~~Confidential~~

Helsinki, 12 November 2021

Addressees
Registrant(s) of JS_272-599-9 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
16/02/2021

Registered substance subject to this decision ("the Substance")
Substance name: 1-phenyldecane-1,3-dione
EC number: 272-599-9
CAS number: 68892-13-7

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 ***20 May 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. 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)

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

1. Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.; test method: EU B.63/OECD TG 421 or EU B.64/OECD TG 422) by oral route, in rats

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

3. 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.

4. 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.

5. 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.

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

method: using an appropriate test method

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

- Appendices entitled "Reasons to request information required under Annex VII of REACH" and "Reasons to request information required under Annex 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 Annex VII to REACH, for registration at 1-10 tonnes per year (tpa), or as a transported isolated intermediate in quantity above 1000 tpa;
- 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 are necessary for the PBT assessment. However, to determine the testing needed to reach the conclusion on the persistency 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. 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 results from two short-term tests for invertebrate toxicity, as follows:

- EU Method C.2 (Acute Toxicity for Daphnia, 48h exposure) [redacted] 1998) and,
- EU Method C.2 (Acute Toxicity for Daphnia, 24h exposure) ([redacted] 1992).

However, you have provided no information on long-term toxicity on aquatic invertebrates for the Substance.

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

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).

You have provided information which indicates that the water solubility of the Substance is 387 µg/L (OECD TG 105/EU Method A.6; I[redacted] 2017)

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 agree to perform the requested study.

Study design

The Substance is difficult to test due to the low water solubility (387 µg/L), adsorptive properties (based on Log Kow 4.2 to 6.5 (OECD TG 117) and Koc >4.5) and rapid hydrolysis (half-life of <10 hours at 20°C and pH 7).

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. Considering that the Substance is rapidly hydrolysable it is important to take into account the relative toxicities of the parent test chemical and degradation products to determine the appropriate test design and test media preparation methods for the Substance.

Taking the rapid hydrolysis, but also low solubility and adsorptivity, of the parent substance into account it may be difficult to achieve and maintain the desired exposure concentrations of the Substance or its hydrolysis products. Therefore, you must monitor the test concentration(s) of the Substance, or its hydrolysis products, 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, or the hydrolysis product, in the test solutions.

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

1. Screening for reproductive/developmental toxicity

A Screening for reproductive/developmental toxicity study (test method: EU B.63/OECD TG 421 or EU B.64/OECD TG 422) is a standard information requirement under Annex VIII to REACH, if there is no evidence from analogue substances, QSAR or *in vitro* methods that the Substance may be a developmental toxicant. There is no information available in your dossier indicating that your Substance may be a developmental toxicant.

You have provided a Screening for reproductive/developmental toxicity according to the OECD TG 422 (GLP; [redacted], 2016) conducted with the Substance.

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

To be considered compliant and to generate information concerning the effects of the Substance on male and female reproductive performance, the study has to meet the requirements of EU B.63/OECD TG 421 or EU B.64/OECD TG 422. The OECD TG 422 specifies that "*It is recommended that, wherever possible, the use of an aqueous solution/suspension be considered first, followed by consideration of a solution/suspension in oil (e.g. corn oil) and then by possible solution in other vehicles. For non-aqueous vehicles the toxic characteristics of the vehicle should be known*." The ECHA Guidance R.7a, Section R.7.6.2.3.2 states that the vehicle should not cause any adverse effects itself as that may interfere with the interpretation of the results and may invalidate the study.

In addition, the study has to be adequate for the purpose of classification and labelling and/or risk assessment as stated in Annex I Section 1.0.1. of REACH, *"the objectives of the human health hazard assessment shall be to determine the classification of a substance in accordance with Regulation (EC) No 1272/2008; and to derive levels of exposure to the substance above which humans should not be exposed"*.

With your dossier and your comments, you submitted the following information:

Related to the vehicle effect(s), in the provided Screening for reproductive/developmental toxicity study, the pre-birth loss was within the range of 16.5 -20.7% in the control, mid and high dose group. You reported that it was higher than the mean historical control data (8.1%; no ranges or other details on historical data provided). You also indicated that the mean duration of gestation for all groups including control was slightly higher than the mean historical control data. For the findings in pre-birth loss and in mean duration of gestation, you indicated that "*A potential effect of the vehicle could not be excluded*.".

In your comments to the draft decision, you explain that the "vehicle effect" is expected due to the high volume of corn oil (10 ml/kg) used for dosing which is considered nowadays as too high and causing discomfort and possibly confounding findings.

Furthermore, ECHA observed that relevant to the classification and labelling and/or risk assessment, the following reproductive parameters were reported (full study report provided) for control, low, mid and high dose levels, respectively:

- The mean number of corpora lutea (CL)/dam was 12.5, 12.9, 11.7 and 10.6;
- The number of implantation sites/dam was 11.9, 12.8, 10.3, and 9.6; and
- The number of pups born/dam was 10.6, 12, 8.9, and 7.3.

In addition to above, the study showed potential test item related effects on survival and weight gain of the pups after birth as well as effects on thyroid (absolute and relative weights, histology) in all dose groups.

ECHA considers that the information obtained from this study does not meet the above guideline requirements, and in particular does not consider it adequate for the purpose of classification and labelling and/or risk assessment. This is for the following reasons:

First, the vehicle used in the study caused effects which interfere with the interpretation of the study. You reported that pre-birth loss (number of implantations – number of pups born/ number of implantations x100) was within the range of 16.5-20.7% in the control, mid and high dose group compared with the historical control mean of 8.1% (no ranges or other details provided for this value) and that the mean duration of gestation for all groups including control was slightly higher than the mean historical control data. In addition, the control group receiving the vehicle only showed clinical signs such as hypersalivation, abnormal foraging, pedalling and straub tail, as well as reduced food consumption. You indicated that "*A potential effect of the vehicle could not be excluded*" and therefore, the high pre-birth loss could be due to the "vehicle effect". In your comments to the draft decision, you agree that the findings in the control group with respect to pre-birth loss and duration of gestation render interpretation of the study results more complicated. You explain that the effects were expected due to the high volume of the oily vehicle (corn oil) used in the study (10 mL/kg). ECHA notes that the OECD TG 422 specifies that "*For non-aqueous vehicles the toxic characteristics of the vehicle should be known*". At the time (2016) when the provided study was conducted, the potential effects of the oily vehicle were known and the OECD test guidelines for the reproductive toxicity that were in place generally specified the maximum volume for oily vehicles (such as corn oil) as 0.4 mL/100 g (OECD TG 414 versions 2001, 2018 and OECD TG 443 versions 2011, 2018). Therefore, while the selection of the version of the OECD TG 422 adopted in 1996 to conduct the study was a valid choice, the potential toxic characteristics of the vehicle should have been considered in the light of the scientific knowledge available on the matter, and a volume that is not expected to cause any adverse effects should have been selected. As a result, the volume of vehicle used is not acceptable.

Second, the reported findings indicate a likely hazard for sexual function and fertility that may be relevant for the classification and labelling and/or risk assessment of the Substance. There were dose dependent reductions in number of CLs, in implantation sites and pups born in mid dose and high dose groups when compared to controls. Furthermore, when the number of CL was compared to the number of pups born (number of CL – number of pups born), there were higher values for the numerical differences, at the mid (2.8) and high dose (3.3) compared with the control (1.9) and low dose (0.9). Furthermore, effects were reported on offspring development as well on thyroid which function is closely linked to the sexual function and fertility. Therefore, there is a concern for sexual function and fertility, due to lower mean value of CL, implantation sites, and also due to lower mean value of pups born compared to the number of CL in the treated group(s) when compared to controls.

In your comments to the draft decision, you disagree with the severity of the effects and consider that the effects observed in the study are due to the (volume of) vehicle used and dependent of the wellbeing of the dams considering the gavage volume used, which might well have impacted the results. However, the findings do not support the conclusion that the effects on reproduction would be solely due to the vehicle as 1) there seem to be dose-related changes such as less than control pups born at MD and HD (8.9 and 7.3 respectively vs 10.6 in control), 2) in the high dose group, the post-implantation loss was higher than controls (24% HD vs 11 % in controls) and the viability index lower than controls (77.3% HD vs 100% in controls), and 3) the lower mean body weights for both sexes at low, mid and high dose offspring on post-natal days 1 and 4 were reported as test item-related. If the effects were expected solely to represent the "vehicle effect", there should be no difference to the control in the test groups as in the provided study all groups received same 10 mL/kg/day. You argue that the effects reported in the thyroid are concluded as adaptive due to the changes also reported in the liver. While it is known that the induction of the metabolic enzymes in the liver

may lead to the increase in thyroid hormone metabolism, resulting in reduced circulating T4, increased TSH and stimulation of thyroid growth manifested by follicular cell hypertrophy[2], you have not provided information on the serum levels of T4 or TSH, liver enzyme induction or any other information to allow conclusion on the adaptive nature of the thyroid changes.

Third, the adequacy of the study for the classification and labelling and/or risk assessment is compromised due to a concurrent control group with results that deviates from the provided information on mean historical controls. The reported high pre-birth loss (and the mean duration of gestation) in the control group may mask a potential effect at dose groups, making conclusive assessment of the no observed adverse effect level (NOAEL), severity of effects as well as dose-response relationship impossible. Furthermore, the reported low number of animals in the control group that completed delivery was only 7 females, compared to 9, 9 and 6 females in the low, mid and high dose, respectively. The low number of control dams completing delivery, together with the indicated potential effect of the vehicle in reproductive parameters further hinders determination of the severity of treatment related effects. Therefore, the derivation of levels of exposure to the Substance above which humans should not be exposed (based on NOAEL values) and a conclusion on if the findings warrant classification for reproductive toxicity is not possible, and the study is not adequate for the purpose of classification and labelling and/or risk assessment.

Based on above, the reproductive toxicity reported in the vehicle controls interferes with the interpretation of the results rendering the study inadequate for the purpose of classification and labelling and/or risk assessment. Therefore, the study is not considered compliant, and the information requirement is not fulfilled.

Study design

A study according to the test method EU B.63/OECD TG 421 or EU B.64/OECD TG 422 must be performed in rats with oral[3] administration of the Substance.

It is noted that the current OECD TG 422 (adopted July 2016) has a higher statistical power (12-13 females per dose group) and, prolonged post-natal exposure period up to PND 13, measurement of serum T4 levels on PND 4 and 13 from the pups and on the termination from all dams and males. Therefore, the currently requested study, with higher statistical power, is expected to clarify the observed effects/concerns on sexual function and fertility, pup toxicity and thyroid toxicity. In consequence it will allow to determine the potential classification for reproductive toxicity and more reliable setting of NOAEL values for general toxicity as well as reproductive toxicity (sexual function and fertility/developmental toxicity/lactation).

2. 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] 2017) 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

[2] ECHA/EFSA Guidance for the identification of endocrine disruptors. EFSA Journal 2018;16(6):5311
[3] ECHA Guidance R.7a, Section R.7.6.2.3.2.

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 information on long-term toxicity on fish must be provided.

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

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 in Appendix A.1, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design' under Appendix A.1.

3. 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).

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.). 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/ EU Method C.4-C), and;
- it is potentially bioaccumulative or very bioaccumulative (B/vB) as:
  - it has a high potential to partition to lipid storage (e.g. log Kow > 4.5)

Your registration dossier provides the following:

- The Substance is not readily biodegradable (30% degradation after 28 days in EU Method C.4-C (Determination of the "Ready" Biodegradability - Carbon Dioxide Evolution Test; [redacted], 1998) equivalent to 301B (Modified Sturm);
- The Substance has a high potential to partition to lipid storage based on the Log Kow of 4.2 to 6.5 (OECD TG 117/EU Method A.24; I. [redacted] 2017)

The information above indicates that the Substance is not readily biodegradable and hence is potentially P/vP. The Substance has a Kow >4.5 and and hence is also potentially B/vB. This indicates that the Substance is a potential PBT/vPvB substance.

In the PBT assessment of the Substance in Section 2.3 of IUCLID you consider that the Substance is not persistent or very persistent based on the rapid hydrolysis of the Substance, and do not consider a need for further degradation testing.

ECHA Guidance R.11.4.1.1.1 states that concern for P/vP cannot be removed by significant and substantial loss of the parent substance by hydrolysis alone. As abiotic degradation is only primary degradation, careful consideration needs to be given to the potential formation

of stable degradation products with PBT/vPvB properties.

In your PBT assessment of the Substance you concluded that: '*The substance is not persistent in the environment from an abiotic point of view. The hydrolysis of the test item was determined in an experimental key study (Klimisch validity one, according to recognised guidelines). The DT50 of the test item has been measured at less than 10h at 20°C and pH=7'* In your assessment, you have focused only on abiotic degradation, which is only primary degradation, and you have not addressed biotic degradation and the potential formation of stable degradation products with PBT/vPvB properties.

You have not considered the fact that abiotic degradation is only primary degradation, and you have not addressed the potential formation of stable degradation products with PBT/vPvB properties.

Therefore, you have not demonstrated that the CSA does not indicate the need for further biotic degradation testing and further degradation testing is required.

In your comments to the draft decision you acknowledge that further testing is needed to conclude on P/vP for the Substance. However, you propose a testing strategy before considering simulation testing. You propose to 1) start with a new hydrolysis study andassess the hydrolysis products for their P/vP, B/vB and T properties using QSAR models and literature; and 2) perform an enhanced ready biodegradability test over 60 days. If these steps do not allow you to conclude on non-PBT/vPvB, you indicate that you may then consider performing the requested simulation testing but you will not investigate the degradation of the Substance in all compartments (water, sediment and soil). You indicate that the surface water study (OECD TG 309) should be omitted based on the fact that the substance has a water solubility below 1 mg/L, a log Koc above 4.5, and is hydrolysable.

We have assessed the information provided in your comments to the draft decision and identified the following issues:

A) In regard to additional abiotic and enhanced biodegradability screening testing:
Your comments on the draft decision do not provide any new data on the biodegradation of the Substance. Your proposed strategy relies essentially on data which is yet to be generated, therefore it cannot yet contribute to conclusions on the compliance of the registration dossier. In proceeding with further degradation testing you should also consult Appendix D (A) which provides general guidance on how to proceed with P/vP testing.

<u>B) In regard to omitting the surface water study:</u>
Annex XI Section 2 allows for testing for a specific endpoint to be omitted if it is technically not possible to conduct the study as a consequence of the properties of the substance. ECHA Guidance R.11.4.1.1.1 states that the OECD TG 309 is the preferred test to start persistency assessment and if another test is selected for further testing, this should be justified, based on the following:

- <u>Aquatic testing is not technically feasible</u> i.e. it can be demonstrated that it has been impossible, with allocation of reasonable efforts, to develop suitable analytical methods and other test procedures to accomplish testing in surface water so that reliable results can be generated. Appropriate analytical methods should have a suitable sensitivity and be able to detect relevant changes in concentration (including that of metabolites). Generally, 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);
- <u>The aquatic compartment is not considered relevant at all, and there are compartment specific concerns for the sediment and soil compartments, including indications from</u>

available data (e.g. literature) suggesting that persistence is likely to occur in a different environmental compartment (i.e. in soil or sediment).

You have not provided an adaptation under Annex XI Section 2 to omit the surface water simulation study. You claim in your comments on the draft decision that the surface water simulation test is not needed because:

- the Substance has a water solubility below 1 mg/L and a log Koc above 4.5, indicating low solubility in water and high absorptivity. Further, due to the fact the Substance is hydrolysable you indicate that the surface water compartment may not represent the worst case scenario for persistence, and that testing in soil and sediment is preferred;

We have assessed your comments and note the following issues:

- Based on the information in the dossier the water solubility of the Substance is 387 µg/L which indicates that the surface water compartment is relevant for this Substance and that conduct of the surface water simulation study is technically feasible.
- The aquatic compartment is considered to be a relevant environmental compartment since, by default, the water compartment receives significant amount of emissions directly or indirectly, and transports/distributes the substance through e.g. deposition and run-off (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). Once entering water, a substance may stay there for very long time and be spread over long distances before it reaches other environmental compartments (via environmental transport, partitioning and distribution processes) such as sediments or (via air) the soil compartment. In addition, particularly for lower water solubility substances which tend to be adsorptive, the OECD TG 309 (with a default concentration of suspended solids of 15 mg dw/L) minimizes potential NER formation. If NER is formed at significant levels in the OECD TGs 307 and 308 studies, this can be difficult to interpret and compare with degradation half-lives criteria of Annex XIII to the REACH Regulation (ECHA Guidance R.11.4.1.1.1). For these reasons the OECD TG 309 is relevant for the Substance and you have not demonstrated in your comments on the draft decision that the aquatic compartment is not a relevant compartment at all.
- As stated in Appendix D of this decision you are advised to consider the intrinsic properties of the Substance, and its identified uses and release patterns, when determining the sequence of simulation degradation testing. You may therefore choose to conduct simulation studies starting with the worst case scenarios for persistence, with appropriate justifications.

To conclude, based on the data in the dossier and the information from your comments on the draft decision, ECHA would not consider an adaptation under Annex XI Section 2 acceptable.

Study design

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

You must perform the test, by following the pelagic test option with natural surface water containing approximately 15 mg dw/L of suspended solids (acceptable concentration between 10 and 20 mg dw/L) (ECHA Guidance R.11.4.1.1.3.).

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

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

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

4. Soil simulation testing

5. 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).

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.). 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 [select as appropriate but must indicate both P and B concern]:

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

As described in Appendix B.3, the information provided indicates that the Substance is a potential PBT/vPvB substance.

Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation.

The Substance has low water solubility (387 µg/L), high partition coefficient (log Kow 4.2 to 6.5) and high adsorption coefficient (log Koc of 9.36 to 12.89), indicating high potential to adsorb to soil and sediments. Therefore soil and sediment are also relevant compartments for degradation testing.

You acknowledge in your comments on the draft decision that further testing is needed to conclude on the P/vP properties of the Substance. Further, you note that the soil and sediment

compartments are relevant based on the low water solubility (below 1 mg/L) and high adsorptivity (log Koc above 4.5) of the Substance.

In your comments on the draft decision you propose to generate additional data via screening tests (hydrolysis testing, QSAR/literature review, enhanced biodegradability testing) prior to conducting simulation testing.

As explained above in B.3, this strategy relies essentially on data which is yet to be generated, therefore it cannot yet contribute to conclusions on the compliance of the registration dossier.

Study designs for the soil and sediment simulation tests

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.

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 307-309.

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 and 308; ECHA Guidance R.11.4.1.).

In accordance with the specifications of OECD TG 307 and 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.

Further details on the study designs are provided below for simulation tests on ultimate degradation in soil (OECD TG 307) and sediment (OECD TG 308), respectively.

Soil Simulation Study (OECD TG 307)

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).

Sediment Simulation Study (OECD TG 308)

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.

6. 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 already explained under Section B.3 to B.5, the Substance is a potential PBT/vPvB substance. Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation.

You have provided no information on the identity of transformation/degradation products for the Substance, or on the PBT/vPvB properties of stable degradation products.

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

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 studies requested under B.3 to B.5 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 (Appendix B.3) must be conducted at 12°C and at a test concentration < 100 µg/L. However, to overcome potential analytical limitations with the identification and quantification of major transformation/degradation products, you may consider running a parallel test at higher temperature (but within the frame provided by the test guideline, *e.g.* 20°C) and at higher application rate (*i.e.* > 100 µg/L).

To determine the degradation rate of the Substance, the requested studies according to OECD TG 307/308 (Appendices B.4 and B.5) must be conducted at 12°C and at a test material application rate reflecting realistic assumptions. 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).

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[4].

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[5].

[4] https://echa.europa.eu/practical-guides
[5] 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.

Since your comments on the draft decision referred to further abiotic testing and additional enhanced biodegradability testing for PBT/vPvB assessment, we refer you in particular to the following ECHA guidance:

Regarding further assessment of abiotic degradation: The identification of hydrolysis products is in alignment with ECHA Guidance R11.4.1.1.1 which recommends this should be done in accordance with the recommendations contained in the test guidelines (e.g. OECD TG 111). However, as noted in ECHA Guidance R11.4.1.1.1, concern for P/vP screening cannot be removed by significant and substantial loss of the parent substance by hydrolysis alone. As abiotic degradation is primary degradation, careful consideration needs to be given to the potential formation of stable degradation products with PBT/vPvB properties.

Regarding enhanced ready biodegradability testing: Positive results from enhanced screening tests may be used together with other supporting information to conclude that the substance is not P/vP. However, it is important that the conditions listed in R11.4.1.1.1 are met. If the results are negative, then it is generally not possible to definitively conclude on the persistence or absence of persistence of the substance and further testing will be needed.

ECHA guidance R.7.9.4.1. should be consulted when considering prolongation of ready biodegradability testing. If extension of the test duration results in an adaptation of the micro-organisms this information would not be adequate to conclude on the P/vP properties for the Substance.

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.

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. Environmental testing for substances containing multiple constituents

Your Substance contains multiple constituents and, as indicated in ECHA Guidance R.11 (Section R.11.4.2.2), you are advised to consider the following approaches for persistency, bioaccumulation and aquatic toxicity testing:

- the "known constituents approach" (by assessing specific constituents), or

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

Selection of the appropriate approach must take into account the possibility to characterise the Substance (i.e. knowledge of its constituents and/or fractions and any differences in their properties) and the possibility to isolate or synthesize its relevant constituents and/or fractions.

Appendix E: Procedure

The information requirement for bioaccumulation testing is not addressed in this decision. This may be addressed in a separate decision once the information from the simulation studies (OECD 307, 308, 309) requested in the present decision is provided.

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 16 November 2020.

ECHA notified you of the draft decision and invited you to provide comments. ECHA took into account the comments and has not amended the requests.

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[6] 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)[7]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[8]

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[9]

[6] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[7] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[8] https://echa.europa.eu/documents/10162/13630/raaf_uvcb_report_en.pdf/3f79684d-07a5-e439-16c3-d2c8da96a316
[9] 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.

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.