~~Confidential~~

Helsinki, 20 September 2021

Addressees
Registrant(s) of JS 254-996-9 / 40601-76-1 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
06/03/2019

Registered substance subject to this decision ("the Substance")
Substance name: 1,3,5-tris[[4-tert-butyl-3-hydroxy-2,6-xylyl]methyl]-1,3,5-triazine-2,4,6(1H,3H,5H)-trione
EC number: 254-996-9
CAS number: 40601-76-1

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

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadline of ***3 January 2024***.

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

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

1. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method: EU C.3./OECD TG 201)

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

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

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

3. 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

4. Identification of degradation products (Annex IX, 9.2.3.; test method: using test method EU C.25./OECD TG 309)

Reasons for the request(s) are explained in the appendices entitled "Reasons to request information required under Annexes VII and 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, 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.

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". For references used in this decision, please consult the Appendix entitled "List of references".

Appeal

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

Failure to comply

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

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

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

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

1. Growth inhibition study aquatic plants

Growth inhibition study aquatic plants is an information requirement under Annex VII to REACH (Section 9.1.2).

You have provided the following information:

i. Key study (2012): OECD TG 201 with the Substance.

We have assessed this information and identified the following issue[s]:

To fulfil the information requirement, a study must comply with OECD TG 201 and the requirements of OECD GD 23 (ENV/JM/MONO(2000)6/REV1) if the substance is difficult to test (Article 13(3) of REACH). Therefore, the following requirements must be met:

1. the mean coefficient of variation for section-by-section specific growth rates (days 0-1, 1-2 and 2-3, for 72-hour tests) in the control cultures is ≤ 35%;
2. the coefficient of variation of average specific growth rates during the whole test period in replicate control cultures is ≤ 7% in tests with Pseudokirchneriella subcapitata;
3. the results can be based on nominal or measured initial concentration only if the concentration of the test material has been maintained within 20 % of the nominal or measured initial concentration throughout the test;
4. if the concentration of the test material has not been maintained within 20 % of the nominal or measured initial concentration throughout the test, results must be based on the geometric mean of measured concentrations during exposure or on a model describing the decline of the concentration of the test material;
5. a justification why the analytical monitoring of exposure concentrations is not technically feasible must be provided.

Your registration dossier provides an OECD TG 201 showing the following:

You indicated that the validity criteria (outlined as points 1-2 above) were fulfilled. However, in your dossier which was assessed for this decision you did not provide any raw data to verify that the validity criteria listed as points 1-2 above are fulfilled.

In your comments to the initial draft decision, you submitted the requested information.

In your dossier which was assessed for this decision, you reported effect concentration based on the measured initial concentration (0.012 mg/l) and this concentration was below the limit of quantification of the analytical method. In addition, you stated that the measured concentrations dropped below the limit of detection of the analytical method (<0.005 mg/L) after 24 hours of exposure for some test concentrations, while at lower test concentrations, the measured concentrations were below the limit of detection from the start of the test. Thus the measured concentrations were not maintained within 20% of the nominal or measured initial concentration throughout the test.

In your dossier which was assessed for this decision, you did not provide any justification why the analytical monitoring of exposure concentrations is not technically feasible nor demonstrated that the most sensitive method to analyse the Substance was used.

Based on the above, in your dossier which was assessed for this decision,
- the validity criteria of OECD TG 201 are not demonstrated to have been met.

- the Substance is difficult to test (low water solubility) and there are critical methodological deficiencies resulting in the rejection of the study results since they do not allow ECHA to assess the reliability of these results.

In your comments to your initial draft decision, ECHA understands that you propose

1. An adaptation under Annex XI, Section 2 specifies the general rules for adapting the standard information requirement when testing is not technically possible.
2. An adaptation under Annex VII, Section 9.1.2.

We have assessed this information and identified the following issues:

1. *Your adaptation under Annex XI, Section 2 specifies the general rules for adapting the standard information requirement when testing is not technically possible.*

Annex XI, Section 2 specifies the general rules for adapting the standard information requirement when testing is not technically possible. The guidance on the technical limitations of the test method given in the test guideline itself or in relevant guidance complementing the test guideline must always be respected.

You have provided a detailed assessment covering different possibilities offered by OECD GD 23 and provided justification in this respect.

This has allowed ECHA to assess the reliability of the results and consider as per Annex XI, Section 2 (which specifies the general rules for adapting the standard information requirement when testing is not technically possible), you have demonstrated that you have explored the different possibilities offered by OECD GD 23 and provided justification(s) in line with the recommendations of OECD GD 23 but that despite all these efforts, the testing is not technically possible. However, as the information is currently not available in your registration dossier, the data gap remains. You should therefore submit this information in an updated registration dossier by the deadline set out in the decision.

2. *Your adaptation under Annex VII, Section 9.1.2. Column 2*

Annex VII, Section 9.1.2. Column 2 specifies that testing of a growth inhibition study aquatic plants (algae preferred) does not need to be conducted if there are mitigating factors indicating that aquatic toxicity is unlikely to occur for instance if the substance is highly insoluble in water or the Substance is unlikely to cross biological membranes.

You indicate that the study does not need to be conducted if there are mitigating factors indicating that aquatic toxicity is unlikely to occur as the Substance is considered as highly insoluble in water (calculated value of $<2x10^{-5}$ g/L) and the Substance is unlikely to cross biological membranes (logKow 15.28, no hazard observed in mammalian studies).

In your comment to the initial draft decision, you have demonstrated that your Substance is very low water solubility and the low likelihood to cross biological membranes (using indicators used for low likelihood of a high bioaccumulation potential (ECHA Guidance R.11, Figure R.11-4 including high octanol-water partition coefficient (log Kow > 10) and supporting experimental evidence of hindered uptake (no chronic toxicity for mammals). The information you have provided in your comments addresses the incompliance identified in this decision for this information requirement. However, as the information is currently not available in your registration dossier, the data gap remains. You should therefore submit this information in an updated registration dossier by the deadline set out in the decision.

It is in your discretion to generate and provide the necessary supporting information in order to justify any adaptation. If you do so, you are responsible for demonstrating the fulfilment

of the specific requirements of Annexes VII-IX and/or the general requirements of Annex XI to REACH.

On this basis, the information requirement is not fulfilled.

The Substance is difficult to test due to the low water solubility (<0.02 mg/L). OECD TG 201 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified and documented. Due to the properties of Substance, it may be difficult to achieve and maintain the desired exposure concentrations. Therefore, you must monitor the test concentration(s) of the Substance throughout the exposure duration and report the results. If it is not possible to demonstrate the stability of exposure concentrations (i.e. measured concentration(s) not within 80-120% of the nominal concentration(s)), you must express the effect concentration based on measured values as described in OECD TG 201. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solution.

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

1. Long-term toxicity testing on aquatic invertebrates

Long-term toxicity testing on aquatic invertebrates is an information requirement under Annex IX to REACH (Section 9.1.5.).

You have provided the following information in your dossier:

i. a justification to omit the study which you consider to be based on Annex IX, Section 9.1, Column 2. In support of your adaptation, you provided the following justification: "According *to REACH, Annex IX, long-term aquatic toxicity testing shall be proposed if the chemical safety assessment according to Annex I indicates the need to investigate further the effects on aquatic organism. In well-conducted studies in a freshwater fish, invertebrate and algal species, there was no significant aquatic toxicity noted up to the limiting water solubility. Thus, no further testing is justified."*

We have assessed this information and identified the following issue:

Annex IX, Section 9.1, Column 2 is not providing a possibility to omit the need to submit information on long-term toxicity testing on aquatic invertebrates under Column 1. It must be understood as a trigger for providing further information on toxicity testing on aquatic invertebrates if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).

In your comments to the initial draft decision, you claim that ECHA has misinterpretated the decision of the Board of Appeal in case A-011-2018 as a reason to avoid testing by referring to (1) a possible plan to amend REACH Annexes; (2) a final decision addressed to a third party applying the interpretation of Column 2 prior to the Board of Appeal in case A-011-2018; (3) animal welfare considerations based on Article 13(1) and Article 25(1) of REACH, including the opinion that further testing on water column organisms would not be necessary in this case.

The Decision of the Board of Appeal in case A-011-2018 is published on the ECHA website, where the reasoning is outlined, including the use of Annex IX, Section 9.1, Column 2. as a trigger for providing further information on long-term toxicity to fish if the chemical safety assessment according to Annex I indicates the need. It does not constitute as such a valid justification to omit the standard information requirements of Annexes VII – IX or a valid adaptation to these information requirements. First, future, potential changes to the REACH Annexes cannot be taken into account. Second, ECHA implemented the decision of the Board of Appeal in case A-011-2018.and eventually applied it to all dossier evaluation assessments. Third, ECHA notes Articles 13(1) and 25(1) of REACH. However, the main objective of REACH is the protection of human health and the environment, which supports the interpretation of the Board of Appeal (see, para. 172-174 of the Board of Appeal decision in A-011-2018).

Your justification is therefore rejected.

In your comments to the initial draft decision, you further submit the following:

a) Adaptation of Annex XI, Section 3.2(a) (Substance-tailored exposure-driven testing)
b) Adaptation of Annex XI, Section 2 (testing is not technically possible)

a) Your adaptation of Annex XI, Section 3.2(a) (Substance-tailored exposure-driven testing)

You propose an adaptation under Annex XI, Section 3.2(a). based on the following arguments:

a) highly insoluble in water based on your OECD 105 water soluble study where significant technical difficulties were observed
    - Out of 16 individual analysis, only 2 showed detection of the Substance
b) Technical difficulties in testing on water column organisms has been observed in the Algae study (static design), where only the stock solution showed a detectable amount of substance with a concentration of 0.012 mg/L measured (this concentration was below the limit of quantification of the method and is therefore considered as indicative)
c) Toxicity is unlikely because the Substance is highly insoluble and there will be no significant exposure of the organisms in the water column
d) REACH guidance R.7 indicates for water solubility that "very low solubility (i.e. in the low ug/L range) could be used as a reason to test non-pelagic organisms preferentially"
e) The Substance has a Log Koc > 5.63, has a high potential for adsorption to soil and/or sediment, which is suggesting that the relevant compartment is soil or sediment, rather than water and that long-term toxicity testing should be run in those compartments.
f) The Substance has a logKow 15.28 and no hazard observed in chronic mammalian studies so unlikely to cross biological membranes, you invoke the testing of non-pelagic organisms in sediment or soil instead of the long term testing of aquatic organisms, as a reason to avoid testing. You propose performing two sediment studies, an OECD 218 sediment-water chironomid toxicity using spiked sediment and an ISO 10872, determination of the toxic effect of sediment and soil samples on growth, fertility and reproduction of Nematoda using spiked sediment.

We have assessed this information and identified the following issues:

Under Annex XI, Section 3, this information may be omitted based on the exposure scenario(s) developed in the Chemical Safety Report. The justification must be based on a rigorous exposure assessment in accordance with Annex I, Section 5 and must meet any one of the following criteria:

(a) It can be demonstrated that all the following conditions are met:

i. a PNEC can be derived from available data, which:

- must be relevant and appropriate both to the information requirement to be omitted and for risk assessment purposes and therefore must be based on reliable information on the hazardous properties of the substance on at least three trophic levels;
- must take into account the increased uncertainty resulting from the omission of the information requirement, in this case by selecting an appropriate assessment factor (AF) as described in ECHA Guidance R.10.3.

ii. the ratio between the results of the exposure assessment (PECs) and the PNEC are always well below 1.

For the reasons explained under request A.1., B.1. and B.2., your dossier does not include reliable information on the hazardous properties of the substance on at least three trophic levels. Further, you did not explain why water solubility data, for example, would be appropriate for deriving a PNEC.

In your RCR calculations using ERC based predictions, whilst the RCRs for the water compartment were found to be well below 1, the RCRs for the sediment compartment were found to be > 1. You indicate you will further revise your CSR and update your dossier. However, ECHA cannot take into account intention for future changes.

Therefore, your adaptation is rejected.

b) An adaptation of Annex XI, Section 2 (testing is not technically possible)

Annex XI, Section 2 specifies the general rules for adapting the standard information requirement when testing is not technically possible. The guidance on the technical limitations of the test method given in the test guideline itself or in relevant guidance complementing the test guideline must always be respected.

While you did not explicitly indicate a proposal for an adaptation of Annex XI, Section 2, ECHA understands you foresee testing will be technically not possible based on points a – b, above and also when you stated the following in your comments:

"Nevertheless, we insist on the extremely poor water solubility (or insolubility) of the substance which will render the performance of this study severely complicated with a serious risk of not meeting the validity criteria due to the utmost complexity of maintaining constant concentrations of insoluble chemicals (even when following the recommendations of OECD GD 23)".

For the long-term toxicity testing, you have not demonstrated that you have explored the different possibilities offered by OECD GD 23 or provided a justification in line with the recommendations of OECD GD 23 for these specific long-term aquatic testing.

Chapter 7.1 of OECD GD 23 provides general guidance on testing poorly/sparingly water-soluble substances. In particular, that guidance mentions newer techniques that may potentially be used to overcome the technical difficulties identified in your comments. Alternatively, OECD GD 23 indicates that where the dissolved fraction cannot be analytically measured (e.g. when solubility is below a quantifiable level) a justification should still be provided: e.g. a statement from an analytical chemist confirming that the analytical methods used were state of the art, a justification as to why lower detection limits were not feasible and a description of any preliminary analytical efforts. However, you have not addressed any of these for this endpoint.

In Long-term aquatic testing, you have more flexibility in the design of the test, semi-static or flow through compared to the Algae study, which can only occur with a static design. These test design options can provide significant control of the test concentrations during the duration of the long term testing. Therefore, you have not demonstrated that testing is technically not possible for the long term testing.

Further, 'complication' in testing does not demonstrate that testing is technically not possible.

Also, there has been further analytical developments since undertaking the algae study, these could be explored for the long term testing.

Therefore, your adaptation is rejected.

In addition regarding "Testing proposals for sediment", your points d – f raised above, in your comments to your initial draft decision, due to the properties of Substance, highly insolubility in water (calculated value of <2x10-5g/L); Log Koc > 5.63 indicates high adsorption potential suggesting the compartment of concern is soil or sediment rather than water. Log Kow 15.28

and no hazard observed in chronic mammalian studies so unlikely to cross biological membranes, you invoke the testing of non-pelagic organisms in sediment or soil instead of the long term testing of aquatic organisms, as a reason to avoid testing. You propose performing two sediment studies, an OECD 218 sediment-water chironomid toxicity using spiked sediment and an ISO 10872, determination of the toxic effect of sediment and soil samples on growth, fertility and reproduction of Nematoda using spliked sediment. It does not constitute as such a valid justification to switch/omit the standard information requirements of Annexes VII – IX or a valid adaptation to these information requirements. It is your responsibility to perform any additional studies not requested by this decision.

As a worst case possible alternative if the above adaptation(s) are not considered valid, you agree to perform a Long-term toxicity testing on aquatic invertebrates.

On this basis, the information requirement is not fulfilled.

Study design

OECD TG 211 specifies that for difficult to test substances OECD GD 23 must be followed.

As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design' under Section A.1.

In addition to your comments to the initial draft decision, as a worst case possible alternative intention if the above adaptation(s) are all not considered valid, you propose as a first step to run the OECD 211, long-term toxicity testing on aquatic invertebrates.

2. Long-term toxicity testing on fish

Long-term toxicity testing on fish is an information requirement under Annex IX to REACH (Section 9.1.6.).

You have provided the following information:

i. a justification to omit the study which you consider to be based on Annex IX, Section 9.1, Column 2. In support of your adaptation, you provided the following justification: "According to REACH, Annex IX, long-term aquatic toxicity testing shall be proposed if the chemical safety assessment according to Annex I indicates the need to investigate further the effects on aquatic organism. In well-conducted studies in a freshwater fish, invertebrate and algal species, there was no significant aquatic toxicity noted up to the limiting water solubility. Thus, no further testing is justified."

We have assessed this information and identified the following issue:

As already explained above for Request B.2. above, Annex IX, Section 9.1, Column 2 is not providing a possibility to omit the need to submit information on long-term toxicity to fish under Column 1. It must be understood as a trigger for providing further information on long-term toxicity to fish if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).

Your justification is therefore rejected.

In addition to your comments to the initial draft decision, as a worst case possible alternative intention if the above adaptation(s) are all not considered valid, you propose as a first step to run the OECD 211, long-term toxicity testing on aquatic invertebrates and if necessary

based on the results in a second step, if significant lethal or non lethal effects are observed, to perform a long term toxicity testing on Fish.

You are responsible for your testing strategy.

It is in your discretion to generate and provide the necessary supporting information in order to justify any adaptation(s). If you do so, you are responsible for demonstrating the fulfilment of the specific requirements of Annexes VII-IX and/or the general requirements of Annex XI to REACH taking into account the deficiencies mentioned above and that Column 2 is not a ground for adapting the information requirement set under Column 1.

On this basis, the information requirement is not fulfilled.

Study design

To fulfil the information requirement for the Substance, the Fish, Early-life Stage Toxicity Test (test method OECD TG 210) is the most appropriate (ECHA Guidance R.7.8.2.).

OECD TG 210 specifies that for difficult to test substances OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design' under Section A.1.

3. Simulation testing on ultimate degradation in surface water

Simulation testing on ultimate degradation in surface water is an information requirement under Annex IX to REACH (Section 9.2.1.2.).

You have provided the following information:

i. an adaptation under Annex IX, Section 9.2., Column 2 with the following justification: "The study does not need to be conducted because the substance is highly insoluble in water".

We have assessed this information and identified the following issue:

This information requirement may be adapted under Column 2 if the substance is highly insoluble in water. Under Guidance R7.9.2.3 (page 189), this is because "*the solubility in water may be so low that the test may be practically difficult or impossible to conduct at concentrations below the water solubility limit of the substance. It is also likely that the surface water environment will not be the principal environment of concern and, if a simulation test is required, consideration should be given to a test in a different environmental media(e.g. soil, sediment).*"

You claim that the Substance has a water solubility of <0.02 mg/L with a HPLC-UV method with a limit of quantification of 0.1 mg/l and a limit of detection of 0.005 mg/l. You have not justified or demonstrated that the most sensitive analytical method was used for deriving water solubility.

Screening information provided in your dossier indicates that the Substance is not readily biodegradable (23.2 % in 28 days, OECD TG 301B).

OECD TG 309 states that the maximum concentration of the test substance should not exceed 100 µg/L, but maximum test concentrations below 10 µg/L or less are preferred to ensure that the biodegradation follows first order kinetics. The lowest concentration should not exceed 10 µg/L, but lowest test concentrations of 1-2 µg/L or less than 1 µg/L are preferred.

First, in your dossier assessed for this decision, you have not demonstrated that testing is practically difficult or impossible. The reported water solubility value could still be covered by OECD TG 309, as described above. Furthermore, you have based your argument on a HPLC-UV measurement without justifying the use of such a method. For example, in section 1.4 of your dossier, you also use other methods that may have a lower limit of quantification/detection, such as HPLC coupled with ELSD (Evaporative Light Scattering Detector) and/or mass detector at high resolution.

In addition, in your dossier assessed for this decision, you have not addressed the possibility, normally available, to achieve an adequate analysis of such low concentration by use of commercially available 14C-labelled substances. The Substance is a mono-constituent substance and it may be possible to perform a test with radiolabelling technique.

Further, in your dossier assessed for this decision, in case of analytical limitations, it may be impossible to measure the concentration of test substance with the required accuracy, if the test substance is applied at a concentration 100 µg/L. Higher concentrations of test substance (>100 µg/L and sometimes >1 mg/L) may, however, be used for the identification and quantification of major transformation products or if a specific analysis method with a low detection limit is not available.

Further, you have not justified why the surface water environment will not be the principal environment of concern.

In your comments to your initial draft decision you point out that the water compartment is not the relevant compartment because:

a) the Substance is highly insoluble in water based on your OECD 105 water soluble study where significant technical difficulties were observed
    - Out of 16 individual analysis, only 2 showed detection of the Substance

b) The performance of the algae study demonstrated it was technically not possible

c) The Substance has a Log Koc > 5.63, has a high potential for adsorption to soil and/or sediment, which is suggesting that the relevant compartment is soil or sediment, rather than water.

Annex IX, Section 9.2.1.2. specifies the specific rule for adapting the standard information requirement when testing need not be conducted if:

- The Substances is highly insoluble in water.

In your comment to the initial draft decision, you have demonstrated that your Substance is very low water solubility and has a low likelihood to cross biological membranes (using indicators used for low likelihood of a high bioaccumulation potential (ECHA Guidance R.11, Figure R.11-4 including high octanol-water partition coefficient (log K_{ow} > 10) and supporting experimental evidence of hindered uptake (no chronic toxicity for mammals). The information you have provided in your comments addresses the incompliance identified in this decision for this information requirement. However, as the information is currently not available in your registration dossier, the data gap remains. You should therefore submit this information in an updated registration dossier by the deadline set out in the decision.

It is in your discretion to generate and provide the necessary supporting information in order to justify any adaptation. If you do so, you are responsible for demonstrating the fulfilment of the specific requirements of Annexes VII-IX and/or the general requirements of Annex XI to REACH.

In your comments to your initial draft decision you point out that the Substance is not a PBT /vPvB Substance. You provide a QSAR summary but you acknowledge that the Substance is out of the applicability domain of the model and that no reliable predictions were obtained. Based on this we have not assessed the prediction. You indicate that the section on bioaccumulation and the assessment of B/vB in the PBT assessment will be updated with a weight of evidence approach to conclude that the Substance is not B not vB.

Therefore, your adaptation(s) is rejected.

On this basis, the information requirement is not fulfilled.

Study design

Simulation degradation studies must include two types of investigations (ECHA Guidance R.7.9.4.1):
1) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and
2) a kinetic study where the degradation rate constants (and degradation half-lives) of the parent substance and of relevant transformation/degradation products are experimentally determined.

You must perform the 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.11.4.1.1.3.).

The required test temperature is 12°C, which corresponds to the average environmental temperature for the EU (ECHA Guidance R.16, Table R.16-8) and is in line with the applicable test conditions of the OECD TG 309.

As specified in ECHA Guidance R.7.9.4.1, the organic carbon (OC) concentration in surface water simulation tests is typically 2 to 3 orders of magnitude higher than the test substance concentration and the formation of non-extractable residues (NERs) may be significant in surface water tests. Therefore, non-extractable residues (NER) must be quantified. The reporting of results must include a scientific justification of the used extraction procedures and solvents. By default, total NER is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NER may be differentiated and quantified as irreversibly bound or as degraded to biogenic NER, such fractions could be regarded as removed when calculating the degradation half-life(s) (ECHA Guidance R.11.4.1.1.3.). Further recommendations may be found in the background note on options to address non-extractable residues in regulatory persistence assessment available on the ECHA website.

Relevant transformation/degradation products are at least those detected at ≥ 10% of the applied dose at any sampling time or those that are continuously increasing during the study even if their concentrations do not exceed 10% of the applied dose, as this may indicate persistence (OECD TG 309; ECHA Guidance R.11.4.1).

4. Identification of degradation products

Identification of degradation products is an information requirement under Annex IX to REACH (Section 9.2.3.).

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

Therefore, this information requirement is not met.

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

Study design

Regarding the selection of appropriate and suitable test method(s), the method(s) will have to be substance-specific. 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, log K_{ow} and potential toxicity of the transformation/degradation may need to be investigated. You may obtain this information from the degradation study requested in Sections B.3 or by some other measure. If any other method is used for the identification of the transformation/degradation products, you must provide a scientifically valid justification for the chosen method.

To determine the degradation rate of the Substance, the requested study according to OECD TG 309 (Section B.3) must be conducted at 12°C and at a test concentration < 100 µg/L. However, to overcome potential analytical limitations with the identification and quantification of major transformation/degradation products, you may consider running a parallel test at higher temperature (but within the frame provided by the test guideline, e.g. 20°C) and at higher application rate (i.e. > 100 µg/L).

In your comments to the initial draft decision, you propose to run a degradation pathway study, where transformation/degradation products are quantified and, if relevant are identified. You propose a reduced OECD TG 308 study using the aerobic test at 20°C with a 14C-labelled test substance in one representative sediment to maximize the transformation of the test material and identify relevant transformation products (either present at > 10% or with an increasing concentration overtime until the end of the study even if 10% is not reached).

You propose to obtain this information by alternative method, including the use of 14C-labelling, which should provide valuable relevant data. However, it is not possible to assess your intention as the proposal for a "reduced" study is unclear. As indicated above if any other method is used for the identification of the transformation/degradation products, you must provide a scientifically valid justification for the chosen method.

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[2].

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 all constituents of each Test Material and their concentration values and other parameters relevant for the property to be tested.

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

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

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

Appendix D: 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 January 2020.

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

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

> In your comments on the draft decision, you requested an extension of the deadline to provide information from 18 to 30 months from the date of adoption of the decision.
>
> You justify the extension by stating "*in regards to the timescale, experience with testing laboratories for other testing and in particular for difficult to test substances shows that lead times for starting testing are increasing, and this is amplified by the COVID situation which obliges laboratories to have reduced teams onsite. Furthermore, a longer time scale would accommodate for potential sequential testing. We believe that 30 months would be a more appropriate timescale than 18 months*".
>
> The deadline in the draft decision already considers sequential testing. However, due to the foreseen reduced laboratory capacity and technical issues of a difficult to test substance, an extension to 24 months is granted.
>
> On the basis of foreseen technical testing difficulties, ECHA has modified the deadline to provide the information. Therefore, the deadline is amended to 24 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 E: List of references - ECHA Guidance[4] and other supporting documents

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

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

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

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

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

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

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

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

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

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

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

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

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

OECD Guidance documents[6]
Guidance Document on aqueous–phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

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

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

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

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

Appendix F: Addressees of this decision and their corresponding information requirements

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

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

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.