrations. Therefore, you must monitor the test concentration(s) of the Substance throughout the exposure duration and report the results. Methods capable of identifying gross changes in the composition of WAFs with time are required. If it is not possible to demonstrate the stability of exposure concentrations (i.e. measured concentration(s) not within 80-120% of the nominal concentration(s)), you must express the effect concentration based on measured values as described in OECD TG 210. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solutions.

3-4. Soil simulation testing and Sediment simulation testing

Soil simulation testing and sediment simulation testing are standard information requirement at Annex IX of REACH for substances with a high potential for adsorption to soil. The Substance has low water solubility of < 0.1 mg/L and high adsorption coefficient (log Koc > 5), indicating high adsorptive properties.

You have sought to adapt this information requirement based on Annex IX, Sections 9.2.1.3 and 9.2.1.4., Column 2. You justified the adaptation by stating that due to the unlikely direct and indirect exposure of the soil and sediment, biodegradation in soil and sediment studies do not need to be conducted.

Simulation testing on soil and on sediment do indeed not need to be conducted if direct or indirect exposure of soil and sediment is unlikely (Annex IX, Section 9.2.1.3 and Section 9.2.1.4., column 2).

The absence of exposure has not been demonstrated:

- based on the reported uses, soil and sediment exposure cannot be excluded e.g. Environmental Release Category (ERC) 8a and 8d.

In addition, the Substance has a low water solubility of < 0.1 mg/L and high adsorption

coefficient (log Koc > 5.63) indicating adsorptive properties.

Furthermore, you have not provided any justification in your chemical safety assessment (CSA) or in the technical dossier for why there is no need to investigate further the degradation of the Substance and its degradation products.

Therefore, your adaptation does not fulfil the information requirement.

In your comments to the draft decision, you have sought to adapt this information requirement based on Annex XI, Section 1.3 by providing the following information:

A. QSAR (Quantitative Structure-Activity Relationship) predictions for biodegradability using EpiSuite BIOWIN v4.10 models;
B. An expected lack of degradation based on the structure, which ECHA considers as a SAR (Structure-Activity Relationship) prediction, since you claim that the Substance contains structural fragments among those listed in an open literature source (Boethling et al. 2007) to be resistent to biodegradation.

We have assessed this information and identified the following issues:

1.
Annex XI, Section 1.3. states that results obtained from valid QSAR models may be used instead of testing when the following conditions are met, among others:

- results are derived from a QSAR model whose scientific validity has been established;

Modelled endpoint not relevant to the information requirement

Under ECHA Guidance R.6.1.3., a (Q)SAR model must fulfil the principles described in the OECD Guidance document on the validation of (Q)SAR models (ENV/JM/MONO(2007)2) to be considered scientifically valid. The first OECD principle requires the endpoint of a (Q)SAR model to be well defined. ECHA Guidance R.6.5.1.2 specifies that for a well-defined endpoint:

- the key observations modelled being predicted by the (Q)SAR must be the same as the endpoints measured by a defined test protocol relevant to the information requirement, which in this case include:
  - the rate of aerobic and anaerobic transformation of the test material in four soil types (OECD TG 307);
  - the rate of aerobic and/or anaerobic transformation of the test material on at least two sediments (OECD TG 308), and
  - the identity and rates of formation and decline of transformation products (OECD TG 307 and 308);

A. QSAR

Regarding the QSAR predictions: the endpoint estimated by EpiSuite BIOWIN is the probability of rapid aerobic and anaerobic biodegradation of an organic compound in the presence of mixed populations of environmental microorganisms.

Therefore the endpoint of the model is not the same as the endpoints measured by a defined test protocol relevant to the information requirement. As a consequence, you have not

established that the use of this model is a scientifically valid approach to meet this information requirement.

B. SAR

Regarding the SAR prediction: you estimate lack of biodegradation based on structure. You have cited the paper of Boethling et al. 2007, listing various chemical features that are known to increase the resistence of a substance to aerobic biodegradation. You explain that as the Substance contains several features as reported in Boethling et al. 2007, it could be concluded that for the Substance: "*There is simply no feature that is amenable to microbial attack*".

ECHA agrees that some of the chemical features contained within the Substance might indicate recalcitrant nature of the Substance. However, this qualitative estimate does not inform on the rate of aerobic and anaerobic transformation of the test material in soil or in sediments nor on the identity and rates of formation and decline of transformation products.

Therefore, the SAR estimate provided in your comments is not the same as the endpoints measured by a defined test protocol relevant to the information requirement. As a consequence, you have not established that the use of this model is a scientifically valid approach to meet this information requirement.

2.

(Q)SAR predictions are only regarded as screening information on P/vP properties (Annex XIII, Section 3.1.1 (c)).

Results obtained from higher tier tests (e.g. simulation studies or other information, such as from field studies or monitoring studies) are regarded as assessment information to conclude on P/vP properties (Annex XIII, Section 3.2.).

You have provided (Q)SAR predictions for the simulation studies.

The results from (Q)SAR estimations cannot be used to conclude that the Substance meets the P/vP criteria.

Based on the above mentioned reasons, your adaptation does not fulfil the information requirement.

Study design

Under Annex XIII, the information must be based on data obtained under conditions relevant for the PBT/vPvB assessment. Therefore:

- You must perform the OECD TG 307 test using four soils representing a range of relevant soils (*i.e.* varying in their organic content, pH, clay content and microbial biomass).

- You must perform the OECD TG 308 test using two sediments. One sediment should have a high organic carbon content (2.5-7.5%) and a fine texture, the other sediment should have a low organic carbon content (0.5-2.5%) and a coarse texture.

- You must perform the tests at the temperature of 12°C, the average environmental temperature for the EU (ECHA Guidance R.16, Table R.16-8). Performing the tests at this temperature is in line with the applicable test conditions of the OECD TG 307.

Non-extractable residues (NER) must be quantified in all simulation studies. The reporting of results must include a scientific justification of the used extraction procedures and solvents. By default, total NER is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NER may be differentiated and quantified as irreversibly bound or as degraded to biogenic NER. Such fractions could be regarded as removed when calculating the degradation half-life(s) (ECHA Guidance R.11).

5. Identification of degradation products

Identification of the degradation products is a standard information requirement at Annex IX of REACH.

You have provided no information on the identity of transformation/degradation products for the Substance.

Therefore, this information requirement is not met.

This information is required for the purpose of the PBT/vPvB assessment (Annex I, Section 4) and the risk assessment (Annex I, Section 6) of the Substance.

In your comments to the draft decision, you propose to adapt this information. As you consider the Substance is persistent and due to the concern that any degradants will be present in such small quantities that their detection will require use of a radiolabelled test material.

We have assessed this information and identified the following two issues:

1. A registrant may only adapt this information requirement based on the specific rules for adaptation set out in Column 2 of Annex IX, Section 9.2.1.3 and 9.2. or the general rules for adaptation set out in Annex XI.

   You consider that based on the information as already presented in section C.4. the substance is persistent.
   Your argumentation does not refer to any legal ground for adaptation under Annex XI to REACH nor to any specific rul set out in Column 2 for this endpoint. In addition, for the reasons described in section C.4. the information provided does not allow to reach any conclusion on the persistency of the substance.

2. To fulfil the information requirement, a study must comply with the OECD TG 308 and/or the TG 307 (Article 13(3) of REACH). Therefore, among others the following requirements must be met:
   - The analytical method used for the quantification of the test material and its transformation/degradation products may require the use of radiolabel test material.
   - Transformation products detected at ≥10% of the applied radioactivity in the total water-sediment system at any sampling time must be identified unless reasonably justified otherwise. Transformation products for which concentrations

are continuously increasing during the study must also be considered for identification, even if their concentrations do not exceed the limits given above.

In addition ECHA Guidance R.11, indicates that a simulation study should be performed using a radiolabeled molecule, whenever feasible (Section R.11.4.1.1.3). Technically not feasible means that it has been impossible, with allocation of reasonable efforts, to develop suitable analytical methods. Appropriate analytical methods must have a suitable sensitivity and be able to detect relevant changes in concentration (including that of metabolites) (Section R.11.4.1.1.).

In your comments you indicate that based on the structure of the Substance, you are concerned that preparation of a radiolabeled test material will be impracticable and highly unlikely to provide meaningful information about the identity or quantity of any minor degradants that might be generated.

However, you have provided no experimental evidence that in a simulation study relevant transformation products (i.e. transformation products detected at > 10% or transformation products with increasing or stable concentrations) would not be formed. Especially in your ready biodegradation study according to OECD TG 301B ([redacted], 2012 (Report [redacted])) 20% of biodegradation occurred, indicating that some degree of biodegradation did take place and therefore suggesting that degradation products are likely to be formed.

Finally, as indicated in the OECD TG 307 and 308, the application of specialised techniques (e.g. radiolabelled test chemical) may be needed to achieve quantitative assessment. You did not provide any laboratory evidence demonstrating that it is technically infeasible to use a radiolabeled test material.

Therefore, you have not demonstrated that this information can be adapted.

Study selection and design

You must obtain this information while performing the simulation studies requested in this decision (requests C.3 and C.4). You must provide a scientifically valid justification for any other method you have used for identification of the transformation/degradation products.

Identity, stability, behaviour, and molar quantity of the degradation/ transformation products relative to the Substance must be evaluated and reported, when analytically possible. In addition, degradation half-life, potential for bioaccumulation and toxicity of the transformation/degradation product must be investigated.

6. Bioaccumulation in aquatic species

Bioaccumulation in aquatic species, preferably in fish, is a standard information requirement at Annex IX to REACH.

You have sought to adapt this information requirement based on Annex XI, Section 1.3 and you have provided, as a support to the claim of low potential for bioaccumulation, a QSAR prediction based on EPISuite (BCFBAF Meylan regression model, EPISuite v4.0).

Annex XI, Section 1.3. states that results obtained from valid QSAR models may be used instead of testing when the following cumulative conditions are met, in particular:

1. results are derived from a QSAR model whose scientific validity has been established;
2. the substance falls within the applicability domain of the QSAR model;
3. adequate and reliable documentation of the applied method is provided; and
4. the results are adequate for classification and labelling and/or risk assessment.

According to ECHA's Practical guide "How to use and report (Q)SARs", section 3.4, a QSAR Model Reporting Format (QMRF) and a QSAR Prediction Reporting Format (QPRF) are required to establish the scientific validity of the model, to verify that the Substance falls within the applicability domain of the model, and to assess the adequacy of the prediction for the purposes of classification and labelling.

You have not provided any documentation for the QSAR predictions. In particular, you have not included a QMRF and a QPRF in your technical dossier for the relevant endpoints. Therefore, ECHA cannot establish whether the model is scientifically valid, whether the Substance falls within the applicability domain of the model, and whether the results are adequate for classification and labelling and/or risk assessment.

In your comments to the draft decision, while not addressing the above noted deficiency of the documentation, you have provided some further information addressing QSAR prediction condition "the results are adequate for classification and labelling and/or risk assessment". You indicated that the Substance falls within the applicability domain of the QSAR model used as it is within the molecular weight domain and log Kow domain for this endpoint, and the Substance type, [redacted], is within the training set type. You further report that the Log Kow used as input for the model is 10.8169.

We have assessed this information and identified the following issue(s):
For the reasons explained above the results obtained from valid QSAR models may be used instead of testing when the following conditions are met, among others:

- the results are adequate for classification and labelling and/or risk assessment.

The prediction is not adequate due to low reliability
Moreover, under ECHA Guidance R.6.1.3.4 a prediction is adequate for the purpose of classification and labelling and/or risk assessment when the model is applicable to the chemical of interest with the necessary level of reliability. ECHA Guidance R.6.1.5.3. specifies that, among others, the following cumulative conditions must be met:

- the model predicts well substances that are similar to the substance of interest, and
- reliable input parameters are used

In your comments to the draft decision, while you claim that the Substance type ([redacted]) is within the training set type, you do not provide any information of the closest analogues in the dataset of the model. As a consequence, it is not possible to verify whether the applied model predicts well for similar substances. Morerover, you used as an input for the QSAR prediction an uncertain log Kow value of 10.82, instead of the experimental value of 8.8, which is considered reliable based on the information provided in the comments.

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

Altogether, the adaptation you provided does not fulfil the cumulative criteria specified in Annex XI, Section 1.3. and it is therefore rejected.

Based on the above, this information requirement is not fulfilled.

Study design

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

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

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

You may only conduct the study using the dietary exposure route (OECD 305-III) if you justify and document that testing through aquatic exposure is not technically possible as indicated above. You must then estimate the corresponding BCF value from the dietary test data according to Annex 8 of the OECD 305 TG and OECD Guidance Document on Aspects of OECD TG 305 on Fish Bioaccumulation (ENV/JM/MONO(2017)16).

7. Effects on soil micro-organisms

Effects on soil micro-organisms is a standard information requirement in Annex IX to REACH.

You have provided an adaptation for this endpoint where you consider that: "*Based on the use pattern of the substance there will be no intentional release into the terrestrial compartment. According to Column 2 of Annex IX of the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) legislation if direct and indirect exposure of soil is unlikely, a toxicity to soil microorganisms study does not need to be conducted, therefore this endpoint has been waived*."

As specified in Annex IX Section 9.4, Column 2, testing for the effects on soil micro-organisms must be performed unless direct and indirect exposure of the soil compartment is unlikely.

Regarding the likelihood of exposure to soil, the substance has a low water solubility (< 0.1 mg/L) and high adsorption coefficient (log Koc > 5.63) indicating adsorptive properties. Furthermore, based on the uses reported in the technical dossier, ECHA considers that such uses are reported for which the likelihood of indirect soil exposure cannot be excluded e.g. Environmental Release Category (ERC) 8a and 8d. ECHA therefore considers that you have not demonstrated that indirect soil exposure is unlikely.

As the conditions for adapting this information requirement are not fulfilled - likelihood of indirect exposure of the Substance to the soil cannot be excluded – your adaptation is rejected.

Therefore, the information requirement is not fulfilled.

In the comments on the draft decision, you agree to perform the requested study to fulfil the information requirement.

8. Long-term toxicity to terrestrial invertebrates

Short-term toxicity to terrestrial invertebrates is a standard information requirement in Annex IX to REACH.

You have adapted this information requirement based on Annex IX, Section 9.4., Column 2 with the following justification: "*Based on the use pattern of the substance there will be no intentional release into the terrestrial compartment. According to Column 2 of Annex IX of the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) legislation if direct and indirect exposure of soil is unlikely, a toxicity to soil microorganisms study does not need to be conducted, therefore this endpoint has been waived*".

As specified in Annex IX Section 9.4, Column 2, short-term toxicity testing on terrestrial invertebrates must be performed unless direct and indirect exposure of the soil compartment is unlikely. However, for substances that have a high potential to adsorb to soil or that are highly persistent, the effect of long-term exposures must be estimated for the hazard assessment (ECHA Guidance R.7c, Table R.7.11-2, and Column 2 of section 9.4 of Annex IX).

Regarding the likelihood of exposure to soil, based on the uses reported in the technical dossier, ECHA considers that such uses are reported for which the likelihood of indirect soil exposure cannot be excluded, e.g., ERC 8a and 8d. ECHA therefore considers that you have not demonstrated that indirect soil exposure is unlikely. Moreover, based on the information you provided, the Substance is adsorptive (log Koc > 5.63) and potentially P/vP (20% degradation in 28 days, OECD TG 301B).

As indicated above, due to the uses of the Substance for which likelihood of indirect exposure of the Substance to the soil cannot be excluded, and due to the properties of the Substance, long-term terrestrial toxicity studies are necessary to assess the hazards.

Therefore, the information requirement is not fulfilled.

In the comments on the draft decision, you agree to perform the requested study to fulfil the information requirement.

9. Long-term toxicity to terrestrial plants

Short-term toxicity to terrestrial plants is a standard information requirement in Annex IX to REACH.

You have adapted this information requirement based on Annex IX, Section 9.4., Column 2 with the following justification: "*Based on the use pattern of the substance there will be no intentional release into the terrestrial compartment. According to Column 2 of Annex IX of the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) legislation if direct and indirect exposure of soil is unlikely, a toxicity to terrestrial plants study does not need to be conducted, therefore this endpoint has been waived*".

As specified in Annex IX, Section 9.4., Column 2, short-term toxicity to plants must be performed unless the direct and indirect exposure of the soil compartment is unlikely. However, for substances that have a high potential to adsorb to soil or that are highly persistent, the effect of long-term exposures must be estimated for the hazard assessment (ECHA Guidance R.7c, Table R.7.11-2, and Column 2 of section 9.4 of Annex IX).The effects

on terrestrial organisms must be addressed for different taxonomic groups: invertebrates, soil micro-organisms and terrestrial plants.

Regarding the likelihood of exposure to soil, based on the uses reported in the technical dossier, ECHA considers that such uses are reported for which the likelihood of indirect soil exposure cannot be excluded, e.g., ERC 8a and 8d. ECHA therefore considers that you have not demonstrated that indirect soil exposure is unlikely. Moreover, based on the information you provided, the Substance is adsorptive (log Koc > 5.63) and potentially P/vP (20% degradation in 28 days, OECD TG 301B).

As indicated above, due to the uses of the Substance for which the likelihood of indirect exposure of the Substance to the soil cannot be excluded, and due to the properties of the Substance, long-term terrestrial toxicity studies are necessary to assess the hazards.

Therefore, the information requirement is not fulfilled.

In the comments on the draft decision, you agree to perform the requested study to fulfil the information requirement.

Test design

OECD TG 208 with six species or ISO 22030 is the preferred guideline to fulfil this information requirement. OECD guideline 208 (Terrestrial plants, growth test) considers the need to select the number of test species according to relevant regulatory requirements, and the need for a reasonably broad selection of species to account for interspecies sensitivity distribution. For long-term toxicity testing, ECHA considers six species as the minimum to achieve a reasonably broad selection. Testing shall be conducted with species from different families, as a minimum with two monocotyledonous species and four dicotyledonous species, selected according to the criteria indicated in the OECD 208 guideline.

Appendix D: Requirements to fulfil when conducting and reporting new tests for REACH purposes

1. Test methods, GLP requirements and reporting

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

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

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

2. Test material

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

A. Selection of the Test material(s)

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

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

B. Information on the Test Material needed in the updated dossier

D. You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
E. The reported composition must include all constituents of each Test Material and their concentration values and other parameters relevant for the property to be tested.

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

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

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

Appendix E: General recommendations when conducting and reporting new tests for REACH purposes

- **Strategy for the PBT/vPvB assessment**

  You are advised to consult ECHA Guidance R.7b (Section R.7.9.), R.7c (Section R.7.10) and R.11 on PBT assessment to determine the sequence of the tests needed to reach the conclusion on PBT/vPvB. The guidance provides advice on 1) integrated testing strategies (ITS) for the P, B and T assessments and 2) the interpretation of results in concluding whether the Substance fulfils the PBT/vPvB criteria of Annex XIII.

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

- **Testing strategy for the terrestrial toxicity testing**

  You are advised to consult ECHA Guidance R.7c, (Section R.7.11.6) which describes the Integrated Testing Strategy for toxicity testing on terrestrial organisms.

Appendix F: Procedure

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

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

The compliance check was initiated on 4 September 2019.

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

ECHA took into account your comments and amended the request(s). You provided comments during the decision-making phase which were found to be compliant with the information required for "Partition coefficient n-octanol/water" and "Growth inhibition study aquatic plants" in the draft decision. These requests were therefore removed.

Deadline to submit the requested information in this decision

In your comments on the draft decision, you requested an extension of the deadline to provide information from 36 to 39 months from the date of adoption of the decision. You indicate that there are negotiations ongoing with the lead registrant of the other existing joint submission of the Substance. Therefore, you request a deadline extension to facilitate the merging of these two separate joint submissions into a single joint submission.

ECHA notes that in accordance with Article 53(1) the registrants will be in any case provided with an additional period of 3 months to reach an agreement as to who is to carry out the tests on behalf of the other registrants.

On this basis, ECHA has not modified the deadline to provide the information.

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

As no amendments were proposed, ECHA adopted the decision under Article 51(3) of REACH.

Appendix G: List of references - ECHA Guidance[4] and other supporting documents

Evaluation of available information
Guidance on information requirements and chemical safety assessment, Chapter R.4 (version 1.1., December 2011), referred to as ECHA Guidance R.4 where relevant.

QSARs, read-across and grouping
Guidance on information requirements and chemical safety assessment, Chapter R.6 (version 1.0, May 2008), referred to as ECHA Guidance R.6 where relevant.

Read-across assessment framework (RAAF, March 2017)[5]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[5]

Physical-chemical properties
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Toxicology
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

Environmental toxicology and fate
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017), referred to as ECHA Guidance R.7b in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

PBT assessment
Guidance on information requirements and chemical safety assessment, Chapter R.11 (version 3.0, June 2017), referred to as ECHA Guidance R.11 in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.16 (version 3.0, February 2016), referred to as ECHA Guidance R.16 in this decision.

Data sharing
Guidance on data-sharing (version 3.1, January 2017), referred to as ECHA Guidance on data sharing in this decision.

OECD Guidance documents[6]

[4] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[5] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[6] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

Guidance Document on aqueous–phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

Guidance document on transformation/dissolution of metals and metal compounds in aqueous media – No 29, referred to as OECD GD 29.

Guidance Document on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption – No 150, referred to as OECD GD 150.

Guidance Document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test – No 151, referred to as OECD GD 151.

Appendix H: Addressees of this decision and the corresponding information requirements applicable to them

You must provide the information requested in this decision for all REACH Annexes applicable to you.

Registrant Name	Registration number	Highest REACH Annex applicable to you
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

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