Helsinki, 13 August 2020

Addressees
Registrants of EC 248-698-8 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
11 April 2019

Registered substance subject to this decision ("the Substance")
Substance name: (tetrapropenyl)succinic acid
EC number: 248-698-8
CAS number: 27859-58-1

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

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadline of ***19 August 2024***.

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

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

1. The same simulation testing on ultimate degradation in surface water as requested in B.3. (triggered by Annex VIII, Section 9.2., column 2)

2. The same soil simulation testing as requested in B.4. (triggered by Annex VIII, Section 9.2., column 2)

3. The same sediment simulation testing as requested in B.5. (triggered by Annex VIII, Section 9.2., column 2)

4. The same identification of degradation products as requested in B.6. (triggered by Annex VIII, Section 9.2., column 2)

5. The same bioaccumulation in aquatic species as requested in B.7. (triggered by Annex I, sections 0.6.1. and 4. in conjunction with Annex XIII, Section 2.1.)

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

1. Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.; test method: OECD TG 408) by oral route, in rats

2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: OECD TG 414) by oral route, in one species (rat or rabbit)

3. 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; including

degradation of each relevant constituent present in concentration at or above 0.1% (w/w)

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

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

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

7. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2; test method: OECD TG 305, aqueous/dietary exposure; including bioaccumulation of each relevant constituent present in concentration at or above 0.1% (w/w) and relevant degradation products

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

- 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 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 "General recommendations 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 VIII of REACH

1.-4. The same simulation testing on ultimate degradation in surface water as requested in B.3., soil simulation testing as requested in B.4., sediment simulation testing as requested in B.5 and identification of degradation products as requested in B.6. (triggered by Annex VIII, Section 9.2., column 2)

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).

Annex I, Section 4 requires that the CSA includes the PBT (persistent, bioaccumulative and toxic) and vPvB (very persistent and very bioaccumulative) assessments. In accordance with Annex XIII, Section 2.1., if the result of the screening tests or other information indicate that the substance may have PBT or vPvB properties, further testing on degradation as set out in Section 3.2 is required.

Screening information demonstrating potential PBT or vPvB properties include the following (ECHA Guidance R.11, Sections R.11.4 and Annex XIII):

- The Substance is not readily biodegradable and thus potentially persistent
- The Substance has high potential for bioaccumulation (log Kow > 4.5)

Screening information provided in your dossier indicates that the Substance may have PBT/vPvB properties:

- The Substance is potentially P or vP since it is not readily biodegradable (18.3% in 28 days in the available OECD TG 301F test).
- It is not possible to conclude on the B or vB potential because:
  a) under Section 2.3. PBT assessment in IUCLID, you provide QSAR predictions to estimate the Bioconcentration Factor (BCF) based on the constituents' Log Kow values. Based on these predictions, you conclude that the Substance is B, but not vB. However, as noted in ECHA Guidance ECHA R.7b, for surface active substances Log Kow is not a valid descriptor to predict bioaccumulation potential. The Substance is surface active (surface tension 29.58 mN/m). Consequently, the provided QSAR predictions cannot be used to reliably predict the bioaccumulation of the individual constituents.
  b) as specified in request B.7 below, there is currently no compliant information on Bioaccumulation and further testing is therefore requested.

The available screening information is not sufficient to conclude on the P/vP properties of the Substance, therefore further testing is required.

The examination of the adaptation proposed, as well as the selection of the requested test and the test design are addressed in Appendix B, Sections 3-6. Your comments to the draft decision are also addressed in Appendix B, Sections 3-6.

5. The same bioaccumulation in aquatic species as requested in B.7. (triggered by Annex I, Sections 0.6.1 and 4; Annex XIII, Section 2.1)

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

Annex I, Section 4 requires that the CSA includes the PBT (persistent, bioaccumulative and

toxic) and vPvB (very persistent and very bioaccumulative) assessments.

In accordance with Annex XIII, Section 2.1., if the result of the screening tests or other information indicate that the substance may have PBT or vPvB properties, further testing on bioaccumulation as set out in Section 3.2 is required..

As described above in Appendix A, sections 1-4, screening information provided in your dossier indicates that the Substance may have PBT/vPvB properties. The available screening information is not sufficient to conclude on the B/vB properties of the Substance, and therefore further testing is required.

The examination of the adaptation proposed, as well as the selection of the requested test and the test design are addressed in Appendix B, Section 7. Your comments to the draft decision are also addressed in Appendix B, Section 7.

EUROPEAN CHEMICALS AGENCY

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

1. Sub-chronic toxicity study (90-day)

A Sub-chronic toxicity study (90 day) is a standard information requirement in Annex IX to REACH.

You have provided an adaptation according to the last paragraph of the preamble to Annex IX. When it is proposed not to provide information for other reasons than those mentioned in column 2 of Annex IX or in Annex XI, this fact and the reasons shall be clearly stated.

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

As provided in the last paragraph of the preamble to Annex IX, when it is proposed not to provide information for other reasons than those mentioned in column 2 of Annex IX or in Annex XI, this fact and the reasons shall be clearly stated.

Whenever such an adaptation is proposed, valid reasons for deviating from the adaptation possibilities mentioned in column 2 of Annex IX or in Annex XI must be provided.

The ECHA Guidance[2] provides that corrosive or highly irritating substances should be tested preferentially via the oral route, however it must be noted that *in vivo* testing with corrosive substances at concentration/dose levels causing corrosivity must be avoided. In order to mitigate the local effects caused by repeated exposure to irritant substances and maximise systemic exposure to the test item, the use of a vehicle minimising gastrointestinal irritation should be considered. For some substances dietary administration may allow adequate dosing without irritation compared with oral gavage dosing.

In your technical dossier you express your views that a "*90-day repeated dose toxicity study becomes redundant in instances where no significant systemic findings have been noted up to irritant/corrosive in the Annex VIII repeated dose toxicity studies*". You conclude that a sub-chronic (90-day) toxicity study "*is not scientifically justified as it will not yield any additional information for the purposes of classification and labelling and/or risk assessment.*"

In order to support your conclusions you refer to the results of a 14-day repeated dose toxicity study, a 28-day repeated dose toxicity study and a reproductive/developmental toxicity screening test conducted with the Substance via the oral route. The stomach was identified as the main target organ in the 14-day study. You associate the findings observed in the mid and high dose groups, 300 mg/kg/d and 1000 mg/kg/d respectively, in this study with corrosive/irritant properties of the Substance. No similar findings were observed in the 28-day study and in the screening study up to the highest dose tested, i.e. up to 100 mg/kg/d.

You also refer to an analysis completed by Taylor et al. (2014) aimed at demonstrating the redundancy of the 90-day study for substances which are not classified for any human health hazard and tested in a 28-day repeated dose toxicity study with negative results. You consider that the conclusions from Taylor et al. apply to your Substance despite its classification as Skin irritant 2 and Eye damage 1.

In your comments to the draft decision you re-iterated your views that "*the oral gavage dosing regime is not considered apropriate since it would result in excessive toxicity*". You refer to the absence of effects observed in the 4-week study and in the

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

reproductive/developmental toxicity screening test conducted with the Substance up to 100 mg/kg/d and consider that further testing is not meaningful to address any additional toxicological properties of the Substance.

Based on the information in the dossier, the Substance is not corrosive but you have self-classified it as Skin irritant 2 and for Eye damage 1. The Substance has been administered by gavage in the 14-day repeated dose toxicity study, in the 28-day repeated dose toxicity study and in the reproductive/developmental toxicity screening test. No other measure than reducing the test doses (100 mg/kg/d was the highest dose) have been reported in your adaptation to attempt reducing the impact of the irritant properties of the Substance. Contrary to the above ECHA Guidance, you have not discussed and demonstrated, neither in your technical dossier nor in your comments to the draft decision, that administration of the Substance either mixed with the diet or formulated in a different vehicle could not allow testing over a period of 90-day at concentrations maximising systemic exposure for the purpose of hazard identification.

The analysis by Taylor *et al.* excluded substances classified for skin and eye irritation and data sets where the highest dose tested in the 28-day repeated dose toxicity study was lower than the limit dose. Your Substance is classified as Skin irritant 2 and for Eye damage 1. The highest dose tested in the 28-day repeated dose toxicity study conducted with the Substance is set at 100 mg/kg/d which is significantly lower than the limit dose of 1000 mg/kg/d set in the OECD test guideline 407. You have not explained why you consider that the conclusions from Taylor *et al.* apply to your Substance despite unambiguously fulfilling exclusion criteria for their analysis. Therefore, without prejudice to the robustness of the analysis and of the conclusions derived by Taylor *et al.*, we consider that the conclusions from Taylor *et al.* are irrelevant in the context of your adaptation.

We conclude that you have not provided valid reasons for deviating from the adaptation possibilities mentioned in column 2 of Annex IX or in Annex XI.

Study design

Referring to the criteria provided in Annex IX, Section 8.6.2, Column 2, the oral route is the most appropriate route of administration to investigate repeated dose toxicity, because the Substance is reported to occur as a dust without a significant proportion (>1% on weight basis) of particles of inhalable size (MMAD < 50 µm).

Therefore the sub-chronic toxicity study must be performed according to the OECD TG 408, in rats and with oral administration of the Substance.

Severe local effects were observed after gavage administration in a screening study for developmental/reproductive toxicity (OECD TG 421) and in a 28-day repeated dose toxicity study (OECD TG 407). This indicates that repeated gavage administration may cause severe local irritating effects. Even though the Substance is not classified as corrosive, in the light of the toxicity observed in the OECD TG 421 and OECD TG 407 studies, the gastrointestinal irritation should be minimised (ECHA Guidance[3]). Dietary administration may allow higher systemic exposure without irritation compared to oral gavage administration. You must select and justify the route of administration following these principles.

2. Pre-natal developmental toxicity study in one species

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

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

You have provided a data waiving argument for this information. You indicate that "*the study does not need to be conducted because relevant human exposure can be excluded*". You consider that "*there is no evidence of reproduction toxicity observed in any mammalian toxicity tests*". In order to support this statement you refer to the results of a screening study for developmental/reproductive toxicity (OECD TG 421), a 28-day repeated dose toxicity study (OECD TG 407) and a 14-day dose range finding study. You also point out that "*the Substance is not considered to have genetic toxicity*". You conclude that "*Given the lack of reproductive toxicity in the 28 day study and the availability of data from a reproduction/developmental toxicity screening study, further testing is considered unnecessary*".

In your comments to the draft decision you claimed that "*the oral gavage dosing regime is not considered appropriate since it would result in excessive toxicity*". You refer to the absence of effects observed in the 4-week study and in the reproductive/developmental toxicity screening test conducted with the Substance up to 100 mg/kg/d and consider that further testing is not meaningful to address any additional toxicological properties of the Substance.

We understand from this justification that you intended to adapt the information requirement according to Annex IX, Section 8.7., Column 2, third indent.

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

According to Annex IX, Section 8.7., Column 2, third indent, the study does not need to be conducted if the substance is of low toxicological activity. This needs to be demonstrated with three concomitant criteria, two of them being:

- it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure; and
- there is no or no significant human exposure.

In your adaptation, you have not provided any toxicokinetic data to show that there is no systemic absorption.

Furthermore, the uses of the Substance indicate that there is significant human exposure. Several PROCs (PROC 4, 8a and 9) indicate potential for exposure in your provided exposure scenarios.

Based on the above, the information you provided do not fulfil the information requirement. The information provided in your comments does not address the outcome of ECHA's assessment of the adaptation provided in your technical dossier for this information requirement. However your comments are reflected in the following section on the design of the requested study.

Study design

A PNDT study according to the test method OECD TG 414 must be performed in rat or rabbit as preferred species with oral[4] administration of the Substance.

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

Severe local effects were observed after gavage administration in a screening study for developmental/reproductive toxicity (OECD TG 421) and in a 28-day repeated dose toxicity study (OECD TG 407). This indicates that repeated gavage administration may cause severe local irritating effects. Even though the substance is not classified as corrosive, in the light of the toxicity observed in the OECD TG 421 and OECD TG 407 studies, the gastrointestinal irritation should be minimised (ECHA Guidance[4]). Dietary administration may allow higher systemic exposure without irritation compared to oral gavage administration. You must select and justify the route of administration following these principles.

In your comments to the draft decision you re-iterated your views that "*the oral gavage dosing regime is not considered appropriate since it would result in excessive toxicity*". You refer to the absence of effects observed in the 4-week study and in the reproductive/developmental toxicity screening test conducted with the Substance up to 100 mg/kg/d and consider that further testing is not meaningful to address any additional toxicological properties of the Substance. Contrary to the above ECHA Guidance, you have not discussed and demonstrated, neither in your technical dossier nor in your comments to the draft decision, that administration of the Substance either mixed with the diet or formulated in a different vehicle could not allow testing at concentrations maximising systemic exposure for the purpose of hazard identification.

3. Simulation testing on ultimate degradation in surface water

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

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

A. according to Annex IX, *Section 9.2,* Column 2 of REACH by providing an argument that the Chemical Safety Assessment (CSA) does not indicate the need for further investigation;
B. according to Annex IX, Section 9.2.1.2., Column 2, based on exposure considerations.

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

A. 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[5]:

- The Substance is not readily biodegradable and thus potentially persistent
- The Substance has high potential for bioaccumulation (log Kow > 4.5)

You justified the adaptation by stating that: "*In accordance with Section 9.2, Column 2, of Annex IX of the REACH regulation, the registrant proposes to waive further biotic degradation testing as the Chemical Safety Assessment (CSA) does not indicate the need for further investigation. As per the CSA, it is modelled that there is negligible exposure to water, soil or sediment. Any exposure is considered to have a Risk Characterisation Ratio (RCR) < 0.1, which is significantly below 1, therefore the Subtance is considered not to be of any further concern.*"

[5] ECHA Guidance Section R.11.4 and Annex XIII

Contrary to your adaptation statement that the CSA does not indicate need for further investigation, the screening information provided in your dossier indicates that the Substance may have PBT/vPvB properties (ECHA Guidance R.11, Section R.11.4 and Annex XIII of REACH) as described above in Appendix B, sections 1-4.

Therefore, no definitive conclusion can be yet reached for PBT/vPvB assessment and further testing is required.

B. 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.

You further justified the adaptation by stating that: *"the study does not need to be conducted because direct and indirect exposure of water/sediment is unlikely".*

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.

Therefore, your adaptation does not fulfil the information requirement.

In your comments to the draft decision you agree to perform the requested study.

In addition, you highlight the technical challenges in developing suitable analytical methods needed for the simulation and bioaccumulation studies requested in this decision, due to the structural complexity of the UVCB Substance. You foresee that numerous feasibility trials will need to be performed in order to select the most appropriate test item to be analysed in the actual tests. You indicate that in the trials you will first perform a characterisation of the Substance to establish which (if any) constituents can be adequately identified and analysed in the actual simulation and/or bioaccumulation studies (i.e. applying a "whole substance" assessment approach or a "fraction" assessment approach following ECHA Guidance R.11, Section R.11.4.2.2.2). If this is not technically feasible, you would then try to synthesise representative structure(s) that would act as a surrogate for the whole substance (i.e. applying a "known constituent" assessment approach following ECHA Guidance R.11, Section R.11.4.2.2.2).

You foresee analytical challenges for all of the testing approaches, but you also indicate that likely the only feasible approach is the "known constituent" approach. Furthermore, you highlight the possible need to synthesise radiolabelled surrogates of the constituents to ensure appropriate assessment of degradation half-lives.

Nevertheless, you consider likely that you would need to apply a Weight-of-Evidence (WoE) approach with scientific judgement to conclude on the PBT/vPvB properties of the whole UVCB substance.

ECHA acknowledges the difficulties arising from the assessment of the PBT/vP properties of a UVCB substance and that for your Substance you will need to conduct feasibility trials in order to identify the most appropriate test item and suitable assessment approach for the actual test. ECHA notes that the approach you will choose for the actual test must be clearly justified, as outlined in ECHA Guidance R.11, Section R.11.4.2.2. Issues related to feasibility and/or proportionality of efforts may play a role in the choice of the assessment approach in addition to the technical elements listed under each approach. These must also be duly described, where appropriate.

If you will choose the "known constituent" approach, ECHA further highlights that the selection of the most relevant constituent(s) should be driven by their relevance for the PBT/vPvB assessment. Whenever feasible, the simulation study should be performed using a radiolabelled test material, as indicated in Section R.11.4.1.1.3 of ECHA Guidance R.11.
ECHA Guidance R.11 foresees the possibility to use a Weight-of-Evidence (WoE) approach to conclude on the P/vP properties. An essential prerequisite for applying such approach is that the reliability and suitability of any experimental studies and the non-experimental data used in the WoE are evaluated according to ECHA Guidance R.4, ECHA Guidance R.7b and ECHA Guidance R.7c. This evaluation must be well documented in the CSR and submitted as part of the technical dossier. A scientifically valid justification must be provided.

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 identify the transformation and/or degradation products detected at ≥10% of the applied concentration at any sampling times unless reasonably justified (OECD TG 309).

- 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) and relevant transformation and/or degradation product 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.

4-5. Soil simulation testing and Sediment simulation testing

Soil simulation testing and sediment simulation testing are standard information requirements at Annex IX of REACH for substances with a high potential for adsorption to soil/sediment. The Substance is ionisable and surface active, indicating high adsorptive properties.

You have sought to adapt this information requirement based on similar arguments as addressed under request B.3 above (A). In addition, your argue that the study is not needed because of unlikely exposure of soil/sediment (B).

A. Your adaptation that the CSA does not indicate the need for further investigation is rejected for the reasons explained under request B.3 above.

B. To comply with the adaptation of Annex IX, Section 9.2.1.3 and 9.2.1.4, Column 2, the following must be demonstrated:

- direct and indirect exposure of soil/sediment is unlikely

Unlikely direct and indirect exposure implies a low probability of rather than low extent of exposure (ECHA Guidance R.7c Section R.7.10.4.5). 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 soil and sediment simulation studies need not to be conducted because direct and indirect exposure of soil/sediment is unlikely.

However, 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, indoor and outdoor uses by professional workers and consumers. These uses result in Environmental Release Categories (ERCs) 9a and 9b (widespread uses).

Therefore, you cannot adapt these information requirements based on unlikely direct and indirect exposure.

In your comments to the draft decision you do not agree with the request to perform the OECD TG 307 and OECD TG 308 studies for the following reasons:
A) you claim that the Substance is not highly adsorptive;
B) you consider that the results of the available ready biodegradability study and of the requested simulation study in surface water (which you agree to conduct, request B.3 above) will be sufficient to conclude that the Substance is not P/vP;

ECHA has assessed this information and identified the following issue(s).

A) As explained above, simulation studies in soil and sediment are required if the Substance is highly adsorptive. ECHA Guidance R.7b, Section R.7.8.14.2 indicates that high adsorption or binding behaviour is assumed for those substances when adsorption is not triggered by other mechanisms than lipophilicity (e.g. ionising substances, surface active substances etc where Kd predicts high binding potential).

The Substance is ionisable and surface active, as already indicated above. In your comments to the draft decision, you indicate that the Substance is a surfactant that is negatively charged at environmentally relevant pH (i.e. anionic surfactant). You claim that anionic surfactants are repulsed by the anionic nature of the organic acid constituents of the soil/sediment matter and consequently the Substance shows very low adsorptive properties. Furthermore, your claim that anionic surfactants do not bind to the negatively charged organic matter present in soil and sediment is not alone sufficient to exclude high adsorption potential to soil and sediment for the Substance. Finally, you do not consider adsorption to inorganic matter (which is the major soil and sediment component), which is important for several substance types,

including surfactants (ECHA Guidance R.7b). For example, anionic compounds can bind to positively charged constituents (e.g. iron oxides). In addition, anionic surfactants can still be sorbed to organic matter present in soil and sediment, as described in scientific literature (see e.g. *Environ. Sci. Technol.* 2007, 41, 3254-3261). As a consequence, your adaptation argument cannot be accepted.

B) In your comments, you consider that the results of the ready biodegradability study and the simulation study in surface water are sufficient to conclude on P/vP.

As described above, soil simulation testing and sediment simulation testing are standard information requirements at Annex IX of REACH for your Substance. These standard information requirements are separate and independent from simulation testing study in surface water requested under section B.3 above. This compliance check seeks to have all these three information requirements in your dossier fulfilled.

In addition, as explained in section A.1-4 above, the Substance is potentially P or vP, and furhter testing is needed to conclude on this property. Accordingly, your adaptation argument cannot be accepted.

Regarding the choice of the compartment for simulation testing, ECHA notes the following. For the purpose of reducing efforts of testing, testing should be started with the compartment foreseen to provide the best possibility to use the results for concluding the P/vP assessment. ECHA agrees that you should start by testing surface water as such test is foreseen to provide with the best possibility for concluding the P/vP assessment. Once it is possible to conclude that the P and/or vP criteria are fulfilled in one environmental compartment, including assessing P/vP for all constituents and any potential transformation and/or degradation products, no further testing is needed for the other compartments. In such a case, a scientifically valid justification for adapting simulation studies in the other compartments will need to be provided to explain why there is no remaining concern for the other compartments. On the contrary, if based on a simulation study conducted it is not possible to conclude the P/vP assessment for all compartments, further simulation testing, in the other compartments, may be needed. The timeline of this decision allows sequential simulation testing of the three environmental compartments.

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 B.3. The biodegradation of each relevant constituent present in concentration at or above 0.1% (w/w) and relevant transformation and/or degradation product 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.

6. Identification of degradation products

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

You have sought to adapt this information requirement based on similar arguments as addressed under requests B.3-5 above. For the reasons explained under those requests, your adaptation is rejected.

In your comments to the draft decision you claim that ECHA requests a disproportionate identification of degradation products >0.1%, far in excess of the OECD TG 309 recommendation of 10%.

Your claim is not correct. ECHA requests that you must provide information on the identity of the transformation and/or degradation products and to assess the PBT/vPvB properities of any relevant transformation and/or degradation products. The limit of 0.1% refers to the relevant constituents, impurities and additives present in the Substance that are also to be considered for the PBT/vPvB assessment.

ECHA notes that, as explained under the section "Study selection and design" below, you can obtain information on the transformation and/or degradation products from the simulation studies also requested in this decision, or from other methods if adequately justified. You agreed to perform the simulation study in water according to OECD TG 309 (request B.3 above). If the identification of transformation and/or degradation products is performed in accordance with the OECD TG 309, the transformation and/or degradation products detected at ≥10% of the applied concentration at any sampling times must be identified unless reasonably justified.

In your comments to the draft decision, you further claim that it is likely that the transformation and/or degradation products are not PBT/vPvB since they are expected to have low logKow values.

Your dossier does not include any information on the identity and PBT properties of the transformation and/or degradation products, therefore your conclusion cannot be verified.

Therefore, information on identification of degradation products is required.

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

Study selection and design

You must obtain this information while performing the simulation studies requested in this decision (Appendix C, sections 3-5 above). You must provide a scientifically valid justification for any other method you have used for identification of the transformation and/or degradation products.

Identity, stability, behaviour, and molar quantity of the transformation and/or degradation 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 and/or degradation products must be investigated.

7. Bioaccumulation in aquatic species

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

You have sought to adapt this information requirement 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):

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 (ECHA Guidance R.7c Section R.7.10.4.5). 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, 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, indoor and outdoor uses by professional workers and consumers. These uses result in Environmental Release Categories (ERCs) 9a and 9b (widespread uses).

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

In your comments on the draft decision, you agree to perform the requested study. You highlight the analytical challenges in choosing the test material, due to the structural complexity of the UVCB Substance. Your comments regarding this issue are addressed in Appendix B, Section 3.

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. If testing through aquatic exposure is technically not possible, you must provide scientifically valid justification for the infeasibility. In case you conduct the study using the dietary exposure route (OECD 305-III), you must also attempt to 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. In any case you must report all data derived from the dietary test as listed in the OECD TG 305-III.

Under Annex XIII, you must assess the PBT/vPvB properties of the relevant constituents and relevant transformation and/or degradation products of the Substance. Therefore, the bioaccumulation of each relevant constituent present in concentrations at or above 0.1% (w/w) and relevant transformation and/or degradation product 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 C: Requirements to fulfil when conducting and reporting new tests for REACH purposes

A. Test methods, GLP requirements and reporting

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

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

3. Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries[6].

B. Test material

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

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

2. Information on the Test Material needed in the updated dossier
   - You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
   - The reported composition must include the careful identification and description of the characteristics of the Tests Materials in accordance with OECD GLP (ENV/MC/CHEM(98)16) and EU Test Methods Regulation (EU) 440/2008 (Note, Annex), namely all the constituents must be identified as far as possible as well as their concentration. Also any constituents that have harmonised classification and labelling according to the CLP Regulation must be identified and quantified using the appropriate analytical methods.
   - The reported composition must also include other parameters relevant for the property to be tested.

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

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

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[7].

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

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

1. 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.

2. Environmental testing for substances containing multiple constituents

Your Substance contains multiple constituens and, as indicated in ECHA Guidance R.11 (Section R.11.4.2.2), 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.

Appendix E: 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 8 July 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) and the deadline.

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 standard granted time to a total of 51 months to ensure adequate time to perform the studies needed to conclude on the PBT/vPvB assessment and to update the registration dossier including the chemical safety assessment.

ECHA acknowledges difficulties arising from the assessment of a UVCB and the complexity of the proposed tiered approach as described in your comments to this decision. You have not supported your request to extent the draft decision deadline by a laboratory certificate or other source of documentary proof. Based on the information provided ECHA considers that a total of 6 additional months are sufficient: 3 months before conducting the studies for the selection of the appropriate test material and 3 months after the completion of the studies for the interpretation of the results and the dossier update.

Therefore, the deadline is set to 45 months.

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 F: List of references - ECHA Guidance[8] 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)[9]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[9]

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.

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[8] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment

[9] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

OECD Guidance documents[10]

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.

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

Appendix G: 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]

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.