Helsinki, 18 June 2021

Addressees
Registrants of Di-tert-butyl 3,3,5-trimethylcyclohexylidene diperoxide listed in the last Appendix of this decision

Registered substance subject to this decision (the Substance)
Substance name: Di-tert-butyl 3,3,5-trimethylcyclohexylidene diperoxide
EC number: 229-782-3
CAS number: 6731-36-8

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

DECISION ON SUBSTANCE EVALUATION

Based on Article 46(3) of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below:

Information required to clarify the potential risk related to PBT/vPvB

1. Soil simulation testing (Aerobic and anaerobic transformation in soil, test method: EU C.23/OECD TG 307), on the Substance, specified as follows:

- Under aerobic conditions;
- At a test temperature of 12°C;
- Using a biometer type flask to prevent losses due to aeration of the test flasks;
- Using the ^{14}C radiolabelled Substance with the radiolabel located in the most stable part of the molecule;
- Using a concentration appropriate to also successfully identify and quantify possibly formed transformation and/or degradation products;
- Transformation and/or degradation products must be identified and quantified at every sampling time at a concentration of ≥ 1% w/w, unless reasonably justified otherwise; transformation and/or degradation products of which concentrations are continuously increasing should also be considered; the duration of the test must be at least 6 months;
- The total amount of non-extractable residues (NER) must be quantified and the reporting of results must include a scientific justification of the used extraction procedures and solvents. Characterisation of non-extractable residues (NER) must be carried out;
- The choice of methods, e.g. extraction methods, must be adequately justified and account for the specific properties of the Substance, in particular for its temperature instability;
- A mass balance calculation must be performed;
- Adaptations to the standard testing protocol to cope with specific substance properties must be reasonably and scientifically justified and documented.
- Sterile controls must be included in the test.

Deadlines

Request 1: The requested information must be provided by **25 September 2023**[1].

Conditions to comply with the information requested

To comply with this decision, you must submit the information in an updated registration dossier, by the deadlines indicated above. The information must comply with the IUCLID robust study summary format. You must also attach the full study report for the corresponding study/ies in the corresponding endpoint of IUCLID.

You must update the chemical safety report, where relevant, including any changes to classification and labelling, based on the newly generated information.

You will find the justifications for the requests in this decision in the Appendix/ces entitled ''Reasons to request information to clarify the potential risk'.
You will find the procedural steps followed to reach the adopted decision and some technical guidance detailed in further Appendices.

Appeal

This decision 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.

Approved[2] under the authority of Christel Schilliger-Musset, Director of Hazard Assessment

[1] The final deadline includes the 90-day period addressed in Article 53(1) of REACH and the seven-day period addressed in point 9(d) of the terms and conditions of REACH-IT.
[2] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

Basis for substance evaluation

The objective of substance evaluation under REACH is to allow for the generation of further information on substances suspected of posing a risk to human health or the environment ('potential risk').

ECHA has concluded that further information on the Substance is necessary to enable the evaluating Member State Competent Authority (MSCA) to clarify a potential risk and whether regulatory risk management is required to ensure the safe use of the Substance.

The ECHA decision requesting further information is based on the following:

(1) There is a potential risk to human health or the environment, based on a combination of hazard and exposure information;
(2) Information is necessary to clarify the potential risk identified; and
(3) There is a realistic possibility that the information requested would allow improved risk management measures to be taken.

The Appendices entitled 'Reasons to request information' describe why the requested information are necessary and appropriate.

Appendix A: Reasons to request information to clarify the potential risk related to PBT/vPvB properties

Based on the evaluation of all relevant information submitted on the Substance and other relevant available information, ECHA concludes that further information is required to enable the evaluating Member State competent authority (MSCA) to complete the evaluation of whether the Substance constitutes a risk to the environment.

The evaluating MSCA will subsequently review the information submitted by you and evaluate if further information should be requested in another decision to clarify the concern, according to Article 46(3) of REACH.

1 The potential risk

The identification of a potential risk is based on a combination of exposure and hazard information.

According to information in the registration dossier the Substance is used as polymerization initiator, crosslinking agent or curing agent. Significant exposure to the environment cannot be excluded.

Based on information in the registration dossier as detailed below in section 4, the Substance may be a PBT or vPvB substance as defined in the Annex XIII of REACH.
Based on this exposure and hazard information, there is a potential risk for the environment. As the available information is not sufficient to conclude on potential PBT/vPvB properties, further information is needed, as explained below.

2 The possible risk management measures

If the obtained data and potential other data including REACH standard information to be potentially requested under compliance check are sufficient to confirm the suspected PBT/vPvB properties as defined in Annex XIII to REACH, the evaluating MSCA will assess the need for further regulatory risk management in the form of identification as a substance of very high concern (SVHC) under Article 59 of REACH and subsequent authorisation or restriction of the Substance.

Stricter risk management measures than those currently in place may be required in case the Substance is identified as a substance of very high concern. Consequently, you would have to identify and apply risk management measures to adequately control the risks (Article 14; Annex I, Section 6.5 of REACH).

Furthermore, you would have an obligation to communicate on the presence of the Substance in articles (if > 0.1%) to ECHA according to Article 7 of REACH and to consumers as well as in your supply chain according to Article 33 of REACH.

Depending on the criteria set out in Article 58 of REACH governing the inclusion of substances in Annex XIV, introducing authorisation obligations could follow. A restriction of the Substance could be proposed if the need for further risk management measures was identified.

3 Explanation of the testing strategy

In the first tier of the testing strategy (first decision), simulation testing in surface water (OECD TG 309) was requested in order to determine the biodegradation potential of the Substance. In case this test was not technically feasible or the result of the test did not

allow to conclude that the substance is very persistent according to Annex XIII of REACH, a simulation test on biodegradation in aquatic sediment systems was required (ECHA, 2015).

The study on biodegradation in surface water was shown to be technically not feasible in a preliminary test. Therefore, the simulation test on biodegradation in sediment was conducted. However, major technical problems occured during testing and the results received from this test do not allow a conclusion on persistence (ECHA, 2017) (see section 4). Therefore, further testing on persistence is required.

Technical problems observed in the former studies as well as considerations on concern for specific compartments must be taken into account when choosing the compartment for a new biodegradation test. In the opinion of the evaluating MSCA the soil compartment is an adequate choice regarding both aspects. In addition, this is the only option left to gain data that is essential for the assessment of persistence. It was shown that neither a test on degradation in surface water nor on degradation in sediment were feasible due to the specific properties of the Substance.

The evaluating MSCA expects that technical problems can be avoided or minimised best when a soil simulation test is conducted with the specific conditions set out below.
The soil compartment is also considered relevant in terms of environmental exposure, given the low water solubility of the Substance and its high adsorption potential. In the OECD TG 308 study, a loss from the water phase of the system was observed due to aeration, although the Substance is not volatile[3]. The volatilised substance deposited and was adsorbed to bung and tubing. It is not yet clear whether this behaviour is environmentally relevant or not. If it was, the substance would most probably adsorb to soil similarly as it did to bung and tubing in the OECD TG 308 study.

Therefore, based on both technical- and concern-based aspects, ECHA requests you to conduct soil simulation testing. This request constitutes the second tier in a testing strategy to clarify the PBT/vPvB properties of the Substance. Hence, the evaluating MSCA will review the information you submitted as an outcome of tier 2 of the testing strategy, and evaluate if further information should be requested to clarify the potential risk for PBT/vPvB, as further described below in this section.

ECHA considers that the available information is sufficient to assess if the Substance meets the criteria for very bioaccumulative (vB) according to Annex XIII to REACH, as explained in the sub-chapter "The potential risk identified" below based on the weight of evidence.

The requested information on soil simulation testing will be considered together with the available information in a weight of evidence approach. If this information demonstrates that the Substance does not fullfill the criterion for persistence (P) according to REACH Annex XIII, the assessment can be concluded and no further information will be required. If the requested information on biodegradation shows that the Substance fullfils the criterion for "very persistent" (vP) according to Annex XIII to REACH, the assessment can also be concluded and no further information will be required.

In case the requested information on biodegradation shows that the Substance fullfils the P but not the vP criterion according toAnnex XIII to REACH (120 days < degradation half-life in soil ≤ 180 days), the third tier of the testing strategy is triggered.

[3] Vapour pressure: 0.009 Pa at 20 °C; water solubility: 92 µg/l at 20 °C; calculated Henry's law constant: 18.435 Pa*m³/mol at 12 °C.

Consequently, further information on ecotoxicity (T) is necessary to define if the Substance meets the criteria for PBT under Annex XIII, including assessing whether gaps related to the standard information requirements exist to be requested under compliance check.

In your comments to the draft decision you explained that adsorption is not the main technical issue complicating the study but rather the initial binding and the potential reactivity with other organics in combination with low test concentrations. ECHA acknowledges this comment and has removed the term "high adsorption potential". It is also noted that the test guideline for the soil simulation test (OECD TG 307) requested in this decision does not impose any specific concentration range.

4 The potential risk identified

The Substance is a suspected PBT/vPvB substance.

4.1 Persistence assessment

There is some indication that the Substance hydrolyses in acidic water systems (preliminary tests). Nevertheless, the available information does not allow for derivation of kinetic data. The Substance was observed to be hydrolytically stable at pH 7.

The Substance is not readily biodegradable in two screening tests. The results of an anaerobic non-standard simulation test on water/sediment system are not conclusive.

Following a request in the first substance evaluation decision (ECHA, 2015), preliminary experiments were conducted, which showed major technical problems with a surface water test system according to OECD TG 309. The same study indicated that a water sediment system according to OECD TG 308 would be technically challenging, but feasible. Hence, an OECD TG 308 study on Aerobic Transformation in Aquatic Sediment Systems was conducted as requested by the first decision.

The results showed a fast dissipation of the Substance. Several transformation and/or degradation products and a low percentage of CO_2 were formed, indicating that biodegradation occurred to a certain extent. Significant amounts of the (non-volatile) parent volatilised from the water phase due to aeration of the system. It is not evident whether this substance loss was continuous or not. As trapping was not complete, recoveries were poor. A significant formation of bound residues was observed. Therefore, the results are considered too uncertain to derive quantitative information on biodegradation.

Based on the significant substance loss from the system and the biodegradation observed (even if low), the available information does not allow to conclude on persistence. However, based on the high uncertainty and the low percentage of biodegradation observed, the available information does not allow to conclude on non-persistence either.

Moreover, the guidance requires to examine a potential risk in the remaining compartments (ECHA, 2017). Due to the particularly high uncertainty of the water sediment study, it is not suitable for extrapolation of results into other environmental compartments. Therefore, the available data do not allow a conclusion whether the persistence criterion according to Annex XIII to REACH is fulfilled or not.

4.2 Bioaccumulation assessment

The Substance has a log K_{ow} ≥ 6.5 indicating a high bioaccumulation potential. This is confirmed by available bioconcentration tests using *Cyprinus carpio*. The bioconcentration

study was carried out based on a generally accepted testing protocol and at two different test concentrations. The higher test concentration (0.2 mg/L) is above the recently established water solubility of 93 µg/L and hence, the respective results are not valid.
The lower test concentration (0.02 mg/L) is below the recently derived water solubility of 93 µg/L and therefore, the respective experimental BCF value is considered reliable. The test with the lower test concentration provides a steady state BCF of 5465 L/kg. Therefore, ECHA considers that the available information is sufficient to assess if the Substance meets the B (BCF > 2000) and vB criteria (BCF > 5000) of Annex XIII.

In your comments you refer to a review of the existing bioaccumulation study outlining deficiencies of this study. The available study as well as the submitted review were taken into account in the bioaccumulation assessment by the evaluating MSCA. As explained above, ECHA considers that no further information is needed to assess if the Substance meets the B/vB criteria of Annex XIII. This regulatory assessment is not within the scope of the current decision, but would take place in the process of the identification as a substance of very high concern (SVHC) under Article 59 of REACH, if any.

4.3 Toxicity assessment

Due to an EC_{50} (48h, *Daphnia magna*) of 0.0211 mg/L the Substance is potentially toxic. The available *Daphnia magna* reproduction test with the limit concentration of 12.8 µg/L (arithmethic mean, measured) showed no effects; but the mortality of control parent animals was slightly above the validity criterion described in OECD TG 211 (23% mortality occurred in the control group – validity criterion: ≤20%).

No effects were observed in the acute toxicity studies on fish and in the algae toxicity study. A long-term fish toxicity study is not available.

Based on the available aquatic toxicity data no final conclusion on the T criterion of Annex XIII to REACH can be taken.

The available sediment toxicity test determined a NOEC of 5.1 mg/kg sediment dw. Using the equilibrium partitioning (EqP) model for comparison against the T criterion following the relevant guidance (ECHA, 2017) ($NOEC_{water}=RHO_{susp}*NOEC_{sed}/(K_{susp\text{-}water}*1000)$), the estimated $NOEC_{water}$ is 0.0017 mg/L. This is considered toxic and an indication that the substance could also fulfil the T criterion in a pelagic test.

Based on the available aquatic toxicity data no conclusion on the T criterion of Annex XIII can be made.

In your comments you refer to comments you submitted in the context of a compliance check draft decision (requesting long-term aquatic studies). As the draft decision on substance evaluation does not contain a request for information on toxicity, it has not been amended.

4.4 Summary and overall conclusions on PBT and vPvB Properties

Based on the available data, no conclusion is possible for persistence and toxicity. ECHA considers that the available information is sufficient to assess if the Substance meets the criteria for very bioaccumulative (vB) according to Annex XIII to REACH. The Substance is a possible PBT/vPvB substance.

5 Why new information is needed

As described above, the available data do not allow a conclusion on persistence and

toxicity. Therefore, a definitive conclusion on the PBT/vPvB properties cannot be drawn. Hence, further information on biodegradation of the Substance is required. The overall testing strategy is described in section 3 above.

Consequently, soil simulation testing is requested in this decision to yield results that are suitable for PBT/vPvB assessment. In case the Substance is persistent, but not very persistent in soil according to Annex XIII to REACH, REACH standard data on toxicity to be potentially requested under compliance check is required to conclude on toxicity.

6 Considerations on the test method: Soil simulation testing

As explained above (section 3), the soil compartment is considered relevant for the PBT/vPvB assessment of the Substance. The available information shows that it is not technically feasible to conduct a simulation test in surface water. Furthermore, serious technical problems were observed in the recent sediment study leading to poor recoveries.

Test method and concentrations

The main technical challenge is that the Substance – though not volatile – is lost from the water phase of the system due to aeration and purging. Therefore, aeration of the water phase containing the Substance should be avoided as far as possible. However, in OECD TG 308 and 309 simulation tests aeration of the water phase is necessary during sampling to purge carbon dioxide from the water phase to the traps. This might also purge the substance from the water phase, which would then adsorb to the bung and tubing. Generally, such sampling-related substance loss does not correspond to continuous volatilisation, and therefore it cannot be adequately corrected for.

In contrast to OECD TG 308 and 309 simulation tests, the OECD TG 307 simulation test system does not contain a water phase, so, the problematic aeration of the water phase is avoided. In addition, a biometer type flask instead of a flow-through system must be used in this test to prevent losses due to aeration of the test flasks as far as possible (OECD TG 307). Therefore, the OECD TG 307 is expected to yield environmentally relevant degradation half-lifes.

In your comments to the draft decision you point out that in order to achieve reliable results in the requested study, adaptions to the standard testing protocol might be necessary due to the specific properties of the Substance. ECHA agrees with you and points out that such adaptations are possible if adequately justified and documented. In particular thermal instability must be taken into account when choosing the extraction methods. Nevertheless, the study has to be conducted in compliance with good laboratory practice (GLP, see Article 13(4) of REACH).

You also commented that the low concentration range given in the guidance was a technical challenge in the initially performed simulation studies (OECD TG 309, 308). In reply to your comment it is noted that the test guideline for the soil simulation test (OECD TG 307) requested in this decision does not impose any specific concentration range. Therefore, technically feasible concentrations can be chosen.

You also describe technical challenges regarding the trapping and analytics of volatiles observed in previous studies. ECHA notes that storage conditions may be refined and improved. The OECD TG 307 also allows for minimum aeration of the test flasks. Therefore, it will be less challenging with regard to trapping and analytics of volatiles compared to OECD TG 309 and 308 tests.

Test temperature

Annex XIII to REACH indicates that information used for PBT/vPvB assessment must be obtained under relevant conditions. Therefore, the simulation test must be performed at a temperature of 12°C, the average environmental temperature for the EU (ECHA, 2016).

Performing the test at this temperature is in line with the recommended test conditions of the OECD TG 307. The study must be conducted to obtain a half-life to be compared against the (v)P criterion to clarify the potential PBT/vPvB properties of the Substance.

Identification of transformation and/or degradation products

If the Substance degrades under environmental conditions, it may form transformation and/or degradation products which themselves have potential PBT/vPvB properties.

Currently, the identity of any potential transformation and/or degradation products is unknown. As indicated in REACH Annex XIII and explained in the relevant ECHA Guidance (ECHA, 2017), the identification of PBT/vPvB substances must also take into account the PBT/vPvB properties of relevant transformation and/or degradation products. The identification of transformation and/or degradation products must therefore be included in the requested study.

Primary degradation determination must also be performed. If the ultimate degradation half-life indicates P or vP, then information on primary degradation and transformation and/or degradation products can be used to assess whether the P or vP criterion is fulfilled for the parent substance or whether there are persistent transformation and/or degradation products.

Mass balance and characterisation of NER

Based on the physico-chemical properties of the Substance and the observations from the OECD TG 308 study, formation of non-extractable residues (NER) is expected.

Characterisation of NER needs to be carried out in order to allow for a differentiation of remobilisable and irreversibly bound fractions as explained in the guidance (ECHA, 2017).

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).

As described in the guidance (ECHA, 2017), there is currently no standard concept available for the characterisation of NER. Therefore, in accordance with the guidance, you "*are advised to follow-up the recent and future developments in the field, e.g. via the ECHA website.*" The Background note on 'Options to address NER in regulatory P assessment', published on the ECHA website, provides some suggestions on the further refinement.[4]

In your comments you mention that NER characterisation is challenging and not yet standardised. ECHA acknowledges this and notes that you in your comments agree to characterise NER. ECHA refers to the paper cited above[4] which describes the current state

[4] https://echa.europa.eu/documents/10162/13632/bg_note_addressing_non-extractable_residues.pdf/e88d4fc6-a125-efb4-8278-d58b31a5d342 (accessed 22.12.2020)

of the art on NERs. This paper contains some suggestions on the further refinement.
It is noted that you along with your comments re-submitted a document on read-across/grouping. The evaluating MSCA has already taken the document into account in the current substance evaluation. ECHA deems that this document does not provide sufficient data to assess if the Substance meets the P/vP criteria of Annex XIII to REACH and therefore, further information is requested. ECHA further notes that in your comments you agreed to perform the requested OECD TG 307 study.

A Proposal for Amendment (PfA) was received to add a request for a mass balance calculation. The eMSCA agrees that calculating a mass balance is necessary as it helps to quantify and address concerns relating to possible losses of a substance by absorption or volatilisation from the test system during the test period. It is noted that there were some difficulties with volatilisation/adsorption in other simulation studies with the Substance. Although calculating the mass balance is a principle part of the OECD 307 test guideline, it is not clear that it is a requirement of the test guideline. ECHA therefore agrees to the PfA to add the mass balance calculation as a request and the draft decision was modified accordingly.

Sterile controls

Another PfA suggested to include sterile controls in the test to determine to what extent the test substance decrease is due to biotransformation or to potential abiotic losses (e.g. volatilization, formation of non-extractable residues (NER)). ECHA agrees with the PfA and modified the draft decision accordingly.

In this context, ECHA notes that it is important to ensure that test conditions in the sterile controls and the active test bottles are as equal as possible. A precondition for conclusion on degradation is that other removal processes are not assessed as degradation. With this aim it is necessary to compare processes observed in sterile controls with those observed in the active test bottles under comparable test conditions.

Therefore, other specifications of the sterile control bottles, such as the headspace volume, sampling times, analytical measurements as well as any potential cause of disturbance (such as aeration events) that might affect the distribution of the test substance or that could cause leakage, must be the same as in the active test bottles, to ensure comparability.

The OECD TG 307 includes instructions for a sterile control but does not include specific advice on soil sterilisation methods. The OECD TG 307 refers to two references for soil sterilization methods (OECD, 1993; Stenberg et al., 1996). However, the eMSCA checked these references and found no information on sterilization of soil samples. Therefore, you are advised to consider relevant publicly available information, such as the articles by Lees et al. (2008) and Berns. et al (2018) for technical guidance on soil sterilization methods. Considering the importance of the integrity of the soil to produce meaningful results for comparison to unsterilised conditions, ECHA recommends to use methods that have the least impact on the mineral phases and the geochemistry of the soil.

Berns et al. (2008) studied the effect of two common soil sterilization methods (gamma radiation and autoclaving) on two different types of agricultural soils. They concluded that the choice of the sterilisation method strongly depends on the type of study or research questions being asked. For degradation experiments, gamma-sterilized soils are better suited as control soils than autoclaved soils, because they are physically and chemically less altered by the process of sterilisation.

Lees et al. (2018) assessed autoclaving, gamma irradiation, and sodium azide as soil sterilisation methods for use in adsorption/desorption studies. They reported that autoclaving destroyed the soil structure, therefore potentially affecting its sorption behaviour while sodium azide changed the pH of the loam soil solution by 0.53 pH units. Gamma irradiation exhibited least disruption to the tested soils physico-chemical properties. The authors concluded that gamma irradiation was the best available method for sterilising soils in preparation for sorption-desorption experiments, but advocated for a case-by-case basis approach for choosing the best sterilisation in different soil types.

In conclusion, you must explain and justify the method and procedure used for establishing the sterile controls in the study report, and determine the efficiency of the sterilisation by measurements of microbial biomass. OECD TG 307 indicates that the microbial biomass must be measured initially, during and at the end of the aerobic studies. Finally, ECHA notes that communication with the eMSCA is possible in case you wish to have a mutual discussion on the preparation of the sterile controls.

Request for the full study report

You must submit a full study report. Considering the complexity and the non-standard adaptations requested as described above, a complete rationale of the test design and interpretation of results and access to all information available in the full study report (implemented method, raw data collected, interpretations and calculations, consideration of uncertainties, argumentation, etc.) are needed.

This will enable the evaluating MSCA to fully assess all the provided information, including the statistical analysis, and to efficiently clarify the potential risk for persistence.

7 Alternative approaches and proportionality of the request

The request for soil simulation testing is suitable and necessary to obtain information that will allow to clarify the potential P/vP properties of the Substance. More explicitly, there is no equally suitable alternative way available of obtaining this information.

The requested soil simulation test OECD TG 307 including the identification of degradation and/or transformation products is a standard information requirement at Annex IX, Section 9.2.1.3 of REACH. It could also be a requirement for concluding your PBT assessment according to Annex XIII, Section 2.1 of REACH. It could therefore be subject to a compliance check under Article 41 of REACH.

However, the requested soil simulation test includes the following non-standard adaptatations to the test guideline:

- Biometer-type flasks must be used to minimise volatilisation of the substance which was shown to happen in large quantities of the substance in other simulation tests. Volatilisation and the resulting poor recovery rates rendered these tests improper for persistence assessment.
- Radiolabelling in the most recalcitrant part of the substance is needed as this is a prerequisite for the identification of transformation products and generally improves interpretability of data. Given the low mineralisation and the significant non-extractable residues observed in previous biodegradation tests, radioactive labelling is crucial to interprete biodegradation data and to yield information on persistence.
- A significant amount of non-extractable residues (NER) was observed in the previous biodegradation study and therefore, characterisation of non-extractable residues (NER) must be carried out in order to allow for a differentiation of remobilisable and

irreversibly bound fractions as recommended in the guidance (ECHA, 2017). The share of non-extractable residues (NER) strongly depends on the extraction procedures used. It is thus important that these extraction procedures are reported and justified in detail. Moreover, differentiation of NER presumes elaborated extraction procedures as described above and a detailed report is necessary to make best use of the generated data.

- For persistence assessment, the simulation test must be performed at the temperature of 12°C, the average environmental temperature for the EU (ECHA, 2016). Performing the tests at this temperature is in line with the recommended test conditions of the OECD TG 307, and more relevant than the option 20 °C given in the same guideline. Data generated at 20 °C would have to be extrapolated to 12 °C which would generate a source of error and uncertainty.

Since these non-standard parameters are required and the information request is based on a potential risk that the Substance poses, the request is necessary under the current substance evaluation.

8 Consideration of the time needed to perform the requested studies

The deadline to provide the requested data takes into account the time required to develop an analytical method, conduct of the study, prepare the study report and report the study in your IUCLID registration dossier.

In your comments to the draft decision, you requested an extension of the timeline from 18 months to 24 months referring to the previous technical difficulties in performing studies with the Substance. The evaluating MSCA acknowledges these difficulties and agrees to the prolongation of the deadline. Therefore, ECHA has granted the request and set the deadline to 24 months.

9 References

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OECD (1993): Guidelines for the Testing of Chemicals. OECD (1994-2000), Paris. Addenda 6-11 to Guidelines for the Testing of Chemicals.

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Appendix B: Procedure

12-month evaluation

On the basis of an opinion of the ECHA Member State Committee and due to initial grounds for concern relating to PBT/vPvB properties, the Substance (EC No 229-782-3, CAS RN 6731-36-8) was included in the Community rolling action plan (CoRAP) for substance evaluation to be evaluated in 2014. The updated CoRAP was published on the ECHA website on 26 March 2014. The competent authority of Germany (hereafter called the evaluating MSCA) was appointed to carry out the evaluation.
In accordance with Article 46(1) of REACH, a substance evaluation decision was issued on 23 November 2015 requesting further information. You submitted all the requested information on 24 April 2019. The evaluating MSCA carried out the evaluation of the information in your updated registration(s) and other relevant and available information.

The evaluating MSCA considered that further information was required to clarify the abovementioned concern. Therefore, it prepared a second draft decision under Article 46(3) of REACH to request further information. It subsequently submitted the draft decision to ECHA on 12 March 2020.

Decision-making

ECHA notified you of the draft decision and invited you to provide comments.
For the purpose of this decision-making, dossier updates made after the date the draft of this decision was notified to you (Article 50(1) of REACH) will not be taken into account.

(i) Registrant(s)' commenting phase

ECHA received your comments and forwarded them to the evaluating MSCA.
The evaluating MSCA took your comments into account (see Appendix A). The request was not amended. Only the deadline to provide the requested information was extended.

(ii) Proposals for amendment by other MSCAs and ECHA and referral to the Member State Committee

The evaluating MSCA notified the draft decision to the competent authorities of the other Member States and ECHA for proposal(s) for amendment. Subsequently, the evaluating MSCA received proposal(s) for amendment to the draft decision and modified the draft decision (see Appendix A).

ECHA referred the draft decision, together with your comments, to the Member State Committee.
ECHA invited you to comment on the proposed amendment(s). You did not provide any comments on the proposed amendment(s).

(iii) MSC agreement seeking stage

The Member State Committee reached a unanimous agreement in its MSC-74 written procedure and ECHA took the decision according to Article 52(2) and Article 51(6) of REACH.
After the deadline set in this decision has passed, the evaluating MSCA will review the information you will have submitted and will evaluate whether further information is still needed to clarify the potential risk, according to Article 46(3) of REACH. Therefore, a subsequent evaluation of the Substance may still be initiated after the present substance evaluation is concluded.

Appendix C: Further information, observations and technical guidance

1. This decision does not imply that the information you provided in the registration(s) is in compliance with the REACH requirements. The decision neither prevents ECHA from initiating compliance checks on your dossier(s) at a later stage, nor does it prevent a subsequent decision under the current substance evaluation or a new substance evaluation process once the present substance evaluation has been completed.

2. Failure to comply with the request(s) in this decision, or to otherwise fulfil the information request (s) with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State.

3. In relation to the required experimental study/ies, the sample of the substance to be used ('test material') has to have a composition that is within the specifications of the substance composition that are given by all registrant(s). It is the responsibility of all the registrant(s) to agree on the tested material to be subjected to the test(s) requested in this decision and to document the necessary information on the composition of the test material. The substance identity information of the Substance and of the sample tested must enable the evaluating MSCA and ECHA to confirm the relevance of the testing for the substance subject to substance evaluation.

4. In relation to the experimental stud(y/ies) the legal text foresees the sharing of information and costs between registrant(s) (Article 53 of REACH). You are therefore required to make every effort to reach an agreement regarding each experimental study for every endpoint as to who will carry out the study on behalf of the other registrant(s) and to inform ECHA accordingly within 90 days from the date of this decision. Further advice can be found at:
   http://echa.europa.eu/regulations/reach/registration/data-sharing.
   If ECHA is not informed of such agreement within 90 days, it will designate one of the registrants to perform the stud(y/ies) on behalf of all of them.