EUROPEAN CHEMICALS AGENCY

Helsinki, 10 March 2020

Addressees
Registrants of JS_266-582-5 listed in the last Appendix of this decision

Date of submission for the jointly submitted dossier subject of this decision
30/01/2019

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: 1-(tert-dodecylthio)propan-2-ol (Note: Substance name does not reflect correctly the identity of the Substance and will be changed at a later stage)
EC number: 266-582-5
CAS number: 67124-09-8

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

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (REACH), ECHA requests that you submit the information listed below by the deadline of ***18 December 2023***.

A. Requirements applicable to all the Registrants subject to Annex VII of REACH

1. Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.; test method EU C.2./OECD TG 202) with the Substance;

2. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method EU C.3./OECD TG 201) with the Substance;

B. Requirements applicable to all the Registrants subject to Annex VIII of REACH

1. Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.; test method OECD TG 203) with the Substance;

C. Requirements applicable to all the Registrants subject to Annex IX of REACH

1. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method OECD TG 414) in a first species (rat or rabbit), oral route with the Substance;

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

3. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method OECD TG 210) with the Substance;

4. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method EU C.25./OECD TG 309) at a temperature of 12 °C with the Substance; including degradation of each relevant constituent present in concentration at or above 0.1% (w/w).

5. Soil simulation testing (Annex IX, Section 9.2.1.3.; test method EU C.23./OECD TG 307) at a temperature of 12 °C with the Substance; including degradation of each relevant constituent present in concentration at or above 0.1% (w/w).

6. Sediment simulation testing (Annex IX, Section 9.2.1.4.; test method EU C.24./OECD TG 308) at a temperature of 12 °C with the Substance; including degradation of each relevant constituent present in concentration at or above 0.1% (w/w).

7. Identification of degradation products (Annex IX, 9.2.3.) using an appropriate test method with the Substance;

8. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2; test method OECD TG 305-I), aquatic exposure) with the Substance; including bioaccumulation of each relevant constituent present in concentration at or above 0.1% (w/w) and relevant degradation products.

Conditions to comply with the requests

Each addressee of this decision is bound by the requests for information corresponding to the REACH Annexes applicable to their own registered tonnage of the Substance at the time of evaluation of the jointly submitted dossier.
To identify your legal obligations, please refer to the following:

- you have to comply with the requirements of Annex VII of REACH, if you have registered a substance at 1-10 tonnes per annum (tpa), or as a transported isolated intermediate in quantity above 1000 tpa;
- you have to comply with the requirements of Annexes VII, VIII and IX of REACH, if you have registered a substance at 100-1000 tpa;

Registrants are only required to share the costs of information that they must submit to fulfil the information requirements for their registration.

The Appendices state the reasons for the requests for information to fulfil the requirements set out in the respective Annexes of REACH.

The Appendix entitled Observations and technical guidance addresses the generic approach for the selection and reporting of the test material used to perform the required studies and provides generic recommendations and references to ECHA guidance and other reference documents.

The studies relating to biodegradation and bioaccumulation (requests C.4 to C.8) 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 section 5 of Appendix E.

You must submit the information requested in this decision by the deadline indicated above in an updated registration dossier and also update the chemical safety report, where relevant, including any changes to classification and labelling, based on the newly generated information. The timeline has been set to allow for sequential testing where relevant.

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.

Approved[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 on Reasons common to several requests

In your comments on the draft decision you provide some reasoning regarding sequential testing for PBT/vPvB, in relation to the tests requested in the current decision (Appendix C, sections 4-8). You indicate that you may perform the requested Bioaccumulation study and only if the Substance is proved to be vB then you consider Simulation testing for biodegradation. This is due to your assumption that the available evidence indicates that the Substance is P, not vP.

However, as indicated under requests Appendix C, sections 4-7 , the conclusion on P or vP is not yet possible based on the information provided, nor on B or vB as described in Appendix C, section 8. Therefore further information on Biodegradation and Bioaccumulation are required.

Furthermore, the sequence of testing that you indicated is inappropriate. To the contrary, simulation studies need to be conducted first as you will then obtain the identity the relevant degradation products (see Appendix C, sections 4-7 for details). This information is necessary to perform the requested Bioaccumulation study (Appendix C, section 8), including bioaccumulation of each relevant constituent present in concentration at or above 0.1% (w/w) *and relevant degradation products*.

Deadline to submit the requested information in this decision

In the draft decision communicated to you, the time indicated to provide the requested information was 39 months from the date of adoption of the decision. In your comments on the draft decision you requested ECHA to extend the deadline by 6 months due to radiolabelling of the UVCB or a component of the UVCB.

ECHA considers that 3 months extension to the original deadline is sufficient for the radiolabelling of the test material. Therefore, the deadline is set to 42 months.

Appendix A: Reasons for the requests to comply with Annex VII of REACH

Under Articles 10(a) and 12(1) of REACH, a technical dossier registered at 1 to 10 tonnes or more per year must contain, as a minimum, the information specified in Annex VII to REACH.

1. **Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.)**

Short-term toxicity testing on aquatic invertebrates is a standard information requirement in Annex VII to REACH.

You have provided a key study ([redacted] 2011) and a supporting study ([redacted] 2004), both conducted according to OECD TG 202 with the Substance.

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

OECD TG 202 is the preferred guideline to fulfil this information requirement. The OECD TG 202 requires that you must (among others):

- perform analytical monitoring to verify the initial concentrations and maintenance of the exposure concentrations during the test; and
- provide evidence that exposure concentrations have been maintained throughout the test >80 % of the nominal or intial measured concentration, in case you use nominal concentrations expressing the results.

You indicate that in the key study the concentrations of the test substance were measured at 0 and 48 hours. However, you report the test results using nominal concentrations and do not report the concentrations measured in the test media at any time point.

In the supporting study the concentrations of the test substance were not measured.

For neither the key study nor the supporting study you initially have provided evidence that the concentration of the test substance was maintained > 80 % of the nominal or measured initial concentration throughout the tests, as required by OECD TG 202. Due to the low water solubility (4.84 mg/L), adsorptive properties (logPow = 4.72 to 6) and surface activity (surface tension = 53.40) of the Substance, it is difficult to test. Therefore, evidence that exposure concentrations have been maintained throughout the test is essential to verify the reliability of the studies.

In the comments on the draft decision you indicate to update the dossier to include the existing analytical data for the key study [redacted] (2011). You claim that this evidence indicates that exposure concentrations have been maintained throughout the test >80 %.

As listed above, evidence needs to be provided to show that exposure concentrations have been maintained throughout the test. In case the evidence shows that exposure concentrations have been maintained throughout the test at > 80 % of the nominal or intial measured concentration, you may use nominal concentrations or measured initial values in expressing the results.

In case the evidence shows that exposure concentrations have not been maintained throughout the test at > 80 % of the nominal or intial measured concentration, you cannot

use nominal concentrations expressing the results but you must use the concentrations measured in the test media during the study as required by the test guideline.

You explain in the comments that the changes in measured concentrations in treatments which are "relevant to toxicity" (i.e. 0.56 and 1.0 mg/L) were above 80% when comparing 48-h concentrations with initial measured values (0-h).

However, you justify the stability of the test item only by comparing measured concentrations at 0-h and 48-h, not from nominal to measured concentrations. Based on the information provided in the comments, the time 0-h measured concentration were 54%, 83% and 61%, and time 48-h measured concentration were 32%, 67% and 50% of the nominal concentrations (at 0.32mg/L, 0.56mg/L and 1.0mg/L nominal).

You do not explain in the comments if you will use measured concentrations from this study to express the results.

The evidence provided in the comments indicates that the measured concentrations over the time course of the study may not be >80% when compared to nominal concentrations. Therefore you must use concentrations measured in the study to express the results.

In conclusion, including the measured concentrations in the dossier may address the deficiencies identified in this decision for this information requirement if measured concentrations are used to express the results. However, as the deficiencies discussed are currently not addressed in the dossier, therefore the provided study does not fulfil the information requirement.

Study design

The substance is difficult to test due to the low water solubility (4.84 mg/L), adsorptive properties (logPow = 4.72 to 6) and surface activity (surface tension = 53.40). OECD TG 202 specifies that for difficult to test substances, the OECD Guidance 23 is to be followed. To get reliable results, the substance properties need to be considered when performing the test, in particular with regard to the test design; including exposure system, test solution preparation, and sampling. OECD GD 23 (Table 1) describes testing difficulties related to a specific property of the substance. You may use the approaches described in OECD GD 23 or other approaches if more appropriate for your substance. The approach selected must be justified and documented.

Due to the substance properties it may be difficult to achieve and maintain the exposure concentrations. Therefore, you have to demonstrate that the concentration of the substance is stable throughout the test (i.e. measured concentrations remains within 80-120% of the nominal concentration). If it is not possible to demonstrate the stability, you must express the effect concentration based on measured values as described in the applicable test guideline. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the test solution preparation method applied was sufficient to maximise the concentration of the Substance in the test solution.

2. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)

Growth inhibition study aquatic plants is a standard information requirement in Annex VII to REACH.

You have provided a key study ([redacted] 2004) conducted according to OECD TG 201 with

the Substance.

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

OECD TG 201 is the preferred guideline to fulfil this information requirement. The OECD TG 201 requires that you must (among others):

- perform analytical monitoring to verify the initial concentrations and maintenance of the exposure concentrations during the test; and
- provide evidence that exposure concentrations have been maintained throughout the test >80 % of the nominal or intial measured concentration, in case you use nominal concentrations expressing the results.

In the key study the concentrations of the test substance were not measured.

You have not provided evidence that the the concentration of the test substance was maintained > 80 % of the nominal or measured initial concentration throughout the test, as required by OECD TG 201. Due to the low water solubility (4.84 mg/L), adsorptive properties (logPow = 4.72 to 6) and surface activity (surface tension = 53.40) of the Substance, it is difficult to test. Therefore, evidence that exposure concentrations have been maintained throughout the test is essential to verify the reliability of the study.

In you comments you have not contested the deficiencies indicated above. However, you have provided new argument why testing on algae is not needed, based on your assumption that it is not the most sensitive species.

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

For the purpose of environmental hazard assessment, the toxicity information should at least cover species of three trophic levels: algae/aquatic plants, invertebrates (*Daphnia* preferred), and fish. This information must be based on data that is generated according to test methods referred to in Article 13(3). OECD TG 201 is the preferred guideline to provide toxicity information on algae/aquatic plants and to fulfil this information requirement.

You consider that, based on the existing study ([redacted] 2004), effects on algae is >100mg/L nominal concentration which supports a conclusion that algae are not the most sensitive species. As decribed above, the study you provided does not fulfil the requirements in OECD TG 201. There is no other study provided that would give the toxicity information on algae/aquatic plants. The issue of sensitivity is irrelevant, as the information for at least three trophic levels is necessary.

Therefore the provided study does not fulfil the information requirement.

Study design

The substance is difficult to test due to the low water solubility (4.84 mg/L), adsorptive properties (logPow = 4.72 to 6) and surface activity (surface tension = 53.40). OECD TG 201 specifies that for difficult to test substances, the OECD Guidance 23 is to be followed. To get reliable results, the substance properties need to be considered when performing the test, in particular with regard to the test design; including exposure system, test solution preparation, and sampling. OECD GD 23 (Table 1) describes testing difficulties related to a specific property of the substance. You may use the approaches described in OECD GD 23

or other approaches if more appropriate for your substance. The approach selected must be justified and documented.

Due to the substance properties it may be difficult to achieve and maintain the exposure concentrations. Therefore, you have to demonstrate that the concentration of the substance is stable throughout the test (i.e. measured concentrations remains within 80-120% of the nominal concentration). If it is not possible to demonstrate the stability, you must express the effect concentration based on measured values as described in the applicable test guideline. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the test solution preparation method applied was sufficient to maximise the concentration of the Substance in the test solution.

Appendix B: Reasons for the requests to comply with Annex VIII of REACH

Under Articles 10(a) and 12(1) of REACH, a technical dossier registered at 10 to 100 tonnes or more per year must contain, as a minimum, the information specified in Annexes VII and VIII to REACH.

1. Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.)

Short-term toxicity testing on fish is a standard information requirement in Annex VIII to REACH.

You have provided a key study ([redacted] 2004, report no [redacted]) and a supporting study ([redacted] 2004, report no [redacted]), both conducted according to OECD TG 203 with the Substance.

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

OECD TG 203 is the preferred guideline to fulfil this information requirement. The OECD TG 203 require(s) that you must (among others):

- perform analytical monitoring to verify the initial concentrations and maintenance of the exposure concentrations during the test; and
- provide evidence that exposure concentrations have been maintained throughout the test >80 % of the nominal or intial measured concentration, in case you use nominal concentrations expressing the results.

Neither in the key study nor supporting study the concentrations of the test substance were measured.

You have not provided evidence that the the concentration of the test substance was maintained >80 % of the nominal or measured initial concentration throughout the tests, as required by OECD TG 203.

In the comments on the draft decision you indicated that the analytical monitoring of test concentration in Short-term invertebrates study ([redacted] (2011)) can be used as evidence that exposure concentrations have been maintained throughout the short term fish test.

We have assessed this information and identified the following issues:

Existing ecotoxicity studies (acute or chronic) may provide an indication of behaviour of the test chemical under test conditions used in the toxicity test.[2]

You claim that the fish toxicity studies listed above for this endpoint ([redacted] 2004, report no [redacted]; [redacted] 2004, report no [redacted] employed a semi-static test regime involving a daily renewal of the test preparations to ensure test concentrations of soluble components of the test material were maintained over the test. This daily renewal of the test concentrations was more frequent than in the acute daphnia study of [redacted] (2011) in which test concentrations were not replaced for the 48hr duration of the test and analysis of toxicologically relevant concentrations demonstrated >80% of initial

[2] OECD GD 23, Section 5

concentrations at 48hr.

While the test media renewal may support the maintanence of the test concentrations, you have not demonstrated that the test media in the key or the supporting fish toxicity study in the dossier were prepared in the same way as in the short-term daphnia [redacted] (2011) study (no information reported). If the test media was prepared differently, different amount of the tested substance may be present in the test solutions.

As you have not demonstrated that the conditions and test solution preparation used in the toxicity tests for short-term daphnia and short-term fish were the same, information on the behaviour of the Substance in the former study is not relevant for the latter studies. Therefore, the analytics performed for the short term daphnia ([redacted] (2011) study) cannot be used as evidence to indicate that exposure concentrations have been maintained throughout the short-term fish test. Additionally, as explained under request A.1 the evidence provided in the comments indicates that the measured concentrations over the time course of the study [redacted] (2011) may not be 80% of the nominal concentration. On the contrary this study indicates that the substance may not be maintained in the test solutions >80% of the nominal concentrations and therefore measured concentrations within the study should be used to derive the effect values.

Due to the low water solubility (4.84 mg/L), adsorptive properties (logPow = 4.72 to 6) and surface activity (surface tension = 53.40) of the Substance, it is difficult to test. Therefore, evidence that exposure concentrations have been maintained throughout the test is essential to verify the reliability of the studies.

Therefore the provided studies do not fulfil the information requirement.

Study design

The substance is difficult to test due to the low water solubility (4.84 mg/L), adsorptive properties (logPow = 4.72 to 6) and surface activity (surface tension = 53.40). OECD TG draft 203 specifies that for difficult to test substances, the OECD Guidance 23 is to be followed. To get reliable results, the substance properties need to be considered when performing the test, in particular with regard to the test design; including exposure system, test solution preparation, and sampling. OECD GD 23 (Table 1) describes testing difficulties related to a specific property of the substance. You may use the approaches described in OECD GD 23 or other approaches if more appropriate for your substance. The approach selected must be justified and documented.

Due to the substance properties it may be difficult to achieve and maintain the exposure concentrations. Therefore, you have to demonstrate that the concentration of the substance is stable throughout the test (i.e. measured concentrations remains within 80-120% of the nominal concentration). If it is not possible to demonstrate the stability, you must express the effect concentration based on measured values as described in the applicable test guideline. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the test solution preparation method applied was sufficient to maximise the concentration of the Substance in the test solution.

Appendix C: Reasons for the requests to comply with Annex IX of REACH

Under Articles 10(a) and 12(1) of REACH, a technical dossier registered at 100 to 1000 tonnes or more per year must contain, as a minimum, the information specified in Annexes VII to IX to REACH.

1. **Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.) in a first species**

A Pre-natal developmental toxicity (PNDT) study (OECD TG 414) in one species is a standard information requirement under Annex IX to REACH.

You provided information from a reproductive toxicity study conducted with the Substance ([redacted] 2002).
We have assessed this information and identified the following issue(s).

In order to be considered compliant and enable assessing if the Substance is a developmental toxicant, information provided has to meet the requirements of OECD TG 414 in one species, including investigation of structural malformations and variations.

You have not provided information following OECD TG 414. Instead, you have provided a one-generation reproductive toxicity study conducted with the Substance according to the OECD test guideline 415 ([redacted] 2002). In this study, structural malformations and variations are not investigated as required in a PNDT study (OECD TG 414). In your comments to the draft decision you acknowledged that structural malformations and variations are not investigated in the reproductive toxicity study that you have provided. However, despite this shortcoming in the design of the study by [redacted] you consider that *"the weight of evidence from the OECD 415 study indicates a low concern for reproductive toxicity"* and provides a basis for deriving a conservative NOAEL for developmental toxicity. You conclude that conducting a pre-natal developmental toxicity with the Substance is unlikely to lead to additional risk management measures.

As indicated above, evaluation of structural malformations and variations after *in utero* exposure are key parameters of a pre-natal developmental toxicity study. In order to determine if the Substance is a developmental toxicant in accordance with the information requirement of Annex IX, 8.7.2, these parameters need to be investigated. The reproductive toxicity study that you have provided in your dossier does not provide information on structural malformations and variations. Therefore the information from this study is neither adequate nor relevant to fulfil the information requirement of Annex IX, 8.7.2. No robust conclusions on the a level of concern for developmental toxicity of the Substance can be derived from this information.

A PNDT study according to the test method OECD TG 414 must be performed in rat or rabbit as preferred species with oral[3] administration of the Substance.

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

Long-term toxicity testing on aquatic invertebrates is a standard information requirement in

[3] ECHA Guidance R.7a, Section R.7.6.2.3.2.

Annex IX to REACH.

You have provided a key study ([redacted] 2003) conducted according to OECD TG 211 with the Substance.

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

OECD TG 211 is the preferred guideline to fulfil this information requirement. The OECD TG 211 requires that you must (among others):

- perform analytical monitoring to verify the initial concentrations and maintenance of the exposure concentrations during the test; and
- provide evidence that exposure concentrations have been maintained throughout the test >80% % of the nominal or intial measured concentration, in case you use nominal concentrations expressing the results.

In the key study the concentrations of the test substance were not measured.
You have not provided evidence that the concentration of the test substance was maintained >80 % of the nominal or measured initial concentration throughout the test, as required by OECD TG 211.

In the comments on the draft decision you indicated that the analytical monitoring of test concentration in Short-term invertebrates study ([redacted] (2011)) can be used as evidence that exposure concentrations have been maintained throughout the long-term aquatic invertebrates test.

We have assessed this information and identified the following issues:

Existing ecotoxicity studies (acute or chronic) may provide an indication of behaviour of the test chemical under test conditions used in the toxicity test.[4] You explain that in the long-term toxicity study on Daphnia ([redacted] 2003) the concentrations of test substance were renewed every 2 or 3 days, with 2 day renewal on 5 occasions and 3 day renewal on 3 occasions. You state that analysis from the acute study [redacted] (2011) demonstrated that at toxicologically relevant concentrations, measured concentrations >80% were maintained over 2 days, giving confidence in likely similar data in the long-term study.

Firstly, in the long-term toxicity study some of the test media renewal interval was longer (3 days) than in the [redacted] (2011) study (2 days). Therefore higher loss of the substance over 3 days can be assumed when compared to 2 days.

As the conditions used in the toxicity test for short-term daphnia and long-term daphnia were different, information on the behaviour of the Substance in the former study is not relevant for the latter study. Therefore, the analytics performed for the short term daphnia ([redacted] (2011) study) cannot be used as evidence to indicate that exposure concentrations have been maintained throughout the long-term daphnia test.

Secondly, as explained under request A.1, the evidence provided in the comments indicates that the measured concentrations over the time course of the study [redacted] (2011) may not be 80% of the nominal concentration and therefore measured concentrations

[4] OECD GD 23, Section 5

within the study must be used to express the results.

In particular, in the comments you explain that the treatment with lowest concentration (0.32 mg/L nominal) showed a measured change >20% comparing 48h to 0h measured values (58% remaining at 48h), indicating that the concentrations did not remain >80%. You consider this treatment, where the largest decline in exposure concentrations is observed, irrelevant for the effect values derived for Short-term toxicity testing on invertebrates. However, you do not consider that the exposure concentrations in this treatment are actually relevant for the present information requirement Long-term toxicity testing on aquatic invertebrates. The lowest 21-d NOELR in this study was 0.32 mg/L (nominal, immobilisation, 95% CI 0.39-0.63 mg/L).

Due to the low water solubility (4.84 mg/L), adsorptive properties (logPow = 4.72 to 6) and surface activity (surface tension = 53.40) of the Substance, it is difficult to test. Therefore, evidence that exposure concentrations have been maintained throughout the test is essential to verify the reliability of the studies.

Therefore the provided study does not fulfil the information requirement.

Study design

The substance is difficult to test due to the low water solubility (4.84 mg/L), adsorptive properties (logPow = 4.72 to 6) and surface activity (surface tension = 53.40). OECD TG 211 specifies that for difficult to test substances, the OECD Guidance 23 is to be followed. To get reliable results, the substance properties need to be considered when performing the test, in particular with regard to the test design; including exposure system, test solution preparation, and sampling. OECD GD 23 (Table 1) describes testing difficulties related to a specific property of the substance. You may use the approaches described in OECD GD 23 or other approaches if more appropriate for your substance. The approach selected must be justified and documented.

Due to the substance properties it may be difficult to achieve and maintain the exposure concentrations. Therefore, you have to demonstrate that the concentration of the substance is stable throughout the test (i.e. measured concentrations remains within 80-120% of the nominal concentration). If it is not possible to demonstrate the stability, you must express the effect concentration based on measured values as described in the applicable test guideline. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the test solution preparation method applied was sufficient to maximise the concentration of the Substance in the test solution.

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

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

You have adapted this information requirement by using Column 2 of Annex IX Section 9.1, claiming that the chemical safety assessment does not indicate the need to investigate further the effects on fish. You further argue that in short-term tests the *Daphnia* demonstrated equivalent sensitivity to the test substance as compared to the fish, and therefore the available long-term test with *Daphnia* is deemed sufficient to characterize the long term endpoint for aquatic organisms.

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

To adapt the information requirement for long-term toxicity testing on fish based on Annex IX, Section 9.1, Column 2, the Chemical Safety Assessment (CSA) needs to assess and document that risks arising from the Substance are controlled (Annex I, Section 0.1).

In particular, you need to take into account of the following elements described in Annex I:

a. Environmental hazard assessment including classification and labelling and identification of PNEC ,
b. PBT/vPvB assessment including information on relevant degradation products and constituents present in concentration at or above 0.1% (w/w).

a. Environmental hazard assessment

For the purpose of environmental hazard assessment, the available toxicity information should at least cover species of three trophic levels: algae/aquatic plants, invertebrates (Daphnia preferred), and fish. Regarding long-term toxicity testing, there are no further requirements for fish testing if there is compelling evidence to suggest that the fish is likely to be at least a factor of about 10 less sensitive than invertebrates or algae. In case the relative sensitivity of fish cannot be predicted, further testing is needed. [1]

Compelling evidence to compare the species sensitivites must be based on data that is reliable and allows to relate the effects observed to concentrations present in the test media.

You have provided short-term toxicity studies on fish, Daphnia and algae, and a long-term toxicity study on Daphnia. As decribed in sections A.1-A.2, B.1 and C.2, these studies are not considered reliable and cannot be used to compare the species sensitivities.

You have not provided any other evidence to compare the species sensitivities that is reliable and relevant to the effect endpoints observed in a study according to OECD TG 210.

In the comments on the draft decision you repeat the arguments to adapt this study and do not provide further evidence or justification to compare species sensitivities relevant to this information requirement.

Therefore there is no compelling evidence to predict the relative sensitivity of fish and long-term testing on fish is needed.

b. PBT/vPvB assessment

Regarding the PBT and vPvB assessment, if the available information does not allow to reach an unequivocal conclusion on the PBT or vPvB properties, all necessary additional information must be generated until a definitive conclusion can be made.[5]

In your justification to adapt the information requirement you claim that the Substance is not assessed to be a PBT or vPvB.

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[1] ECHA Guidance R.7b, Section R.7.8.5.3
[5] ECHA Guidance R.11, Section R.11.3.2

However, the screening information provided in your dossier indicates that the Substance may have PBT/vPvB properties, and further testing is now requested, as described in sections C.4-C.8 below.

Taking into account the above, no definitive conclusion can be reached for the P/vP and B/vB. Therefore, your CSA does not rule out the need to investigate further the toxicity of the Substance for the purpose of the PBT/vPvB assessment.

In conclusion, with the current data you cannot reach the conclusion that the risks to the aquatic environment are controlled.

This conclusion stands notwithstanding the argument submitted in your comments that you have self-classified the Substance as chronic toxic to aquatic life (Aquatic Chronic 1). The CSA needs to take into account identification of PNEC and PBT/vPvB assessment in addition to classification and labelling, and as explained above, this is not met.

Therefore, your adaptation does not fulfil the information requirement.

Study design

The substance is difficult to test due to the low water solubility (4.84 mg/L), adsorptive properties (logPow = 4.72 to 6) and surface activity (surface tension = 53.40). OECD TG 210 specifies that for difficult to test substances, the OECD Guidance 23 is to be followed. To get reliable results, the substance properties need to be considered when performing the test, in particular with regard to the test design; including exposure system, test solution preparation, and sampling. OECD GD 23 (Table 1) describes testing difficulties related to a specific property of the substance. You may use the approaches described in OECD GD 23 or other approaches if more appropriate for your substance. The approach selected must be justified and documented.

Due to the substance properties it may be difficult to achieve and maintain the exposure concentrations. Therefore, you have to demonstrate that the concentration of the substance is stable throughout the test (i.e. measured concentrations remains within 80-120% of the nominal concentration). If it is not possible to demonstrate the stability, you must express the effect concentration based on measured values as described in the applicable test guideline. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the test solution preparation method applied was sufficient to maximise the concentration of the Substance in the test solution.

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

Simulation testing on ultimate degradation in surface water is a standard information requirement in Annex IX to REACH.

You have sought to adapt this information requirement with the following:

a. according to Annex IX, Section 9.2., by providing an argument that based on ECHA REACH Guidance Chapter R.7B if the substance is not considered a PBT or vPvB candidate, then it is considered not necessary to conduct further testing on the compartment;
b. according to Annex IX, Section 9.2.1.2., Column 2, based on low water solubility and exposure considerations; and
c. in your comments to the draft decision, according to Annex XI, Section 3 (in conjunction

with Annex XIII Section 2.1), based on uses in sealed systems.

ECHA has assessed your arguments and identified the following issue(s):

a. Arguments on PBT/vPvB properties

Further testing on degradation is required if the CSA indicates the need for such investigations, for example if there are indications from screening or other information that the substance may have PBT or vPvB properties (Annex 1. Section 0.1; Annex IX, Section 9.2, Column 2; Annex XIII, Section 2.1).

Screening information demonstrating potential PBT or vPvB properties include[6]:
- The Substance is not readily biodegradable and thus potentially persistent
- The Substance has high potential for bioaccumulation (log Kow > 4.5)

In the assessment of PBT/vPvB properties of the Substance in section 8 of your CSR you indicate that *"substance is regarded as not PBT and not vPvB, although persistence in the environment cannot be ruled out. Since the substance is not classified as bioaccumulative (B) or toxic (T), the criteria for a PBT or vPvB substance are not fulfilled."*

However, the screening information provided in your dossier indicates that the Substance may have PBT/vPvB properties:
- The Substance is not readily biodegradable and thus potentially P or vP (5.9% degradation in 28 days in an a study according to OECD Guideline 301 F).
- Based on the screening information the constituents of the Substance have potential for bioaccumulation (logPow 4.72 to 6.51).

In the comments on the draft decision you provided QSAR Toolbox prediction for degradation from three read-across substances and EPISuite prediction (BIOWIN3). You further claim that the value of 2.5714 from the BIOWIN prediction represent a half life time of about 37.5 days and consider that this result means that the Substance is not very persistent.

However, with this new information you have not established a conclusion on P or vP properties for the following reasons:

- *Information provided is not relevant to assess and conclude on the P or vP properties*

Results obtained from biodegradation (Q)SAR models in accordance with Section 1.3 of Annex XI can be used as screening information to indicate that the substance may be P or vP (Annex XIII, Section 3.1.1).
Section 2.1 of Annex XIII requires that you must generate relevant additional information if the results from the screening tests indicate that the substance may have PBT or vPvB properties. This additional information includes simulation testing on degradation in surface water, soil and sediment as set out in Section 3.2 of Annex XIII.

You claim that based on the results from the QSAR model BIOWIN 3 the Substance is not very persistent.

[6] ECHA Guidance R.11 Section R.11.4 and REACH Annex XIII

While the BIOWIN prediction, as screening information, indicates that the Substance may be P or vP, it does not provide information in accordance with Section 3.2 of Annex XIII to assess the P or vP properties and to be able to conclude on them.

- *Information provided is not reliable*

1) Regarding the EPISuite prediction, 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:
   - results are derived from a QSAR model whose scientific validity has been established;
   - the substance falls within the applicability domain of the QSAR model;
   - adequate and reliable documentation of the applied method is provided; and
   - 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.

   For the EPISuite prediction you submitted in the comments you did not provide QSAR Model Reporting Formats (QMRF) or a QSAR Prediction Reporting Formats (QPRF). Therefore the conditions according to Annex XI, Section 1.3. are not met and the information cannot be regarded as reliable.

2) Regarding the use of information from other substances, REACH, Section 1.5 of Annex XI requires explicitly that "adequate and reliable documentation of the applied method shall be provided". According to the ECHA Guidance Section R.6.2.3.1 "the approach should be documented according to an appropriate format in order to justify that the approach may be used instead of testing. The justification for the read-across should include an explanation of the rationale, as well as the assessment including all relevant supporting information". The Guidance also specifies the following elements that must be included in the documentation of the adaptation:
   - A read-across hypothesis, establishing why a prediction for a toxicological or ecotoxicological property is reliable;
   - Scientific information substantiating that the prediction of the properties is justified for each relevant endpoint, taking into account the structural differences between the substances;
   - Robust study summaries of the source studies.

   You provided QSAR Toolbox predictions from three read-across substances and provided documentation for them in the comments. Within that documentation, you have not provided a category definition, read-across hypothesis, robust study summaries of the source data to allow assessment of their reliability, nor supporting information substantiating that the prediction of the properties is justified. In the absence of such information, you have not established that relevant properties of the Substance can be predicted from data on the analogue source substance(s).

   Furthermore, the Substance is an UVCB and neither for QSAR Toolbox predictions nor EPISuite prediction you have indicated how all the constituents of the Substance were considered.

Therefore, the requirements in accordance with Annex XI, Section 1.5. are not met and the information cannot be regarded as reliable.

Taking into account the above, no definitive conclusion can be reached for the P/vP and B/vB assessments. Therefore, your CSA does not rule out the need to investigate further the degradation of the Substance for the purpose of the PBT/vPvB assessment.

Therefore, your adaptation does not fulfil the information requirement.

b. Adaptation based on Annex IX, Section 9.2.1.2, column 2

To adapt the information requirement for simulation testing on ultimate degradation in surface water based on Annex IX, Section 9.2.1.2, column 2, the substance must be either readily biodegradable or highly insoluble in water. If the substance is highly insoluble in water or the water solubility is lower than test concentrations recommended in the OECD TG 309 the test may be considered technically not feasible to conduct. In this context, the substance can not be considered highly insoluble if the test concentration of 1-10 µg/L recommended in OECD TG 309 can be reached. [7]

You have concluded in your dossier that the Substance is not readily biodegradable (5.9% degradation after 28 days). However, you claim that the testing is not needed as the Substance is of low solubility (water solubility of 4.8 mg/L, [redacted] 2003). You further argue that direct and indirect exposure of the aquatic compartment is unlikely.

Based on the water solubility value of 4.8 mg/L the Substance cannot be considered as highly insoluble. Furthermore, the absence of exposure of the aquatic compartment is not a basis – in accordance with Annex IX, Section 9.2.1.2, column 2 - to adapt the current information requirement.

c. Exposure based adaptation (Annex XI, Section 3 in conjunction with Annex XIII Section 2.1)

In your comments to the draft decision you claim that the uses are in sealed systems and that some uses are irrelevant and will be removed from your Chemical Safety Assessment.

Annex XIII, Section 2.1 of REACH specifies that the generation of additional information listed in Annex IX or X to REACH, which are required to conclude on the PBT/vPvB properties of the Substance, may only be omitted if the conditions set out in Annex XI, Section 3.2(b) or (c) applies. In such case, the Substance must be considered as if it is a PBT/vPvB in the registration dossier.

Annex XI Section 3.2(b) specifies that the manufacturer or importer demonstrates and documents for all relevant scenarios that throughout the life cycle strictly controlled conditions as set out in Article 18(4)(a) to (f) apply.

You explain in your comments that there are negligible known potential uses for consumers because commercial vehicles are professionally serviced. Hence, you consider that there are no wide open or dispersive consumer uses and the uses are in sealed systems.

[7] ECHA Guidance R.11 Section R.11.4.1.1.3

As explained above under point (a), the results from the screening tests indicate that the substance may have PBT or vPvB properties.

In your comments you have not specified how you intend to revise your exposure assessment with respect to the uses. Currently in the registration dossier you have reported that the Substance has uses in formulation, at industrial sites, widespread uses by professional workers and consumers (including e.g. general consumer and professional use of lubricants and greases in vehicles or machinery, and consumer use of lubricants and greases in open systems). You do not provide any demonstration and documentation that strictly controlled conditions are applied in accordance with Section 3.2(b)(in conjuction with Article 18(4)) or (c) of Annex XI. Therefore, you cannot omit generating this information based on exposure considerations.

Therefore, your adaptation does not fulfil the information requirement.

Study design

OECD TG 309 is an appropriate method for studying the degradation in surface water. 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 309 test, by following the pelagic test option with natural surface water containing approximately 15 mg dw/L of suspended solids (acceptable concentration between 10 and 20 mg dw/L) (ECHA Guidance R.11).

- You must perform the test at the temperature of 12 °C, the average environmental temperature for the EU (ECHA Guidance R.16, Table R.16-8). Performing the test at this temperature is in line with the applicable test conditions of the OECD TG 309.

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 Chapter R.11).

Under Annex XIII, you must assess the PBT/vPvB properties of the relevant constituents of the Substance. Therefore, the persistence of 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 must be assessed. Alternatively, you would have to justify why you consider these not relevant for the PBT/vPvB assessment.

5-6. Soil simulation testing (Annex IX, Section 9.2.1.3.) and Sediment simulation testing (Annex IX, Section 9.2.1.4.);

Soil simulation testing and sediment simulation testing are standard information requirements in Annex IX to REACH for substances with a high potential for adsorption to soil. The Substance has high adsorption coefficient (logKoc: 3.28 - 4.01), indicating high adsorptive properties.

You have sought to adapt this information requirement with the following:

a. according to Annex IX, Section 9.2., by providing an argument that based on ECHA REACH Guidance Chapter R.7B if the substance is not considered a PBT or vPvB candidate, then it is considered not necessary to conduct further testing on the compartment;
b. according to Column 2 of Annex IX, Sections 9.2.1.3. and 9.2.1.4, based on low water solubility and exposure considerations; and
c. in your comments to the draft decision according to Annex XI, Section 3 (in conjunction with Annex XIII Section 2.1), based on uses in sealed systems.

ECHA has assessed your arguments and identified the following issue(s):

a. Arguments on PBT/vPvB properties

Further testing on degradation is required if the CSA indicates the need for such investigations, for example if there are indications from screening or other information that the substance may have PBT or vPvB properties (Annex 1. Section 0.1; Annex IX, Section 9.2, Column 2; Annex XIII, Section 2.1).

Screening information demonstrating potential PBT or vPvB properties include[8]:
- The Substance is not readily biodegradable and thus potentially persistent
- The Substance has high potential for bioaccumulation (log Kow > 4.5)

In the assessment of PBT/vPvB properties of the Substance in section 8 of your CSR you indicate that the criteria for a PBT or vPvB substance are not fulfilled.

However, the screening information provided in your dossier indicates that the Substance may have PBT/vPvB properties:
- The Substance is not readily biodegradable and thus potentially P or vP (5.9% degradation in 28 days in an a study according to OECD Guideline 301 F).
- Based on the screening information some of the constituents have potential for bioaccumulation (logPow 4.72 to 6.51).

In the comments on the draft decision you provided QSAR Toolbox prediction for degradation from three read-across substances. You claim that one reference substance was completely biodegraded in sediment compartment.

For the same reasons as described under request C.4 (Simulation testing on ultimate degradation in surface water), the provided QSAR Toolbox predictions based on read-across are considered unreliable. Therefore, the information provided does not allow to predict the properties of the Substance and to conclude that Substance would be completely biodegraded in sediment systems.

Taking into account the above, no definitive conclusion can be reached for the P/vP and B/vB. Therefore, your CSA does not rule out the need to investigate further the degradation of the Substance for the purpose of the PBT/vPvB assessment.

In conclusion, with the current data you cannot reach the conclusion that the risks to the aquatic environment are controlled.

[8] ECHA Guidance R.11 Section R.11.4 and REACH Annex XIII

b. Adaptation based on Column 2 of Annex IX, Sections 9.2.1.3 and 9.2.1.4.

To adapt the information requirement for simulation testing on soil (Annex IX, Section 9.2.1.3) or sediment (Annex IX, Section 9.2.1.4), the substance should be either readily biodegradable or the direct and indirect exposure of soil or sediment is unlikely.

You have concluded in your dossier that the Substance is not readily biodegradable (5.9% degradation after 28 days).

However, you claim that the testing is not needed as the Substance is not directly applied to water and sediments and the indirect exposure of soil to this substance via sewage sludge is also of no concern based on the treatment of the sludge. You further argue that the Substance is of low solubility.

Based on the information provided in your dossier, your claim of unlikely direct and indirect exposure is not supported. Specifically, the Substance has uses in formulation, at industrial sites, widespread uses by professional workers and consumers. These uses result in Environmental Release Categories covering ERCs 2, 4, 7, 8a, 8d, 9a, 9b. Furthermore, the low water solubility is not a basis – in accordance with column 2 of Annex IX, Sections 9.2.1.3 and 9.2.1.4. - to adapt the current information requirements.

c. Exposure based adaptation (Annex XI, Section 3 in conjunction with Annex XIII Section 2.1)

In your comments to the draft decision you state that not all reported uses are relevant and that you intend to remove the irrelevant uses from your Chemical Safety Assessment. You claim that the uses are in sealed systems.

For the reasons described under request C.4 (Simulation testing on ultimate degradation in surface water), the provided arguments on exposure do not allow you to omit generating the required information.

In conclusion, your adaptation does not fulfil the information requirement.

Study design

OECD TG 308 and 307 are appropriate methods for studying the degradation in sediment and soil. The requested simulation tests shall be performed under relevant conditions (12°C) and non-extractable residues (NER) must be quantified, for the reasons explained above in section C.4. 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. Alternatively, you shall provide a justification for why you consider these as not relevant for the PBT/vPvB assessment.

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

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

You have not provided any information on 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.

In the comments on the draft decision, you indicate that read-across and QSAR analysis demonstrated that this substance will be ultimately biodegraded in aquatic and sediment systems. ECHA understands that you have sought to adapt this information requirement based on Annex IX, Section 9.2.3, Column 2., i.e. Identification of degradation products does not need to be conducted if the substance is readily biodegradable.

You provided in your comments read-across and QSAR analysis to substantiate your claim that the Substance will be ultimately biodegraded in aquatic and sediment system.

You submitted in you technical dossier a ready biodegradation study according to OECD Guideline 301 F, resulting in 5.9% degradation in 28 days.

For the same reasons as described under request C.4 (Simulation testing on ultimate degradation in surface water), the provided QSAR and read-across predictions are considered unreliable.

Based on the provided experimental study the Substance is not readily biodegradable, and therefore your adaptation is rejected.

Furthermore in you comments, you also state that "*long term invertebrate toxicity testing (OECD 211) has displayed its aquatic chronic toxlcity* [redacted] *believes it will be finally mineralized into CO2 and the long term hazards of the parent compound has already been tested.*" However, long-term aquatic toxicity data is not a basis – in accordance with column 2 of Annex IX, Sections 9.2.3. - to adapt the current information requirement.

Identity and relevance and of degradation products must be included in the risk assessment and PBT assessment.

Screening information provided in your dossier indicates that the Substance may have PBT/vPvB properties, as explained section C.4 above.

Therefore, information on identification of degradation products is required.

Study selection and design

You must obtain this information while performing the simulation studies requested in this decision (Appendix C, sections 4-6 above). 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 degradation/ transformation products must be investigated.

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

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

You have sought to adapt this information requirement with the following:

a. according to Annex XI, Section 1.3., by providing the following three QSAR predictions:

- - QSAR, Reliability 2, BCFBAF v3.1, BCF of 105.5 (Regression-based estimate - most relevant), and BCF of 17700 L/kg (Arnot-Gobas Method)
- - QSAR, Reliability 2, BCF model (CAESAR) (version 2.1.8) / VEGA, BCF of 143 L/kg
- - QSAR, Reliability 2, CAESAR QSAR model version 1.0.0.1, BCF of 142 L/kg

In addition, in your comments to the draft decision you provided the following results:

- QSAR, EPI BAFBCF, Arnot method, no version indicated, BCF of 779, 731 and 541 L/kg for low trophic, middle trophic and high trophic levels;
- QSAR, T.E.S.T prediction, methods of Hierarchical clustering, single model, group contribution, FDA and Nearest neighbour, BCF of 36 to 794;
- QSAR, CAESAR and Read across under VEGA, BCF of 204 and 113 L/kg.

b. according to Annex IX, Section 9.3.2., Column 2, based on exposure considerations.

ECHA has assessed your arguments and identified the following issue(s):

a. Adaptations according to Annex XI, Section 1.3

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 did not provide any QSAR Model Reporting Formats (QMRF) or a QSAR Prediction Reporting Formats (QPRF) for the QSAR predictions on BCF, neither for the predictions submitted in the dossier nor for the results provided in the comments on the draft decision.

For BCF model (CAESAR) (version 2.1.8) you report that the test compound is out of the applicability domain.

In addition you do not report which constituent(s) of the UVCB you have used for the

predictions and did not specify BCF estimates for the different constituents of the UVCB substance.

In the absence of QMRFs and QPRFs, ECHA cannot establish whether the models are scientifically valid, whether the Substance falls within the applicability domain of the models. Furthermore, you have already indicated that the Substance is out of the applicability domain of some of the models. Therefore they cannot be used to predict reliably the BCF of the Substance. You also do not report which constituents the predictions cover and do not consider all the constituents of the UVCB substance in your predictions. Therefore the QSAR models provided are not considered reliable for the UVCB substance and are not adequate for classification and labelling and/or risk assessment.

These adaptations you provided do not fulfil the criteria specified in Annex XI, Section 1.3. and are therefore rejected.

b. Adaptation according to Annex IX, Section 9.3.2., Column 2

To comply with Column 2 specific rules for adaptation, the following must be demonstrated:
- direct and indirect exposure of the aquatic compartment is unlikely

Unlikely direct and indirect exposure implies a low probability of rather than low extent of exposure.[9] This information requirement may be omitted from further consideration on exposure grounds only under exceptional circumstances. This might include, for example, a site-limited chemical intermediate that is handled under rigorous containment, with incineration of any process waste.

You justified the adaptation by stating that the bioaccumulation study need not to be conducted because direct and indirect exposure of the aquatic compartment is unlikely.

However, information in your registration dossier does not demonstrate it. To the contrary, the Substance has uses in formulation, at industrial sites, widespread uses by professional workers and consumers. These uses result in Environmental Release Categories covering ERCs 2, 4, 7, 8a, 8d, 9a, 9b.

Therefore you cannot adapt this information requirement based on unlikely direct and indirect exposure.

In conclusion, your adaptations do not fulfil the information requirement.

Study selection and design

Bioaccumulation in fish: aqueous and dietary exposure (test method EU C.13. / OECD TG 305) is the preferred test to investigate bioaccumulation (ECHA *Guidance, Chapter R.7c, R.7.10.3.1*). Whenever technically feasible, the aqueous route of exposure (OECD TG 305-I) must be used as the results obtained can be used directly for comparison with the B and vB criteria of Annex XIII of REACH. Therefore the requested study must be conducted with aqueous exposure. If testing through aquatic exposure is technically not possible, you must provide scientifically valid justification for the infeasibility.

[9] ECHA Guidance R.7c Section R.7.10.4.5

Under Annex XIII, you must assess the PBT/vPvB properties of the relevant constituents of the Substance and relevant degradation products. Therefore, the bioaccumulation of each relevant constituent present in concentrations at or above 0.1% (w/w) and relevant degradation products or, if not technically feasible, in concentrations as low as technically detectable must be assessed. Alternatively, you would have to justify why you consider these not relevant for the PBT/vPvB assessment.

Appendix D: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of registration dossiers after the date on which you were notified the draft decision according to Article 50(1) of REACH.

The compliance check was initiated on 15 March 2019.

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

ECHA notified you of the draft decision and invited you to provide comments within 30 days of the notification.

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

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

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

Appendix E: Observations and technical guidance

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

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 the Member States.

3. Test guidelines, GLP requirements and reporting

   Under Article 13(3) of REACH, all new data generated as a result of this decision needs to be conducted according to the test methods laid down in a European Commission Regulation or according 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 shall 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: 'How to report robust study summaries'[10].

4. Test material

Selection of the test material(s) for UVCB substances

The registrants of the Substance are responsible for agreeing on the composition of the test material to be selected for carrying out the tests required by the present decision. The test material selected must be relevant for all the registrants of the Substance, i.e. it takes into account the variation in compositions reported by all members of the joint submission. The composition of the test material(s) must fall within the boundary composition(s) of the Substance.

While selecting the test material you must take into account 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. Any constituents that have harmonised classification and labelling according to the CLP Regulation (Regulation (EC) No 1272/2008) must be identified and quantified using the appropriate analytical methods.

The OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, Number 11 [ENV/MC/CHEM(98)16] requires a careful identification of the test material and description of its characteristics. In addition, the Test Methods Regulation (EU) 440/2008, as amended by Regulation (EU) 2016/266, requires that "*if the test method is used for the testing of a* [...] *UVCB* [...] *sufficient information on its composition should be made available, as far as possible, e.g. by the chemical identity of its constituents, their quantitative occurrence, and relevant properties of the constituents*".

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

In order to meet this requirement, all the constituents of the test material used for each test must be identified as far as possible. For each constituent the concentration value in the test material must be reported in the Test material section of the endpoint study record.

Technical Reporting of the test material for UVCB substances

The composition of the selected test material must be reported in the respective endpoint study record, under the Test material section. The composition must include all constituents of the test material and their concentration values. Without such detailed reporting, ECHA may not be able to confirm that the test material is relevant for the Substance and to all the registrants of the Substance.

Technical instructions are available in the manual "How to prepare registration and PPORD dossiers" on the ECHA website[11].

5. 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 and the necessity to conduct all of them. 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.

You are advised to first conclude whether the Substance may fulfil the Annex XIII criteria of being P or vP, and then continue with the assessment for bioaccumulation. The sequence of the simulation tests also needs to consider the intrinsic properties of the Substance, its identified use and release patterns as these could significantly influence the environmental fate of the Substance. You shall revise the PBT assessment when the new information is available.

6. Testing strategy for aquatic testing

Before conducting the aquatic toxicity tests you should consult the Integrated Testing Strategy described in ECHA Guidance R.7b, Section R.7.8.5 (including Figure R.7.8-4), to determine the necessity to conduct all of the long-term aquatic toxicity tests and the sequence in which they are to be conducted.

REACH Annex VII Section 9.1.1 and Annex VIII Section 9.1.3 explain that you may consider conducting long-term toxicity testing on daphnia and fish instead of short-term testing.

If you decide to omit some of the studies requested in this decision, you must provide full documentation to justify your adaptation.

7. Environmental testing for UVCB substances

The purpose of environmental testing under REACH is threefold:
- To determine classification and labelling, and
- To inform the PBT assessment
- To inform the risk assessment (e.g. for PNEC derivation)

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

Your Substance is a UVCB and, as indicated in ECHA Guidance R.11 (Section R.11.4.2.2), to fulfil your information requirements and inform the PBT assessment, you are advised to consider the following approaches for persistency, bioaccumulation and aquatic toxicity testing:

- the "known constituents approach" (by assessing specific constituents), or
- the "fraction/block approach, (performed on the basis of fractions/blocks of constituents), or
- the "whole substance approach", or
- various combinations of the approaches described above.

Selection of the appropriate approach must take into account:

- the possibility to characterise the Substance (i.e. knowledge of its constituents and/or fractions and any differences in their properties) and the possibility to isolate or synthetize its relevant constituents and/or fractions.
- the adequacy and relevance of the approach for the three purposes of environmental testing under REACH outlined above.

8. Use of Water Accommodated Fraction (WAF) approach for ecotoxicity *testing*

If you use the Water Accommodated Fraction (WAF) approach in your aquatic toxicity testing, you must follow the OECD GD 23:

- Choose/develop appropriate analytical methods for your substance, and conduct chemical analysis of the test medium
- Prepare the WAF in a consistent manner to the applied test conditions (including e.g. the same co-solvents and the stirring methods in all test solutions preparations).

The following key information must be reported:

- Full description of the method used to prepare the WAF.
- Identity of the constituents the test organisms are exposed to.
- Demonstration that dissolved concentration of the UVCB is equilibrated and maximised.
- Demonstration of stability in the exposure concentrations during the conduct of the test.
- Test results expressed in terms of measured concentrations, unless you can justify that exposure concentrations remain within ±20% of the initial loading rate.

If it is not possible to obtain the above information you should consider the use of alternative techniques (e.g. passive dosing) given in OECD GD 23 as/if these may be better suited for your Substance. Any deviations from the above need to be fully documented and justified.

9. List of references of the ECHA Guidance and other guidance/ reference documents[12]

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 in this decision.

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 in this decision.

ECHA Read-across assessment framework (RAAF, March 2017)[13]

[12] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[13] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

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.

OECD Guidance documents[14]
Guidance Document on aqueous-phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.
Guidance Document on Mammalian Reproductive Toxicity Testing and Assessment – No 43, referred to as OECD GD43.

[14] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

Appendix F: List of the registrants to which the decision is addressed and the corresponding information requirements applicable to them

Registrant Name	Registration number	(Highest) Data requirements to be fufilled
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]