EUROPEAN CHEMICALS AGENCY

Helsinki, 26 January 2021

Addressees
Registrant(s) of JS_TMDDD_2014 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
12/08/2014

Registered substance subject to this decision ("the Substance")
Substance name: 2,5,8,11-tetramethyldodec-6-yne-5,8-diol
EC number: 269-348-0
CAS number: 68227-33-8

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 in A.1, A.2, B.1 and B.2 by the deadline of ***31 October 2022***, the information listed in B.5 and B.6 by the deadline of ***3 May 2023*** and all the remaining information listed by the deadline of ***31 October 2024***.

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

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

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

2. 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 VIII of REACH

1. Adsorption/ desorption screening (Annex VIII, Section 9.3.1.; test method:OECD TG 106)

2. Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.; test method: OECD TG 203)

3. Long term toxicity testing on aquatic invertebrates (triggered by Annex VIII, Section 9.1.3., column 2; test method: OECD TG 211)

4. Long-term toxicity testing on fish (triggered by Annex VIII, Section 9.1.3., column 2; test method: OECD TG 210)

5. Simulation testing on ultimate degradation in surface water (triggered by Annex VIII, Section 9.2.; test method: EU C.25./OECD TG 309) at a temperature of 12 °C

6. Identification of degradation products (triggered by Annex VIII, Section 9.2)

7. Bioaccumulation in aquatic species (triggered by Annex I, sections 0.6.1. and 4.; Annex XIII, Section 2.1.; test method: OECD TG 305)

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

- Appendices entitled "Reasons to request information required under Annex VII to VIII of REACH".

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.

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

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

Appeal

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

Failure to comply

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

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

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

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

1. Short-term aquatic toxicity on invertebrates

Short-term toxicity testing on aquatic invertebrates is an information requirement under Annex VII to REACH (Section 9.1.1.).

You have provided a key study according to OECD TG 202 (2010) in your dossier.

We have assessed this information and identified the following issues:

To fulfil the information requirement, a study must comply with OECD TG 202 (Article 13(3) of REACH). Therefore, the following requirements must be met:

- the test design is reported (*e.g.* number of replicates);
- the test procedure is reported (*e.g.* composition of the test medium, loading in number of *Daphnia* per test vessel);
- the number of immobilised daphnids is determined at 24 and 48 hours. Data are summarised in tabular form, showing for each treatment group and control, the number of daphnids used, and immobilisation at each observation;
- the dissolved oxygen and pH measured at least at the beginning and end of the test is reported;
- adequate information on the analytical method (including performance parameters of the method) and on the results of the analytical determination of exposure concentrations are provided;

Your registration dossier provides an OECD TG 202 without information on:

- the test design,
- the test procedures,
- the number of immobilised daphnids at 24 and 48 hours,
- dissolved oxygen concentration,
- pH (at least at the beginning and end of the test),
- analytical method and the results of the analytical determination of exposure concentrations.

Based on the above, you did not demonstrate that the validity criteria (percentage of immobilised daphnids and dissolved oxygen concentration) are met. Furthermore, the reporting of the study is not sufficient to conduct an independent assessment of its reliability.

In your comments to the draft decision, you note that you will first revise the robust study summary (RSS) of the existing study and check, whether this study fulfills the information requirement. Furthermore, you agree to perform a study on short-term toxicity on aquatic invertebrates, if the existing data do not fulfill the information requirement.

Therefore, the requirements of OECD TG 202 are not met.

On this basis, the information requirement is not fulfilled.

2. Growth inhibition in aquatic plants

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

You have provided a key study according to OECD TG 201 in your dossier.

We have assessed this information and identified the following issues:

To fulfil the information requirement, a study must comply with OECD TG 201 (Article 13(3) of REACH). Therefore, the following requirements must be met:

- the test design is reported (*e.g.*, number of replicates, number of test concentrations and geometric progression used);
- the test conditions are reported (*e.g.*, composition of the test medium, biomass density at the beginning of the test);
- the method for determination of biomass and evidence of correlation between the measured parameter and dry weight are reported;
- the results of algal biomass determined in each flask at least daily during the test period are reported in a tabular form;
- microscopic observation performed to verify a normal and healthy appearance of the inoculum culture are reported. Any abnormal appearance of the algae at the end of the test is reported;
- adequate information on the analytical method (including performance parameters of the method) and on the results of the analytical determination of exposure concentrations is provided.

Your registration dossier provides an OECD TG 201 without information on:
- the test design,
- the test conditions,
- the method for determination of biomass and evidence of correlation between the measured parameter and dry weight,
- the results of algal biomass determined in each flask at least daily,
- any abnormal appearance of the algae at the end of the test
- the analytical method with the results of the analytical determination of exposure concentrations reported in the dossier for the provided key study.

Based on the above, you did not demonstrate that the validity criteria (determination of biomass and correlation between the measured parameter and dry weight) are met. Furthermore, there is no information to conduct an independent assessment of its reliability.

In your comments to the draft decision, you note that you will first revise the RSS of the existing study and check, whether this study fulfills the information requirement. Furthermore, you agree to perform growth inhibition study in aquatic plants, if the existing data do not fulfill the information requirement.

Therefore, the requirements of OECD TG 201 are not met.

On this basis, the information requirement is not fulfilled.

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

1. Adsorption/desorption screening

Adsorption/desorption screening is an information requirement under Annex VIII to REACH (Section 9.3.1.).

You have adapted this information requirement by using a QSAR approach under Annex XI, Section 1.3. of the REACH Regulation and you have provided:

(i) a key study to estimate the Log Koc of the Substance by calculation (KOCWIN Program (v2.00), Estimation Programs Interface Suite™ United States Environmental Protection Agency, Washington, DC, USA. version 4.00)

We have assessed this information and identified the following issues:

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

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

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

You have not included a QMRF and a QPRF in your dossier. You have provided an estimated Log Koc based on KOCWIN Program (V2.00) without any information on the scientific validity of this approach nor on the applicability domain of that QSAR model and how the Substance would fall within that domain.

Based on the properties of the Substance, it is surface active (34.4 mN/m).

Your adaptation does not meet the general rule for adaptation of Annex XI, Section 1.3. because:

- Without any information, on this issue, you have not established the scientific validity of the selected QSAR approach, in particular considering that the Substance is surface active.
  Indeed, as indicated in ECHA Guidance on information requirements and chemical safety assessment (version 6.0., July 2017), Chapter R.7a, Section R.7.1.15.3.: *'...measured values will normally be needed for surface active substances (e.g. surfactants)'.*

- You did not demonstrate that the selected chemical structure falls within the applicability domain of the selected QSAR.

Therefore, your adaptation of the information requirement cannot be accepted.

In your comments to the draft decision, you agree to perform the study on adsorption/desorption using a batch equilibrium method.

As explained above, your adaptation is rejected. Therefore the information provided does not fulfil the information requirement and there is a data gap that needs to be filled in.

Batch equilibrium method (OECD TG 106) is to be used for surface active substances, as indicated in the ECHA Guidance on information requirements and chemical safety assessment (version 6.0., July 2017), Chapter R.7a, Section R.7.1.15.3.

2. Short-term toxicity testing on fish

Short-term toxicity testing on fish is an information requirement under Annex VIII to REACH (Section 9.1.3.).

You have provided a key study, performed according to EU Method C.1 (Acute Toxicity for Fish), equivalent to the OECD TG 203.

We have assessed this information and identified the following issues:

To fulfil the information requirement, a study must comply with OECD TG 203. Therefore, the following requirements must be met:

- the analytical measurement of test concentrations is conducted
- the test design is reported (*e.g.* number of fish, age (or size) of fish);
- the test procedure is reported (*e.g.* composition of the test medium, fish loading);
- The results of total organic carbon (TOC) determinations in the dilution water are reported;
- adequate information on the analytical method (including performance parameters of the method) and on the results of the analytical determination of exposure concentrations are provided;
- mortalities and sub-lethal effects (*e.g.* with regard to equilibrium, appearance, ventilator and swimming behaviour) are reported. The frequency of observations includes at least 2 observations within the first 24 hours and at least two observations per day from day 2 to 4.

Your registration dossier provides and OECD TG 203 without information on:
- the test design,
- the test procedure,
- the results of TOC determination in the dilution water,
- mortalities and sub-lethal effects,
- analytical method with the results of the analytical determination of exposure concentrations reported in the dossier for the provided key study.

Based on the above, you did not demonstrate that the validity criteria (mortality in the control(s) is ≤ 10% at the end of the test and dissolved oxygen concentration) are met. Furthermore, the reporting of the study is not sufficient to conduct an independent assessment of its reliability.

In your comments to the draft decision, you note that you will first revise the RSS of the existing study and check, whether this study fulfills the information requirement. Furthermore, you agree to perform a study on short-term toxicity on fish, if the existing data do not fulfil the information requirement.

Therefore, the requirements of OECD TG 203 are not met.

On this basis, the information requirement is not fulfilled.

3. Long-term toxicity testing on aquatic invertebrates

Long-term aquatic toxicity testing as described in Annex IX shall be considered if the chemical safety assessment according to Annex I indicates the need to investigate further effects on aquatic organisms (Annex VIII, Section 9.1.3., column 2).

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

- it is potentially persistent or very persistent (P/vP) as:
  - it is not readily biodegradable (*i.e.* <60/70% degradation in an OECD 301 A-F, and
- it is potentially bioaccumulative or very bioaccumulative (B/vB) as:
  - for some groups of substances (e.g. organometals, ionisable substances, surfactants) other partitioning mechanisms may drive bioaccumulation (e.g. binding to protein/cell membranes) and high potential for bioaccumulation cannot be excluded solely based on its potential to partition to lipid;

Your registration dossier provides the following:

- The Substance is not readily biodegradable (3% degradation after 28 days in non-standard biodegradability test: [redacted] (2010). Ready Biodegradability Test of [redacted]. Unpublished report);
- The Substance is a surfactant and therefore high potential for bioaccumulation cannot be excluded based on water-octanol partitioning coefficient.

You have also submitted ISO9439 data (see Appendix B Section 5. below).

Furthermore, the information in your dossier is currently incomplete and therefore:
- it is not possible to conclude on the persistence of the Substance (see Appendix B Sections 5. and 6.); as explained below in this section;
- there is no adequate data to conclude on bioaccumulation potential of the Substance (see Appendix B Section 7.) as explained below in this section;
- it is not possible to conclude on the toxicity of the Substance (in addition to this request and see Appendix A Sections 1. And 2. and Appendix B Sections 4.).

The information above indicates that the Substance is a potential PBT/vPvB substance. We note in this respect that the ISO9439 data are not reliable and cannot be used for any PBT conclusion (see Appendix B Section 5.). Therefore, the chemical safety assessment (CSA) indicates the need the need for long-term aquatic toxicity investigation

In your comments to the draft decision, you agree to perform the study on long-term toxicity testing on aquatic invertebrates to investigate further effects on aquatic organisms.

Therefore, this information requirement is triggered.

You have not provided information on long-term toxicity to aquatic invertebrates for the Substance in the dossier.

On this basis, the information requirement is not fulfilled.

4. Long-term toxicity testing on fish

Long-term aquatic toxicity testing as described in Annex IX shall be considered if the chemical safety assessment according to Annex I indicates the need to investigate further effects on aquatic organisms (Annex VIII, Section 9.1.3., column 2).

This information requirement is triggered in case the chemical safety assessment (CSA) indicates the need for further investigation of effects on aquatic organisms, such as if the substance is a potential PBT substance (Annex I, Section 4; Annex XIII, Section 2.1; ECHA Guidance R.11.4).

As already explained in the Appendix B, Section 3 above, the Substance is a potential PBT substance. Therefore, the CSA indicates the need to investigate further effects on aquatic organisms and this information requirement is triggered.

You have not provided information on long-term toxicity to fish for the Substance in the dossier.

In your comments to the draft decision, you agree to carry out a study on long-term toxicity testing on fish only, if this is triggered, i.e. in case the CSA (including PBT/vPvB assessment and risk characterisation) indicates the need to investigate further effects on aquatic organisms.

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.).

5. Simulation testing on ultimate degradation in surface water

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).

You have provided the following information in the dossier on the degradation simulation in water: *"Due to an enhanced biodegradation test according to International Standard ISO 9439, Annex D, on a surrogate (2,4,7,9-tetramethyl-5-decyne-4,7-diol) of the test substance it is supposed to persist in the environment. Therefore, further testing on biodegradation is supposed to not reveal any further usefull information for the assessment of the substance. hence, no testing on soil/sediment/surface water biodegradation is performed."*

This information requirement is triggered in case the chemical safety assessment (CSA) indicates the need for further degradation investigation (Annex I, Section 4; Annex XIII,

Section 2.1), such as if the substance is a potential PBT/vPvB substance (ECHA Guidance R.11.4).

As already explained in the Appendix B, Section 3 above, the Substance is a potential PBT/vPvB substance. Therefore, the CSA indicates the need for further degradation investigation and this information requirement is triggered.

You have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5 using the following:

- enhanced biodegradation test according to International Standard ISO 9439, Annex D, on a surrogate (2,4,7,9-tetramethyl-5-decyne-4,7-diol)

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

Annex XI, Section 1.5. specifies two conditions which must be fulfilled whenever a read-across approach is used. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group.

Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance R.6 and related documents.

You have not provided a read-across justification document in your dossier.

ECHA notes the following shortcomings with regards to the predictions of (eco)toxicological properties.

Missing justification

Annex XI, Section 1.5 requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must provide a justification for the read-across including a hypothesis, explanation of the rationale for the prediction of properties and robust study summary(ies) of the source study(ies).[2]

You have provided no justification.

In the information provided on simulation degradation in water you refer to the biodegradability study conducted with other substances than your Substance in order to comply with the REACH information requirements. You have not provided any information about this study nor results of this study. Moreover, you have not provided documentation as to why this information is relevant for your Substance.

In the absence of such documentation, ECHA cannot verify that the properties of your Substance can be predicted from the data on the source substance(s). Thus, provided information is not sufficient to conclude on degradation of the substance in the water.

Source study(ies) not meeting A.XI Requirements

[2] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.6.1

According to Annex XI, Section 1.5., if the grouping concept is applied then in all cases the results to be read across should:

- be adequate for the purpose of classification and labelling and/or risk assessment;
- have adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3), in this case OECD TG 309 whose key parameter is:
    - degradation half-life of a substance in surface water.

In the information provided on simulation degradation in water you refer to the *"enhanced biodegradation test according to International Standard ISO 9439"* and that on the basis of results of this test *"the test substance it is supposed to persist in the environment".*

As noted in ECHA Guidance R.7b ISO 9439 test is a screening test for persistence assessment and does not allow to conclude on the above key parameter.

Therefore, this study must be rejected.

In your comments to the draft decision, you indicate that the data is requested in order to clarify the potential PBT/vPvB properties of the substance. You propose to employ a stepwise approach, i.e. first to clarify the bioaccumulation potential of the substance and based on the outcome of it to conclude, whether further examination on degradation of the substance is needed to clarify whether the substance fulfills the PBT/vPvB criteria. You state that if the substance does not fulfil the B criterion, the PBT/vPvB characteristics do not apply and consequently a generation of further data for the PBT/vPvB assessment are not necessary.

According to the Annex XIII PBT/vPvB assessment shall also take account of the PBT/vPvB properties of relevant constituents of a substance and relevant transformation/degradation products. Therefore, after addressing bioaccumulation potential only of the major constituent or of some of constituents of the Substance, may not be possible to conclude if the Substance is a potential PBT/vPvB substance and consequently, not possible to justify omission of the simulation degradation testing and identification of degradation products.

On this basis, the information requirement is not fulfilled.

Study design

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

- You must perform the OECD TG 309 test, by following the pelagic test option with natural surface water containing approximately 15 mg dw/L of suspended solids (acceptable concentration between 10 and 20 mg dw/L) (ECHA Guidance R.11).

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

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

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

6. Identification of the degradation products

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).

This information requirement is triggered in case the chemical safety assessment (CSA) indicates the need for further degradation investigation (Annex I, Section 4; Annex XIII, Section 2.1), such as if the substance is a potential PBT/vPvB substance (ECHA Guidance R.11.4).

As already explained in Appendix B, Section 3 above, the Substance is a potential PBT/vPvB substance. Therefore, the CSA indicates the need for further degradation investigation including identification of degradation products.

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

For ECHA's response, to your comments to the draft decision regarding this request, see request B.5 above.

On this basis, the information requirement is not fulfilled.

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 Section on degradation simulation in surface water 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 on degradation simulation in surface water) 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).

7. Bioaccumulation in aquatic species

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

For this information requirement, you have provided a key study: Bioconcentration test of chemical substances in fish and shellfish (Yakushokuhatsu No.1121002, Heisei 15.11.13 Seikyoku No.2, Kanpokihatsu No.031121002, November 21, 2003; the latest revision, November 20, 2006).

This information requirement is triggered in case the chemical safety assessment (CSA) indicates the need for further investigation on bioaccumulation in aquatic species (Annex I, Section 4; Annex XIII, Section 2.1), such as if the substance is a potential PBT/vPvB substance (ECHA Guidance R.11.4).

As already explained in the Appendix B, Section 3 above, the Substance is a potential PBT/vPvB substance. Therefore, the CSA indicates the need for bioaccumulation investigation.

We have assessed the bioaccumulation study provided by you and identified the following issues:

To fulfil the information requirement, a study must comply with the OECD TG 305 (Article 13(3) of REACH). In the dossier you indicated that the route of exposure is 'feed', so ECHA understands that the test with dietary exposure of fish was performed. Therefore, the following requirements must be met:

- Coverage of the key parameter which is the bioaccumulation potential of the test substance in whole fish, which must be determined based on the following parameters:
  1) the uptake rate constant (k_1) and loss rate constants including the depuration rate constant (k_2), and/or
  2) the kinetic bioconcentration factor (BCF_K), and/or
  3) the dietary biomagnification factor (BMF).
- For a test to be valid the following conditions apply:
  1) the concentration of the test substance in fish food before and at the end of the uptake phase is within a range of ± 20% (based on at least three samples at both time points);
  2) a high degree of homogeneity of substance in the spiked food is demonstrated (i.e. less than ± 15% from the mean in at least three sample);
  3) concentrations of test substance is below detection level, or only at typical trace levels, in un-spiked food or control fish tissues;
  4) Mortality or other adverse effects/disease in both control and test group fish should be ≤10% at the end of the test.
- a study can be terminated at the end of the uptake period (or with the second depuration sample) only if:
  1) all validity criteria are fulfilled, and
  2) the lack of uptake is not due to some other shortcoming of the test, and
  3) appropriate justification is provided (*e.g.* analysis of faeces for undigested test substance as part of a "mass balance" approach);
- the analytical method used for the quantification of the test material in the feed and in fish tissues is described;
- the BCF/BMF is based on the total concentration in the fish (*i.e.* per total wet weight of the fish);
- tabulated test material concentration data in fish, mean measured concentration at end of uptake, the derived (overall) depuration rate constant and concentration in fish at start of depuration phase are provided;
- the results of the determination of the test substance in test and control diets at least in triplicate are reported;

- method of estimation of the corresponding BCF value from the dietary test is reported.

However, you have provided a study record without information on the above key parameters and validity criteria.

Without this information, you have not demonstrated that study fulfils the OECD TG 305's key parameters and validity criteria and therefore it is rejected.

In your comments to the draft decision, you note that you will first revise the robust study summary (RSS) of the existing study and check, whether this study fulfills the information requirement. Furthermore, you agree to perform bioaccumulation in aquatic species study, if the existing data do not fulfill the information requirement.

On this basis, the information requirement is not fulfilled.

Study design

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

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

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

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

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

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[3].

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[4].

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

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

A. 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.

B. Testing strategy for aquatic toxicity testing

You are advised to consult ECHA Guidance R.7b, (Section R.7.8.5) which describes the Integrated Testing Strategy, to determine the sequence of aquatic toxicity tests and testing needed.

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 5 November 2019.

The decision making followed the procedure of Article 51 of the REACH Regulation, as described below:

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.

Deadline to submit the requested information in this decision

The timeline indicated in the draft decision to provide the information requested is as follows:

A.1, A.2, B.1, B.2, B.5 and B.6 by the deadline of exact date of 18 months from the date of the decision and all the remaining information listed by the deadline of exact date of 42 months from the date of the decision.

In your comments on the draft decision, you requested an extension of the timeline from 18 months to 30 months for the information requested under B.5 and B.6. You justified your request on the following grounds:

"The timeline of 18 months for the simulation testing on ultimate degradation in surface waterand identification of degradation products indicated in the draft decision for submitting the update of the registration dossier containing the information required is too short. Please note, that this substance is considered as difficult to analyze due to its surface-active properties. From experience we are aware that we need to develop and validate sophisticated analytical methods, which is time consuming and will extend the timeframe of the study enormously. Further, this requested test is of a complex nature which requires careful planning and selection of a reliable testing facility who is able to carry out such tests. Experience shows that these activities require a considerable period of time. Last not least, if the proposed sequential testing approach is implemented, also the timeline has to be extended accordingly. For these studies, at least 24 months have to be calculated including experimental setup, synthesis of the radiolabeled substance, analytical work and reporting. It is not clear, if experienced laboratories are able to start such type of studies immediately. Additionally there are the same data requests in other draft decisions on compliance checks for the same group of substances, all within the category. These are: EC 204-809-1; EC 500-022-5; EC 451-160-7 and EC 269-348-0 So it would be best to perform this type of study for all of the relevant substances in the same laboratory. Which might be difficult to deal in parallel and needs additional time for the laboratory. Therefore, we ask to prolong the timeline to at least 30 months."

In support of your request you provided document from the test laboratory justifying the extension of the deadline. In the document it is explained that the testing might take between 16-26 months.

It is not clear from the documentation whether longer or shorter testing period would be needed for the Substance. Therefore, in order not to delay the testing mean duration of 21 months for the testing is granted with additional 3 months to cover necessary administrative steps. In respect of the sequential testing, as noted in the Appendix D above, it is advised to first conclude whether the Substance (including relevant constituents and relevant transformation/degradation products) fulfils the Annex XIII criteria for P and vP, and then continue with the assessment for bioaccumulation.

Therefore, on these grounds, ECHA has partially granted the request and set the deadline to 24 months for the information requested under B.5 and B.6.

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[5] 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)[6]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[6]

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[7]

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

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

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

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

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

EUROPEAN CHEMICALS AGENCY

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]
[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.