~~Confidential~~

Helsinki, 12 November 2021

Addressees
Registrant(s) of JS_43100-47-6 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
26/11/2015

Registered substance subject to this decision ("the Substance")
Substance name: 5',5''''-(1,1,1-trifluoropropane-2,2-diyl)bis(1,1':3',1''-terphenyl-2'-ol)
EC number: 610-104-3
CAS number: 43100-47-6

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 ***19 February 2025***.

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

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

1. Long-term toxicity testing on aquatic invertebrates (triggered by Annex VII, Section 9.1.1., column 2; test method: EU C.20./OECD TG 211)

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

2. 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. Non-extractable residues (NER) must be quantified and a scientific justification of the selected extraction procedures and solvents must be provided.

3. Soil simulation testing (triggered by Annex VIII, Section 9.2.; test method: EU C.23./OECD TG 307) at a temperature of 12°C. Non-extractable residues (NER) must be quantified and a scientific justification of the selected extraction procedures and solvents must be provided.

4. Sediment simulation testing (triggered by Annex VIII, Section 9.2.; test method: EU C.24./OECD TG 308) at a temperature of 12°C. Non-extractable residues (NER) must be quantified and a scientific justification of the selected extraction procedures and solvents must be provided.

5. Identification of degradation products (triggered by Annex VIII, Section 9.2; test method: using an appropriate test method

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

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

- Appendix entitled "Reasons common to several requests";
- Appendices entitled "Reasons to request information required" under Annexes VII to VIII 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.

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 on Reasons common to several requests

1. Triggers for further testing to clarify PBT properties of the Substance

Further testing to clarify degradation and bioaccumulation properties is triggered by the chemical safety assessment (CSA) if the substance is a potential PBT/vPvB substance (Annex VIII, Section 9.2., Column 2 as well as Annex I, Sections 0.6.1. and 4; Annex XIII, Section 2.1). This is the case if the Substance itself or any of its constituent or impurity present in concentration ≥ 0.1% (w/w) or relevant transformation/degradation product meets the following criteria:

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

Your registration dossier provides the following:

- The Substance is not readily biodegradable (<10 % degradation after 28 days in an OECD TG 301B study);
- The Substance has a high potential to partition to lipid storage (Log K_{ow} of >6.2 based on an OECD TG 117 study, and Log K_{ow} of 11.11 based on QSAR / KOWWIN v1.68).

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

You have not provided simulation or bioaccumulation studies which would allow assessment of the PBT properties of the Substance. Furthermore, it is not possible to conclude on the toxicity of the Substance (see Appendices A.1-2 and B.1 of this decision).

You however conclude your PBT assessment claiming that the Substance is not B/vB with the following justification: "*It is known that logKow values greater than 10 will already result in BCF values of below 1000. To verify this assumption, a BCF calculation using OASIS Catalogic v5.11.16 with BCF base-line model v.02.08 has been accomplished (QPRF attached under 2.3 Endpoint summary). According to this calculation and in line with the very high logKow, bioaccumulation is not expected for this substance (logBCF = 0.96)".*

We have assessed this information and identified the following issue:

Under Annex XI, Section 1.3. and ECHA Guidance R.6.1.5.3., one of the cumulative conditions of this adaptation is that a substance must fall within the applicability domain specified by the model developer.

You describe the following regarding the structural fragment domain in the attached documentation for the prediction based on OASIS Catelogic v5.11.16:

"*ii. Structural fragment domain:*
The following ACF are identified:
Fragments in correctly predicted training chemicals – 13.64%
Fragments in non-correctly predicted training chemicals – 2.27%
Fragments not present in the training chemicals – 84.09%
CONCLUSION:
The chemical is out of the interpolation structural space"

Based on the information provided, the Substance does not fall within the applicability domain of the model.

In your comments to the draft decision, you do agree that the Substance is outside the structural domain of the training set but you consider that significant bioaccumulation of the Substance is not expected due to hindered uptake based on average maximum diameter (DiamMaxAverage) of the molecule of 18.988 Angstrom (Å).

ECHA Guidance R.7.8.5. explains that there is no scientific basis to define molecular characteristics that would render a substance unlikely to cross biological membranes. In this context, the indicators used for low likelihood of a high bioaccumulation potential (ECHA Guidance R.11, Figure R.11-4) must be considered, including:

- physico-chemical indicators of hindered uptake due to large molecular size (*e.g.* DiamMaxAverage > 17.4 Å and MW > 1100 or MML > 4.3 nm) or high octanol-water partition coefficient (log K_{ow} > 10) or low potential for mass storage (octanol solubility (mg/L) < 0.002 x MW), and
- supporting experimental evidence of hindered uptake (no chronic toxicity for mammals and birds, no chronic ecotoxicity, no uptake in mammalian toxicokinetic studies, very low uptake after chronic exposure).

In your comments to the draft decision you provide the following:

- physico-chemical indicators which you consider supportive of hindered uptake (DiamMaxAverage of 18.988 Å);
- no arguments to support your claim of hindered uptake based on toxicokinetic study(ies) in rats/mice/other, chronic toxicity studies in rodents, a long-term toxicity study in aquatic invertebrates/fish.

Available physico-chemical indicators on the Substance support that the Substance is unlikely to cross biological membranes. However, you have not provided any justification regarding toxicokinetic information or chronic toxicity studies supporting the hindered uptake arguments. Based on the information provided in the dossier, there is no toxicokinetic study provided for the Substance to support your arguments on hindered uptake. Furthermore, you have submitted an OECD Guideline 422 repeated dose toxicity study in your dossier where you indicate the following treatment-related effects: increased liver weights at doses from 100 to 1000 mg/kg bw/d and minimal hepatocellular hypertrophy in a dose-dependent manner at doses of 300 and 1000 mg/kg bw/d. You have not considered these findings in your claim of hindered uptake.

Therefore, your conclusion of the B/vB properties is not reliable and the chemical safety assessment (CSA) indicates the need for further investigation of the PBT/vPvB properties.

The selection of the requested tests and the tests design are addressed respectively in Appendices B.2-B.5.

2. Omitting information releated to PBT properties based on exposure considerations

In the comments to the draft decision, you indicate an intention to omit further persistency testing (Appendices B.2-B.5) based on exposure considerations. You claim that strictly controlled conditions apply for the Substance.

According to Annex XIII section 2.1 additional information to assess PBT properties may be omitted if the process and use conditions of the substance meet the conditions as specified in Section 3.2(b) of Annex XI, demonstrating and documenting for all relevant scenarios that throughout the life cycle strictly controlled conditions as set out in Article 18(4)(a) to (f) apply.

Article 18(4) requires, amongst other, that the substance is rigorously contained by technical means during its whole lifecycle including manufacture, purification, cleaning and maintenance of equipment, sampling, analysis, loading and unloading of equipment or vessels, waste disposal or purification and storage. To be able to confirm and document the rigorous containment of the substance, the registrant should characterise (by a description or a flow chart) the process conditions and the equipment used during the whole life-cycle of the substance (ECHA Guidance on Intermediates, Section 2.1.1).

In your comments to the draft decision you provide a general process description for the Substance. You describe that the Substance is used as a catalyst only and strictly controlled conditions (SCC) are met. Furthermore you state that based on the physicochemical properties and the closed process, it is not released to the environment. Lastly you explain that no release is confirmed by analytical determination of "Fluoric atoms" in the a) wastewater and b) in the final product. You indicate your intentions to submit this analytical information in a dossier update.

You have not provided a description or a flow chart that would characterise all specific activities performed on the site concerning the handling and use of the Substance. Furthermore, you have not provided a brief description of the process conditions and the equipment used to demonstrate how the Substance is rigorously contained by technical means during the whole life-cycle of the Substance (e.g. cleaning and maintenance of equipment, loading and unloading of equipment etc.).

Therefore, the information provided in your comments is not sufficient for ECHA to make an assessment if all requirements of Article 18(4) are met. Please note that this decision does not take into account updates of the registration dossiers after the date on which you were notified of the draft decision according to Article 50(1) of REACH (see section 5.4. of ECHA's Practical Guide "How to act in Dossier Evaluation"). You remain responsible for complying with this decision by the set deadline.

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

1. Long-term toxicity testing on aquatic invertebrates

Short-term toxicity testing on aquatic invertebrates is an information requirement under Annex VII to REACH (Section 9.1.1.). Long-term toxicity testing on aquatic invertebrates must be considered (Section 9.1.1., Column 2) if the substance is poorly water soluble.

You have provided an OECD TG 202 study ([redacted] 2009) but no information on long-term toxicity on aquatic invertebrates for the Substance.

We have assessed this information and identified the following issue:

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

In the provided OECD TG 105 study (2008), the saturation concentration of the Substance in water was determined to be <0.1 mg/L.

Therefore, the Substance is poorly water soluble and information on long-term toxicity on aquatic invertebrates must be provided.

In the comments to the draft decision, you acknowledge that the Substance is poorly soluble and agree to perform the requested study.

Study design

The Substance is difficult to test due to the low water solubility (<0.1 mg/L, as indicated above) and adsorptive properties (logKow >6.5 based on OECD 117 study). OECD TG 211 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified and documented. 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 211. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solutions.

2. 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 according to OECD TG 201 ([redacted] 2009).

We have assessed this information and identified the following issues:

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 specifications must be met:

- the results of algal biomass determined in each flask at least daily during the test period are reported in a tabular form;
- 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%;
- 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* / *Desmodesmus subspicatus*].
- a reliable analytical method for the quantification of the test material in the test solutions with reported specificity, recovery efficiency, precision, limits of determination (*i.e.* detection and quantification) and working range must be available. Alternatively, a justification why the analytical monitoring of exposure concentrations is not technically feasible must be provided;
- if the test material is tested at the saturation concentration, evidence must be provided that all reasonable efforts have been taken to achieve a saturation concentration, which include:
  1) an analytical method validation report demonstrating that the analytical method is appropriate, and
  2) information on the saturation concentrations of the test material in water and in the test solution, and
  3) a description of the method used to prepare the test solution, and
  4) the results of a preliminary experiment demonstrating that the test solution preparation method is adequate to maximize the concentration of the test material in solution;
- a justification for, or validation of, the separation technique is provided.

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

- tabulated data on the algal biomass determined daily for each treatment group and control are not reported;
- the mean coefficient of variation for section-by-section specific growth in the control was not reported;
- the coefficient of variation of average specific growth rates during the whole test period in replicate control cultures was not reported;
- no analytical monitoring of exposure was conducted and you did not provide justification why analytical monitoring of exposure concentrations was not technically feasible;
- you indicate that saturated test solution was generated for the test but you did not provide evidence that all reasonable efforts were taken to achieve a saturation concentration (e.g. results of a preliminary experiment demonstrating that the test solution preparation method is adequate to maximize the concentration of the test material in solution);
- you indicate that undissolved test substance was removed by filtration (poresize 0.2 µm) but you did not provide a justification for, or validation of, the separation technique. Use of filters can cause losses of the substance when preparing the test solution.

Based on the above,

- you have not demonstrated that all the validity criteria of OECD TG 201 are met, and because the tabulated data on the algal biomass is not provided in the dossier, the validity of the study is not confirmed;
- there are critical methodological deficiencies resulting in rejection of the study results.

More specifically, you have not performed analytical monitoring of the exposure concentrations to demonstrate stability of the Substance in the test media;

- the Substance is difficult to test (based on indicator values given in Table 2 of OECD GD 23: water solubility <100 mg/L and logKow >4) and there are critical methodological deficiencies resulting in rejection of the study results. More specifically, you have not demonstrated that the methods to prepare the test solutions maximised the concentration of the test material in solution, and that filtration did not cause losses of the test material. Considering these deficiencies and the lack of analytical verification of exposure concentrations, there is no evidence that the test material has been sufficiently solubilised in the solutions. Therefore, the effects, or absence of effects, observed in the study may have been underestimated.

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

On this basis, the information requirement is not fulfilled.

In the comments to the draft decision, you acknowledge the methodological deficiencies listed above and agree to perform the requested study.

Study design

OECD TG 201 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 Appendix A.1.

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

1. Long-term toxicity testing on fish

Short-term toxicity testing on fish is an information requirement under Annex VIII to REACH (Section 9.1.3.). Long-term toxicity testing on fish must be considered (Section 9.1.3., Column 2) if the substance is poorly water soluble.

You have provided an OECD TG 203 study ([redacted] 2009) but no information on long-term toxicity on fish for the Substance.

We have assessed this information and identified the following issue:

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

As already explained under Section A.1, the Substance is poorly water soluble and therefore information on long-term toxicity on fish must be provided.

In your comments to the draft decision you express the intention to adapt the required information. You mention the necessary revision of your chemical safety assessment, referring to possible sequential testing, the provision in Annex IX, Section 9.1, Column 2 of REACH, and preliminary observations on release to the environment.

In response, regarding the necessity to provide information on long-term toxicity on fish besides other information related to the aquatic compartment, we refer you to our above reasons for why ECHA considers this a requirement already at Annex VIII.

Further, we point out that the provision in Annex IX, Section 9.1, Column 2 of REACH does not allow omitting the required information. By contrast to what appears to be your interpretation, this provision must be interpreted as meaning that registrants are required to submit information on a further study than the information mentioned in Column 1 of Annex IX, Section 9.1, if the chemical safety assessment according to Annex I indicates that it is necessary to investigate the effects of a substance on aquatic organisms beyond what the information mentioned in Column 1 can provide (see the Decision of the Board of Appeal in case A-011-2018).

As far as you finally indicate exposure based considerations, ECHA points out that the Annex XI Section 3.1 does not allow waiving of the information required under Annex VIII, Section 9.1.3 of REACH. Annex XI Section 3.1 stipulates that only the information required in Sections 8.6 and 8.7 of Annex VIII and in accordance with Annex IX and Annex X may be omitted based on the exposure scenario(s) developed in the Chemical Safety Report.

In particular, the information on aquatic toxicity is needed for C&L, PBT assessment and risk assessment (PNEC derivation), and for $PNEC_{aquatic}$ derivation information on species from at least three trophic levels is necessary. As described above, the short-term tests does not give a true measure of toxicity for poorly soluble substances and therefore the long-term tests on daphnia and fish required for hazard assessment of the Substance. Without the information on long-term toxicity to fish a reliable $PNEC_{aquatic}$ cannot be derived (see also the pertinent condition set out in Annex XI, Section 3.2(a)(ii) of REACH).

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 Appendix A.1.

2. 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).

As explained in the Appendix on Reasons common to several requests, Section 1, the Substance is a potential PBT/vPvB substance and the chemical safety assessment (CSA) indicates the need for further degradation investigation.

In the comments to the draft decision, you indicate the intention to adapt this information requirement according to column 2 of Annex IX, Section 9.2.1.2, of the REACH Regulation, claiming that the Substance is highly insoluble in water and that thus surface water is not a compartment of concern. In your comments on the draft decision you further indicate that no further persistency testing is needed because strictly controlled conditions are met.

We have assessed this information and identified the following issues:

First, under Section 9.2.1.2., Column 2, Annex IX to REACH, the study may be omitted if the substance is highly insoluble in water. ECHA Guidance R.11.4.1.1.1 further describes that when water solubility of a substance is very low (typically below 1 µg/L), testing on sediment (OECD TG 308) and/or soil (OECD TG 307) may be needed instead of a pelagic test (OECD TG 309) for the purpose of PBT assessment if aquatic simulation degradation testing is not technically feasible due to analytical limitations and low solubility of the test substance.

The water solubility study provided in your dossier indicates that the water solubility of the Substance is below 0.1 mg/L (OECD TG 105). You further claim in the comments to the draft decision that a water solubility of 2,407E-007 mg/L was predicted using the QSAR model WSKOW v1.42 (EPISUITE v4.11). On this basis, you consider that water is not the compartment of concern for the environmental fate and distribution of the Substance, also considering the calculated logKoc value of 7.4. Based on this estimation, the substance is expected to adsorb to the solid particles within the phase.

While the new information on water solubility based on QSAR estimation indeed indicates that the water solubility is well below 1 µg/L and therefore surface water study may not be feasible to conduct, we cannot confirm on the basis of the available information that the water solubilty result is reliable: no QMRF and QPRF have been provided for the prediction.

Based on the available information, you have not demonstrated that the Substance is highly insoluble and that the aquatic compartment is not relevant for testing, and therefore substantiate the adaptation under Section 9.2.1.2., Column 2, Annex IX to REACH.

Furthermore, the aquatic compartment is considered to be a relevant environmental compartment by default because it receives significant amount of emissions directly or indirectly, and transports/distributes the substance through e.g. deposition and run-off. This is the case unless, based on the fate and release(s) of the substance, it is considered that the water compartment is not a relevant environmental compartment at all.

Second, as explained in the Appendix on Reasons common to several requests, Section 2, the information you provided related to the exposure does not allow ECHA to conclude on strictly controlled conditions and therefore a possible adaptation on this basis.

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.).

3. Soil simulation testing

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

As explained in the Appendix on Reasons common to several requests, Section 1, the Substance is a potential PBT/vPvB substance and the chemical safety assessment (CSA) indicates the need for further degradation investigation.

In your comments on the draft decision you indicate that according to Annex IX 9.2.1.3. column 2, the study need not be conducted if direct and indirect exposure of soil is unlikely and no further persistency testing is needed because strictly controlled conditions are met.

However, the exposure related information provided in the comments on the draft decision

does not allow ECHA to conclude on strictly controlled conditions, as explained in the Appendix on Reasons common to several requests, Section 2.

The Substance has low water solubility <0.1 mg/L, high partition coefficient (log Kow >6.5) and high adsorption coefficient (log Koc of 7.4), indicating high potential to adsorb to soil and sediment. Therefore soil and sediment are also relevant compartments for degradation testing.

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.

In accordance with the specifications of OECD TG 307, you must perform the test using at least four soils representing a range of relevant soils (*i.e.* varying in their organic content, pH, clay content and microbial biomass).

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 307.

In accordance with the specifications of OECD TG 307, non-extractable residues (NER) must be quantified. The reporting of results must include a scientific justification of the used extraction procedures and solvents (ECHA Guidance R.7.9.4.1.). 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 307; ECHA Guidance R.11.4.1.).

4. Sediment simulation testing

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

As explained in the Appendix on Reasons common to several requests, Section 1, the Substance is a potential PBT/vPvB substance and the chemical safety assessment (CSA) indicates the need for further degradation investigation.

In your comments on the draft decision you indicate that no further persistency testing is needed because strictly controlled conditions are met.

However, the exposure related information provided in the comments on the draft decision

does not allow ECHA to conclude on strictly controlled conditions, as explained in the Appendix on Reasons common to several requests, Section 2.

The Substance has low water solubility <0.1 mg/L, high partition coefficient (log Kow >6.5) and high adsorption coefficient (log Koc of 7.4), indicating high potential to adsorb to soil and sediment. Therefore soil and sediment are also relevant compartments for degradation testing.

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.

In accordance with the specifications of OECD TG 308, you must perform the test using two sediments. One sediment should have a high organic carbon content (2.5-7.5%) and a fine texture, the other sediment should have a low organic carbon content (0.5-2.5%) and a coarse texture. If the Substance may also reach marine waters, at least one of the water-sediment systems should be of marine origin.

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 308.

In accordance with the specifications of OECD TG 308, non-extractable residues (NER) must be quantified. The reporting of results must include a scientific justification of the used extraction procedures and solvents (ECHA Guidance R.7.9.4.1.). 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 308; ECHA Guidance R.11.4.1.).

5. Identification of 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).

As explained in the Appendix on Reasons common to several requests, Section 1, the Substance is a potential PBT/vPvB substance and the chemical safety assessment (CSA) indicates the need for further degradation investigation.

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

In your comments on the draft decision you indicate that no further persistency testing is needed because strictly controlled conditions are met.

However, the exposure related information provided in the comments on the draft decision does not allow ECHA to conclude on strictly controlled conditions, as explained in the Appendix on Reasons common to several requests, Section 2.

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 studies requested in Appendices B.2-B.4 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 studies according to OECD TG 307-309 (Appendices B.2-B.4) must be conducted at 12°C and at test material application rate reflecting realistic assumptions (OECD TGs 307 and 308) or at a test concentration < 100 µg/L (OECD TG 309). 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) and at higher application rate (e.g. 10 times, OECD TG 307-308; or > 100 µg/L, OECD TG 309).

6. 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, and Annex XIII, Section 2.1 to REACH).

As explained in the Appendix on Reasons common to several requests, the Substance is a potential PBT/vPvB substance and the chemical safety assessment (CSA) indicates the need for further investigation on bioaccumulation in aquatic species.

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).

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

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 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.

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

A. Strategy for the PBT/vPvB assessment

Under Annex XIII, the information must be based on data obtained under conditions relevant for the PBT/vPvB assessment. You must assess the PBT properties of each relevant constituent of the Substance present in concentrations at or above 0.1% (w/w) and of all relevant transformation/degradation products. Alternatively, you would have to justify why you consider these not relevant 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.

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 11 December 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).

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[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)[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.

Guidance on intermediates and strictly controlled conditions

[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] https://echa.europa.eu/documents/10162/13630/raaf_uvcb_report_en.pdf/3f79684d-07a5-e439-16c3-d2c8da96a316

Guidance on intermediates (version 2, December 2010), referred to as ECHA Guidance on Intermediates.

OECD Guidance documents[7]
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.

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

Appendix G: 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]

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.