ECHA
EUROPEAN CHEMICALS AGENCY

Helsinki, 15 February 2021

Addressees
Registrant(s) of N-[4-[(9,10-dihydro-4-hydroxy-9,10-dioxo-1-anthryl)amino]phenyl]acetamide listed in the last Appendix of this decision

Registered substance subject to this decision (the Substance)
Substance name: N-[4-[(9,10-dihydro-4-hydroxy-9,10-dioxo-1-anthryl)amino]phenyl]acetamide
EC number: 267-636-0
CAS number: 67905-17-3

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

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

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

1. Simulation testing on ultimate degradation in surface water: Aerobic mineralisation in surface water – simulation biodegradation test, test method EU C.25./ OECD TG 309 (Request A.1), on the Substance, specified as follows:
   - a pelagic test using EU representative surface water with a suspended solids concentration of approximately 15 mg_{dw}/L (but not outside the range of 10 to 20 mg_{dw}/L);
   - at a test temperature of 12°C;
   - the test must also be performed with sterile control;
   - using a concentration appropriate to also successfully identify and quantify possibly formed transformation and/or degradation products. Moreover test concentrations used must not exceed the solubility limit of the Substance in the test medium;
   - concentration of the test substance must be measured at appropriate intervals during the study so that a reliable primary degradation half-life can be determined;
   - 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;

- using the ^{14}C radiolabelled Substance with the radiolabel located in the most stable part of the molecule. However according to the OECD TG 309, the most stable part does not necessarily include the relevant functional moiety of the molecule (that can be related to a specific property such as toxicity, bioaccumulation, etc.). If this is the case, it may be appropriate to use a test substance, which is 14C-labelled, in the functional part in order to follow the elimination of the specific property;
- a mass balance must be provided;
- 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.

If it can be demonstrated by sound justification that simulation testing in surface water is not technically feasible (i.e.: impossible to analytically quantify the parent compound), the following test is required instead:

Sediment simulation testing; test method: Aerobic and anaerobic transformation in aquatic sediment systems, EU C.24/ OECD TG 308 (Request A.1), on the Substance, specified as follows:

- at a test temperature of 12°C;
- the test must also be performed with sterile control;
- under aerobic conditions;
- 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;
- using the ^{14}C radiolabelled Substance with the radiolabel located in the most stable part of the molecule;

- a mass balance must also be provided;
- 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.

However if a high enough test concentration in water can be established to follow the degradation of parent compound (thus expected to allow the determination whether the degradation half-life of the parent compound exceeds the P (vP) criterion), the OECD TG 309 is still required, and cannot be replaced by perfoming OECD TG 308. The reason that the degradation products cannot be sufficiently investigated is not a valid argument for not performing a water simulation test.

Deadlines

Request A.1: The requested information must be provided by 21 November 2022 from the date of the decision.

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 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.

Authorised[1] by 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.

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 is necessary and appropriate.

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

1. Potential risk

1.1 Potential hazard of the Substance

Following its assessment of the available relevant information on the Substance, the evaluating MSCA and ECHA have identified the following potential hazard(s) which must be clarified.

a) Potential P/vP properties

If a substance fulfils the criteria in Section 1.1.1 or 1.2.1 of Annex XIII to REACH, it is considered that it has persistent (P) or very persistent (vP) properties.

For the purpose of the P/vP assessment and to check whether the criteria are fulfilled, the information listed in Section 3.2.1 to Annex XIII, including results from simulation tests, must be considered.

If no such data are available, it is necessary to consider the screening information of Section 3.1.1 to Annex XIII, such as QSAR predictions.

The available information suggest that the Substance may have P/vP properties.

Evidence based on experimental data

- Two OECD TG 111 studies, measuring hydrolysis as a function of pH, are available on two read-across substances (EC 201-423-5 and EC 203-150-7). Both studies showed that these read-across substances were hydrolytically stable at pH 4, 7 and 9.
- Screening tests for biodegradation in water are only available for read-across substances. Four experimental biodegradation studies are mentioned in the registration dossier, performed with three different read-across substances (OECD TG 302B study performed with EC 224-546-6, non-guideline study performed with EC 224-546-6, and two OECD TG 301 C studies performed with EC 219-693-8 and EC 200-806-4, respectively). These read-across studies indicate that the Substance is not readily biodegradable, as the pass criteria are not met. However, this information must be considered only as part of a weight of evidence approach since you have not

provided sufficient supporting information to justify your read-across hypothesis, and to support that it may provide a reliable basis to predict the properties of the Substance.
- There is no hydrolysis or photolysis data available for the Substance itself.
- No ready biodegradability study, or water, water-sediment or soil simulation test is currently available for the Substance.

Evidence based on model predictions
- A half-life (50% degradation in water) estimated in EPI Suite (BIOWIN v4.10) of 2.20 months for the Substance is reported in the registration dossier.
- You mention an EPI Suite (EPIWEB v4.1) estimated half-life (HYDROWIN v2.00) of 3950 yr (pH 7; 25 °C) for the Substance.
- You only mention half-lives estimated in EPI Suite (Level III Fugacity model), with an estimated half-life in water of 60 d, an estimated half-life in sediment of 542 d and an estimated half-life in soil of 120 d (at 25°C).
- Estimations performed by the evaluating MSCA in EPI Suite show BIOWIN values which meet the screening criteria for persistence (BIOWIN v4.10: BIOWIN 2 = 0.1836 < 0.5, BIOWIN 3 = 2.1985 < 2.25, BIOWIN 6 = 0.0055 < 0.5). These estimations further support the findings that the Substance shows no indication of ready biodegradation.

Based on the weight of evidence from all available data the Substance could meet the criteria for P or vP.

The available and current information is not sufficient to draw a conclusion on the hazard. Further information is needed on the P/vP property.

b) Potential B/vB properties

If a substance fulfils the criteria in Section 1.1.2 or 1.2.2 of Annex XIII to REACH, it is considered that it has bioaccumulative (B) or very bioaccumulative (vB) properties.
For the purpose of the B/vB assessment and to check whether the criteria are fulfilled, the information listed in Section 3.2.2 of Annex XIII must be considered, including bioconcentration factor (BCF) values. Notably, if the BCF value is > 5000, the Substance fulfils the criteria for vB.

Evidence based on experimental data

- An experimentally derived log K_{ow} (P_{ow}) value of 3.15 at 20°C (OECD TG 117, HPLC method) is available in the registration dossier.
- No experimental studies on bioaccumulation are available for the Substance.

Evidence based on model predictions

- Extremely high log K_{oa} value of 20.57 (KOAWIN v1.10) was estimated by the evaluating MSCA in EPI Suite (by applying measured log K_{ow} value).

Based on the available data, the Substance currently does not fulfil the screening criterion for bioaccumulation in aquatic organisms (Log K_{ow} > 4.5). The screening criterion for bioaccumulation in air-breathing organisms (Log K_{ow} > 2 and log K_{oa} > 5) is fulfilled, as specified in the ECHA's Guidance on information requirements and chemical safety assessment Chapter R.11 (PBT assessment, 2017).

Based on the weight of evidence from all available data the Substance could meet the criteria for B or vB.

The available and current information is not sufficient to draw a conclusion on the hazard. Further information may be needed on the B/vB property in a follow-up procedure, if the results from OECD TG 309 or 308 demonstrate that the Substance fulfils the criteria for persistence (degradation half-life in freshwater of > 40 days or the degradation half-life in soil > 120 days) according to REACH Annex XIII.

Recommendation for the registrants' consideration to perform the slow-stirring test (OECD TG 123)

We recommend that you consider performing the slow-stirring test (OECD TG 123), which may provide higher Log K_{ow} values as estimated with Bioloom for Windows version 1.5 (ClogP) and KOWWIN version 1.67 the log K_{ow} (5.06 and 4.81, respectively). The results of this recommended test may allow the derivation of a more appropriate Log K_{ow} value and may subsequently support the consideration of the need for a bioaccumulation study according to OECD TG 305 during the follow-up evaluation of the present Decision (i.e. in case the information requested in the present Decision demonstrates the substance to be persistent).

c) Potential T property

If a substance fulfils the criteria in Section 1.1.3 of Annex XIII to REACH, it is considered that it fulfils the toxicity (T) criterion.
For the purpose of the assessment of T and to check whether the criteria are fulfilled, the information listed in Section 3.2.3 of Annex XIII must be considered.

You have indicated in your chemical safety report that the substance is T based on the reasoning that a long-term NOEC for aquatic organisms is expected to be at a concentration below 0.01 mg/L for this substance.

Based on the weight of evidence from all available data the Substance could meet the criteria for T. The available and current information is not sufficient to draw a conclusion on the hazard. Further information on the T property may be needed in a follow-up procedure.

1.2 Potential exposure

According to the information you submitted in all registration dossiers, the aggregated tonnage of the Substance manufactured or imported in the EU is in the range of 100 – 1000 tonnes per year.

Furthermore, you reported that among other uses, the Substance is used by industrial workers:

- The uses at industrial sites include: polymer preparations and compounds, ink and toners, lubricants, greases, release products, laboratory chemicals, coatings and paints, thinners, paint removers, polishes and wax blends.

The Substance can be released to the environment as emissions from industrial use. Therefore, exposure to the environment cannot be excluded.

1.3 Identification of the potential risk to be clarified

Based on all information available in the registration dossier, and QSAR data, the Substance may be a PBT/vPvB substance.

The information you provided on manufacture and uses demonstrates a potential for exposure of the environment.

Based on this hazard and exposure information the substance poses a potential risk to the environment.

As explained in Section 1.1 above, the available information is not sufficient to conclude on the hazard. Consequently further data is needed to clarify the potential risk related to PBT/vPvB properties.

1.4 Further risk management measures

If the properties(s) of the Substance are confirmed, the evaluating MSCA will analyse the options to manage the risk(s). New regulatory risk management measures could be:

- Identification as a substance of very high concern (SVHC) under Article 57 of REACH;
- a subsequent authorisation or a restriction of the Substance. This would lead to stricter risk management measures than those currently in place, such as minimisation of emissions.

2. How to clarify the potential risk

2.1 Development of the testing strategy

The information resulting from Request A.1 will constitute the first tier in a testing strategy to conclude on the PBT/vPvB hazard. The evaluating MSCA will review the information you submitted as an outcome of the first tier of the testing strategy, and evaluate whether further information is still needed to clarify the potential risk for PBT/vPvB.

2.2 Request A.1 (Simulation testing on ultimate degradation in surface water: Aerobic mineralisation in surface water – simulation biodegradation test, test method EU C.25. / OECD TG 309 or Sediment simulation testing; test method: Aerobic and Anaerobic Transformation in Aquatic Sediment Systems, EU C.24/ OECD TG 308)

a) Aim of the study

The aims of the testing requested are:

- to obtain the half-life of the Substance in water or soil to determine whether the P criterion is met in water or soil;
- to identify and quantify any relevant transformation/degradation products which are formed. Subsequently, if formed, further information may need to be generated on

these products to assess whether they meet the PBT/vPvB criteria of Annex XIII.

b) Specification of the requested study

Three simulation test methods are available that assess persistence in soil (OECD TG 307), sediment (OECD TG 308) or surface water (OECD TG 309). In order to determine which simulation test is the most appropriate method for addressing degradation of the Substance, the compartment of concern needs to be identified.

Assuming equal emissions to air, water and soil, the EPI Suite™ Level III fugacity model (by applying measured log K_{ow} value) predicts that 78% of the Substance emitted in the environment will be distributed to soil, 15% in sediment and 7% in surface water. In EPI Suite high adsorption coefficients log K_{oc} (KOCWIN v2.00) were estimated of 4.48 (MCI Method) and 3.69 (based on measured log K_{ow} value), which support the high potential for adsorption to organic matter. An in EPI Suite estimated Henry's Law Constant (HENRYWIN v3.20) of $9.42*10^{-15}$ Pa*m³/mol at 25 °C (Bond Method) indicates low volatility from the water surface. As there is no single compartment of specific concern, simulation testing on ultimate degradation in surface water (OECD TG 309) is the preferred method.

Firstly, the aquatic compartment is by default considered a relevant compartment due to its large global volume, i.e. it receives significant amounts of emission directly and/or indirectly, and substances that have entered the compartment tend to reside there for long periods of time before reaching other compartments and because water serves as an important medium for transport in contrary to soil and sediment. Secondly, interpretation of the surface water simulation test is more straightforward compared to the soil and sediment simulation studies, as formation of non-extractable residues (NERs) is minimised. Finally, the surface water simulation test is suitable to test lower, environmentally relevant, test concentrations. In addition, most of the Substance release is expected to the water compartment, given the registered uses. Considering all above, ECHA requests simulation testing on ultimate degradation in surface water as a first option. In your comments to the draft decision you agreed to perform the requested study.

In your comments on the proposals for amendments you indicated a preference to perform the requested OECD TG 309 study. As specified above, simulation testing on ultimate degradation in surface water (OECD TG 309) is the preferred method requested and must therefore be performed if technically feasible. However, if it can be demonstrated by sound

justification that simulation testing in surface water is not technically feasible, the requested sediment simulation test (OECD TG 308) must be performed instead. It must be noted however that if a high enough test concentration in water can be established to follow the degradation of the parent compound (thus expected to allow the determination whether the degradation half-life of the parent compound exceeds the P (vP) criterion), the OECD TG 309 is still required and cannot be replaced by performing OECD TG 308. The reason that the degradation products cannot be sufficiently investigated is not a valid argument for not performing a water simulation test.

Test conditions

- You must conduct a pelagic test using EU representative surface water with a suspended solids concentration of approximately 15 mg_{dw}/L (but not outside the range of 10 to 20 mg_{dw}/L).

Temperature

- You must perform the test at the mean temperature of 12 °C which is the average environmental temperature for the EU, including surface waters [REACH guidance (cf. section R.7.9.4.1)].

Test material and concentration

- You must ensure that all test concentrations are below the aqueous solubility of the Substance in the test medium.
- To identify transformation and/or degradation products relevant for PBT assessment, the test material must be ^{14}C radiolabelled and the radiolabel must located in the most stable part of the molecule. However, according to the OECD 309, the most stable part does not necessarily include the relevant functional moiety of the molecule (that can be related to a specific property such as toxicity, bioaccumulation, etc.). If this is the case, it may be appropriate to use a test substance, which is ^{14}C-labelled, in the functional part in order to follow the elimination of the specific property.

Measurement of test substance concentration and primary degradation

- The concentration of the test substance must be measured at appropriate intervals during the study so that a primary degradation half-life can be determined, in addition to the half-life based on measurement of residual ^{14}C activity or the evolved $^{14}CO2$. This is required for the following reasons:

- The measurement of the test substance concentration is important for the comparison between the active test and sterile controls, to estimate the potential contribution of abiotic losses to the decrease in test substance concentration.
- Primary degradation half-life is important for the conclusion on the P/vP property of the parent substance in case that degradation half-life based on residual ^{14}C is above the P or vP criterion.
- Primary degradation half-life may be important for the estimation of the persistence of the transformation products.

Identification of transformation/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. Identification and quantification of transformation and/or degradation products whose concentrations are continuously increasing should also be considered if technically feasible. Therefore, the concentration used must be high enough to allow detection, with the applied analytical method, of transformation and/or degradation products formed.
- Therefore, you must attempt as far as technically possible, to quantify these products down to 1%, otherwise you must provide justification as to why it was not technically feasible. Technically feasible means that you have demonstrated within allocation of reasonable efforts to develop suitable analytical methods and other test procedures to accomplish testing in water so that reliable results can be generated. In case identification is not technically feasible, then the molecular weight must be determined.
- ECHA considers that quantification of transformation and/or degradation products down to 1% can possibly be achieved using LC-HRMS (liquid chromatography high resolution mass spectrometry).
- You must provide a mass balance.

Quantification of the total amount of non-extractable residues (NER)

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.

- You must explain and scientifically justify the extraction procedure and solvent used obtaining a quantitative measure of non-extractable residues (NER).
- The total amount of NER must be quantified, to demonstrate that all transformation and/or degradation products which have formed have been extracted and can be quantified. By default, total NER is regarded as non-degraded parent. 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.).
- You have the option to further characterise the types of NER to refine the P assessment. The Background note on 'Options to address NER in regulatory P assessment', published on the ECHA website (https://echa.europa.eu/documents/10162/13632/bg_note_addressing_non-extractable_residues.pdf/e88d4fc6-a125-efb4-8278-d58b31a5d342), provides some suggestions on the further refinement.

In your comments on the proposals for amendments you expressed your view that '*measurement of non-extractable residues (NERs) formation is not needed as their formation in surface water is lower and can be direct compared to the soil and sediment simulation studies'.* However, ECHA Guidance R.7.9.4.1. states that 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. Hence, quantification of the total amount of non-extractable residues (NER) is still required.

If it can be demonstrated by sound justification that simulation testing in surface water is not technically feasible (i.e. impossible to analytically quantify the parent compound), the following test using the Substance is then required: Sediment simulation testing; test method: Aerobic and Anaerobic Transformation in Aquatic Sediment Systems, EU C.24/ OECD TG 308.

Based on the estimated half-lives in EPI Suite™ (Level III fugacity model), the half-lives for sediment are much higher than estimated for soil (542 versus 120 d). Moreover, if the fugacity model is run with emission to water only, most of the substance will be present in sediment. A soil simulation test might have been preferred if there was only a very low

concern for emission to the aquatic environment, which is not the case. Therefore, sediment is considered as a more relevant compartment than soil, in case performance of the OECD 309 is not technically feasible.

Test conditions

- You must perform the test at the temperature of 12°C which is the average environmental temperature for the EU [ECHA's Guidance on information requirements and chemical safety assessment Chapter R.11 (PBT assessment, 2017)].

Sterile controls

- Sterile water-sediment controls must be included in the test to determine to what extent the test substance decrease is due to biotransformation or to potential abiotic losses (e.g. volatilisation, formation of non-extractable residues (NER)).
- ECHA notes that it is important to ensure that test conditions in the sterile controls and the active test bottles are as identical 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 test specifications of the sterile control bottles, such as the headspace volume, sampling times, analytical measurements as well as any potential causes 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 water-sediment test bottles, to ensure comparability.
- OECD TG 308 does not include instructions for a sterile control. However, OECD TG 309 gives guidance on the preparation of sterile water controls as well as sterile controls containing water with sediment added in large amounts. Furthermore, ECHA notes that the OECD TG 308 test (Unnamed, 2010; ECHA, 2018) for decamethylcyclopentasiloxane (EC 208-764-9), as well as other published water-sediment degradation simulation studies (e.g. Liu et al, 2013; Shrestha et al 2016, 2020) included sterile controls and can provide guidance on the preparation of sterile controls. In these studies the sterilisation was done either by the addition of sodium azide, autoclaving or both. In addition, in another publication (Otte et al, 2018) different methods for sterilisation of marine sediment were compared.
- The selection of the sterilisation method and time to perform the sterilisation in the sterile water-sediment controls, e.g. before or after the acclimation period specified in

the paragraph 31 of OECD TG 308, may have an effect on the sediment properties. Based on Otte et al (2018), thermal sterilisation, gamma radiation and chemical sterilisation have all advantages and disadvantages. Considering the importance of the integrity of the sediment phase 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 sediment. OECD TG 309 indicates that the sorption characteristics of the sediment may be altered by autoclaving. According to Otte et al (2018) autoclaving and gamma radiation lead to a large increase in dissolved organic carbon and have impacts on the mineral phase, while chemical sterilisation seems to be the method that would likely have the least impact on the geochemistry of the sediment phase. However, it should be noted that chemical sterilisation may also affect some sediment properties, e.g. triggering changes in pH.

- In conclusion, you must explain and justify the methods 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 308 indicates that the microbial biomass of both water and sediment must be measured at post-handling, test start and test end, and mentions methods for that.

Test concentration

- You must also ensure that an adequate concentration of test substance is applied in order to characterise the route of transformation and the formation and decline of transformation products.
- To identify transformation and/or degradation products relevant for PBT assessment, the test material must be ^{14}C radiolabelled and the radiolabel must be located in the most stable part of the molecule. However, according to the OECD 309, the most stable part does not necessarily include the relevant functional moiety of the molecule (that can be related to a specific property such as toxicity, bioaccumulation, etc.). If this is the case, it may be appropriate to use a test substance, which is 14C-labelled, in the functional part in order to follow the elimination of the specific property.

In your comments on the proposal for amendments from one Member State Competent Authority you expressed your view that radiolabelling of test material is not needed considering the degradation products can be predicted as it would be similar to a read-across substance 1,4-Bis(p-tolylamino)anthraquinone (EC 204-909-5). ECHA notes that you have not provided sufficient information on the properties under consideration for your

Substance and the proposed read-across substance. In the absence of such information, you have not established that the Substance and the proposed read across substance are likely to have similar properties. Therefore, you have not provided sufficient supporting information to justify your view that radiolabelling of test material is not needed. As indicated above, radiolabelling is needed to identify transformation and/or degradation products relevant for PBT assessment. Consequently, ECHA considers that the test material must be ^{14}C radiolabelled as explained in section A.1.

Identification of transformation/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. Identification and quantification of transformation and/or degradation products whose concentrations are continuously increasing should also be considered if technically feasible. Therefore, the concentration used must be high enough to allow detection, with the applied analytical method, of transformation and/or degradation products formed.
- Therefore, you must attempt as far as technically possible, to quantify these products down to 1%, otherwise you must provide justification as to why it was not technically feasible. Technically feasible means that you have demonstrated within allocation of reasonable efforts to develop suitable analytical methods and other test procedures to accomplish testing in water so that reliable results can be generated. In case identification is not technically feasible, then the molecular weight must be determined.
- ECHA considers that quantification of transformation and/or degradation products down to 1% can possibly be achieved using LC-HRMS (liquid chromatography high resolution mass spectrometry).
- You must provide a mass balance.

Quantification of the total amount of non-extractable residues (NER)

- You must explain and scientifically justify the extraction procedure and solvent used obtaining a quantitative measure of non-extractable residues (NER).
- The total amount of NER must be quantified, to demonstrate that all transformation and/or degradation products which have formed have been extracted and can be quantified.

- You have the option to further characterise the types of NER to refine the P assessment. The Background note on 'Options to address NER in regulatory P assessment', published on the ECHA website (https://echa.europa.eu/documents/10162/13632/bg_note_addressing_non-extractable_residues.pdf/e88d4fc6-a125-efb4-8278-d58b31a5d342), provides some suggestions on the further refinement.

Overall the test performed should meet the validity criteria of the OECD test guideline, and provide results suitable for comparison with the Annex XIII criteria of REACH.
To address the missing information identified above, the test required will allow to identify information on the persistence, which is required to conclude on the P/vP properties.

Request for the full study report
You must submit the full study report which includes:

- a complete rationale of test design and;
- interpretation of the results;
- access to all information available in the full study report, such as implemented method, raw data collected, interpretations and calculations, consideration of uncertainties, argumentation, etc.

This will enable the evaluating MSCA to fully and independently assess all the information provided, including the statistical analysis, and to efficiently clarify the potential hazard for the PBT/vPvB properties for the Substance.

c) Alternative approaches and how the request is appropriate to meet its objective

The request is:

- appropriate, because the tests are suitable and necessary to obtain information which will allow clarifying whether the Substance has a half-life in water or sediment which fulfils the P or vP criteria and whether transformation and/or degradation products of the Substance, having potentially PBT/vPvB properties, are formed under environmentally relevant conditions;
- the least onerous measure, because there is no equally suitable alternative methodology available to obtain the information that would clarify the potential hazard.

2.3 References relevant to the requests (which are not included in the registration dossier)

ECHA's Guidance on information requirements and chemical safety assessment Chapter R.11 (PBT assessment, 2017)

https://echa.europa.eu/documents/10162/13632/bg_note_addressing_non-extractable_residues.pdf/e88d4fc6-a125-efb4-8278-d58b31a5d342

ECHA 2018. Member State Committee support document for identification of dodecamethylcyclohexasiloxane (D6) as a substance of very high concern because of its PBT and vPvB properties (Article 57 D&E) adopted on 13 June 2018. https://echa.europa.eu/documents/10162/a9682f4b-fc3e-cd99-3db9-b0f9f383c3c5

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Appendix B: Procedure

This decision does not imply that the information you submitted in your registration dossier(s) are in compliance with the REACH requirements. ECHA may still initiate a compliance check on your dossiers.

12-month evaluation

- Due to initial grounds of concern for PBT/vPvB, the Member State Committee agreed to include the Substance (EC No 267-636-0, CAS 67905-17-3) in the Community rolling action plan (CoRAP) to be evaluated in 2019. Belgium is the competent authority ('the evaluating MSCA') appointed to carry out the evaluation.

- In accordance with Article 45(4) of REACH, the evaluating MSCA carried out its evaluation based on the information in the registration dossier(s) you submitted on the Substance and on other relevant and available information.

- The evaluating MSCA completed its evaluation considering that further information is required to clarify the following concerns: PBT/vPvB.

- Therefore, it submitted a draft decision (Article 46(1) of REACH) to ECHA on 13/03/2020.

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, as you agreed to perform the test.

(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 and B).

ECHA referred the draft decision, together with your comments, to the Member State Committee.

ECHA invited you to comment on the proposed amendment(s).

Your comments on the proposed amendment(s) were taken into account by the Member State Committee.

MSC agreement seeking stage

The Member State Committee reached a unanimous agreement in its MSC-73 written procedure and ECHA took the decision according to Article 52(2) and Article 51(6) of REACH.

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Appendix C: Technical Guidance to follow when conducting new tests for REACH purposes

Test methods, GLP requirements and reporting

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.

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.

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].

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] https://echa.europa.eu/practical-guides

2. *Information on the Test Material needed in the updated dossier*

   a) 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.

   b) The reported composition must include all constituents of each Test Material and their concentration values

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 "How to prepare registration and PPORD dossiers"[3].

[3] https://echa.europa.eu/manuals