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Helsinki, 23 June 2021

Addressees
Registrant(s) of A mixture of: propan-2-one-O,O'(methoxyvinylsilandiyl)dioxime; propan-2-one-O-(dimethoxyvinylsilyl)oxime; propan-2-one-O,O',O''-(vinylsilantriyl)trioxime listed in the last Appendix of this decision

Registered substance subject to this decision (the Substance)
Substance name: A mixture of: propan-2-one-O,O'(methoxyvinylsilandiyl)dioxime; propan-2-one-O-(dimethoxyvinylsilyl)oxime; propan-2-one-O,O',O''-(vinylsilantriyl)trioxime
EC number: 458-680-3
CAS number: 797751-44-1

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. Soil simulation testing (Aerobic transformation in soil; test method EU C.23/OECD TG 307), with Propan-2-one-O,O',O''-(vinylsilantriyl)trioxime (CAS RN 54948-34-4), constituent of the Substance, specified as follows:

- Under aerobic conditions;
- At a test temperature of 12ºC;
- Using a biometer type flask to prevent losses due to aeration of the test flasks;
- The types of soils tested must include at least one soil with high (> 10%) organic carbon content;
- Using the ^{14}C radiolabelled constituent of the 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; transformation and/or degradation products of which concentrations are continuously increasing should also be considered;
- The duration of the test must be at least 120 days;
- 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;
- A mass balance calculation must be included in the test;
- Sterile soil controls must be included in the test.

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2. **Only if the results from Request A.1 demonstrate that the Propan-2-one-O,O',O''-(vinylsilantriyl)trioxime (CAS RN 54948-34-4) constituent of the Substance fulfils the criteria for P or vP according to Annex XIII to REACH, Bioaccumulation in fish (test method EU C.13/OECD TG 305) using dietary exposure route, with Propan-2-one-O,O',O''-(vinylsilantriyl)trioxime (CAS RN 54948-34-4), constituent of the Substance, specified as follows:**
   - Using ^{14}C radiolabelled constituent of the Substance with the radiolabel located in the most stable part of the molecule;
   - A homogeneous distribution of the test substance in the feeding material must be ensured;
   - The stability of the test material in the spiked food after application of the food into the test medium must be assessed;
   - A reference substance must be used to demonstrate the adequacy of the food spiking technique;
   - Identification and quantification of major metabolites must be performed;
   - Growth-corrected lipid-normalised kinetic BMF and tentative BCFs must be determined.

Deadlines

A sequential testing strategy must be applied, and the information requested must be provided according to the multiple deadlines detailed in Table 1 below.

Table 1: Overview of requested studies and corresponding deadlines, reflecting the sequential testing strategy.

Requested information	**Conditions when to perform the test**	**Deadline**
Request A.1: Aerobic transformation in soil (test method EU C.23/ OECD TG 307)	None - always to be performed	**30 December 2022[1]**
Request A.2: Bioaccumulation in fish; dietary exposure route) (test method EU C.13/ OECD TG 305)	**Only if** the results from Request A.1 show that the constituent of the Substance fulfils the criteria for persistency (P) or very persistency (vP) according to Annex XIII to REACH, Sections 1.1.1 and 1.2.1	**25 September 2023**

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 studies in the corresponding endpoint of IUCLID.

[1] The final deadline includes the seven-day period addressed in point 9(d) of the terms and conditions of REACH-IT.

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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.

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

[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.

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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.

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

The registered Substance is a multi-constituent substance consisting of three main constituents that have a linear structure of silicon and oxygen atoms with one, two or three ketoxime groups. The ketoxime groups have a methyl substitution in the R and R´chains. All three main constituents are slightly or moderately volatile based on the predicted Henry's Law constants. The water solubility of the constituents decreases and the log Kow and log Koc values increase with the increasing number of ketoxime groups.

1. Potential risk

1.1 Potential hazard of the Substance

Following its assessment of the available relevant information on the Substance and its constituents, the evaluating MSCA and ECHA have identified the following potential hazards 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 of 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 of Annex XIII, such as QSAR predictions.

The available information suggest that the constituent propan-2-one-O,O',O''-(vinylsilantriyl)trioxime (CAS RN 54948-34-4), referred to as the "Trioxime Constituent" of the Substance in this Appendix, may be persistent or very persistent according to the Annex XIII criteria.

Evidence based on experimental data

- The Substance is not readily biodegradable (23% degradation in 28 days in an OECD TG 301B test) and therefore screens as P and vP, according to the ECHA Guidance, section R11 (Version 3.0, June 2017). This information was considered as supporting information since the OECD tests are applicable for individual substances and not for mixtures or multi-constituents substances and there is no possibility to know the contribution of each constituent to the final result.
- The three main constituents hydrolyse totally with a very short half-life (1 hour at pH 4, 7 and 9).

Evidence based on model predictions and other information

- However, the Trioxime Constituent is poorly soluble in water (WS of 0.25 mg/L; EPISUITE - WSKOW v1.42), volatile (Henrys Law constant of 2.12E-003 at·m3/mole) and also adsorbs strongly to organic matter in suspended solids, soil and sediment (log Koc of 7.56; EPISUITE – KOCWIN v2.00). This strong adsorption may limit the rate of hydrolysis of the Trioxime Constituent.
- No information is available on the potential for hydrolysis of the Substance's constituents in soils. Hindering of hydrolysis by adsorption cannot be excluded.

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- Other substances reaching rapid hydrolysis rates are well known to be P/vP in sediment, e.g. the cyclic siloxanes D4 (EC number 209-136-7) and D5 (EC number 208-764-9) which have long degradation half-lives in sediment, meeting the Annex XIII criteria for vP (ECHA, 2015).
  ECHA also notes that hydrolysis rates for these cyclic siloxanes were significantly impeded by dissolved organic carbon (DOC) (ECHA, 2015). Therefore ECHA is concerned that the degradation half-lives of the constituents of the Substance, especially of the Trioxime Constituent, may be longer in soil than suggested by the hydrolysis results in pure water, since it has the highest adsorption potential.
- Characteristics of other linear siloxanes such as hexamethyldisiloxane (HMDS, or L2) (EC number 203-492-7), octamethyltrixilosane (L3) (EC number 203-497-4), decamethyltetrasiloxane (L4) (EC number 205-491-7) and dodecamethylpentasiloxane (L5) (EC 205-492-2) are currently under assessment due to concern of persistency in sediments.
  Based on the information provided on the ECHA dissemination website for the linear HMDS (L2), vP can be suspected for sediments based on the results from an OECD TG 308 test.

Based on the weight of evidence from all available data, the Trioxime Constituent of the Substance may potentially meet the criteria for P or vP. However, the available and current information are not sufficient to draw a conclusion on the hazard. Therefore, further information are needed on the persistency of the Trioxime Constituent. An aerobic transformation in soil test (OECD TG 307 guideline) is deemed necessary to remove the current uncertainties on the P/vP pontial of the Trioxime Constituent of the Substance. Anaerobic transformation in soil test is not considered necessary due to substance specific considerations, such as the very fast hydrolysis rate (half-life less than 1 hour).

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, including bioconcentration factor (BCF) values, must be considered.

Evidence based on experimental data

No experimental information is available on the bioaccumulation of the Substance. Due to rapid hydrolysis, you waived the testing on bioaccumulation for the Substance. However, the available information suggest that the Trioxime Constituent of the Substance could be bioaccumulative or very bioaccumulative according to the Annex XIII criteria.

Evidence based on model predictions and other information

- The estimated log Kow value for the Trioxime Constituent is higher than 4.5, and hence, it meets the screening criterion for potential B/vB according to the ECHA Guidance, R11 (Version 3.0, June 2017).
- Based on estimations using BCFBAF QSAR model, the Trioxime Constituent could potentially fulfill the criteria for bioconcentration. A fish biotransformation half-life of 163 days has been estimated for this constituent.
- Additionally, if the results of the Request A.1 demonstrate that the Trioxime Constituent fulfills the P/vP criteria, this would be an indication that the adsorbed constituent has a lower hydrolysis rate and slow degradation. In this case, potential B/vB properties via dietary exposure route could not be excluded.

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- Other linear hydrolysable siloxanes such as L4 and L5 meet the B/vB criteria even with initially calculated BFCs of 1756 and 170, respectively.

Therefore, a bioaccumulation test in fish, dietary exposure (OECD TG 305) will be needed to conclude on the B/vB properties of the Trioxime Constituent, if its P/vP properties are confirmed based on the results of Request A.1.

c) Potential T properties

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 T assessment and to check whether the criteria are fulfilled, the information listed in Section 3.2.3 of Annex XIII, such as results of long-term toxicity tests, must be considered.

Due to high hydrolysis rates (totally hydrolysed in 1h at 25°C),the aquatic toxicity of the Substance cannot be tested. The available aquatic toxicity data, which indicate no toxicity under short-term static toxicity tests, seem to correspond to the hydrolysis products. None of the three constituents of the Substance seem likely to be bioavailable enough to exert toxicity in the aquatic pelagic environment before hydrolytic transformation.

Therefore, toxicity testing in sediment or soil organisms could be more relevant for the Trioxime Constituent of the Substance. Furthermore, based on the available information it cannot be excluded that the Annex XIII criteria for T, based on human health is fulfilled.

At this moment, no definitive conclusion on the hazard can be drawn. No further information on toxicity is requested in this decision but depending on the outcome of the testing requested in this decision, further toxicity testing may be necessary and may be requested in a follow-up decision.

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 and professional workers, and consumers in adhesive, sealants, coatings and paints, thinners, paint removers, [redacted], building and construction work and intermediate.

Hindering of hydrolysis by adsorption cannot be excluded. Therefore, there is a concern that the degradation half-life of the Trioxime Constituent of the Substance may be longer in soil than suggested by the hydrolysis results in pure water.

Considering the high adsorption potential of the Trioxime Constituent of the Substance, adsorption into aerosols and particulate material and consequently dry deposition could occur to some extent. Furthermore, exposure of soil due to the use at construction sites and application of sewage treatment plant sludge containing the Substance on agricultural soil cannot be excluded.

In your comments to the draft decision you claimed that the only actual use of the Substance is as [redacted] in silicon sealants and that the registration dossier included a rationale demonstrating that there is no exposure of the Substance to soil during its

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manufacturing, formulation and end-use. You pointed out that no reference to this rationale was included in the draft decision and thus assumed that it was not considered in the evaluation.

ECHA notes that no such rationale was found in the registration dossier which was considered in the Substance Evaluation (only dossiers submitted before 17 January 2020 considered). In the registration dossier you only indicated that waiving of soil simulation studies was applied because exposure to soil during manufacturing of the product as well as during its use for the sealant production and use by the customer is unlikely. As you also indicated in your comments, no exposure information about different uses of the Substance was included in the dossier. ECHA also notes that all the different product categories mentioned in the draft decision were included in the registration dossier considered in this Substance Evaluation.

According to ECHA's current approach regarding dossier updates during substance evaluation (published on ECHA website on 31 March 2020)[3], after ECHA has sent registrants a draft decision for commenting, the Agency and evaluating Member States no longer take dossier updates into account in their decision making.

In your comments you referred to point 9.2.1.3, column 1 of Annex IX to REACH which says that a "*Soil simulation testing (for substances with a high potential for adsorption to soil)*" is required which can be waived according to column 2 of the same point: "*The study need not be conducted: if the substance is readily biodegradable, or if direct and indirect exposure of soil is unlikely*". You pointed out that ECHA's request for the soil degradation simulation testing falls under the assessment of the potential hazard of the substance. However, in your opinion, according to Annex IX of REACH the likelihood of the exposure of soil to the substance or the Trioxime Constituent should be assessed and considered.

You provided information on the life-cycle of the Substance in the use as [redacted] in silicone sealants. According to your information the manufacture and formulation take place in closed systems and all residues from cleaning of equipments are incinerated. Furthermore, you indicated that in the end-use of the sealants the Substance reacts and becomes part of a polymer structure, and that the Substance is not detectable in the final product. Therefore, in your view, the exposure of the substance to environment can be discarded.

In ECHA's view, based on the information in the registration dossier and provided in your comments, it is not possible to exclude exposure of the environment, especially for the use at construction sites and the professional and consumer uses of products containing the Substance. ECHA reminds that the whole life-cycle of the substance must be considered, including service life and waste stage. No measured data demonstrating complete reaction of the Substance during the end-use in the silicone sealants or the lack of release of the Substance from the sealant during its service life is provided in your comments.

Therefore, based on the available information it cannot be excluded that some part of the Substance remains unreacted during the end-use of the silicone sealants or that leaching of the reacted/unreacted Substance occurs during the service-life or waste stage as a result of ageing of the polymeric matrix. ECHA also notes that the information in the

[3] https://echa.europa.eu/-/updates-to-registration-dossiers-not-taken-into-account-during-substance-evaluation-decision-making

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Substances in Preparations in Nordic Countries (SPIN) Database indicate potential exposure of the environment, including soil, resulting from use of products containing the Substance (SPIN, 2020).

Therefore, ECHA concludes that exposure of 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 information from the published literature, 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, the available information is not sufficient to conclude on the hazard. Consequently further data are needed to clarify the potential risk related to PBT/vPvB properties.

In your comments you argued that since you have demonstrated that no exposure of the environment to the Substance will take place during its whole life-cycle, there is no potential of risk to human health or the environment and the requests of soil simulation (OECD TG 307) and bioaccumulation (OECD TG 305) testing are not applicable. As explained in Section 1.2, ECHA disagrees with you and concludes that the exposure of the environment cannot be excluded based on the available information. Therefore, there is a potential risk to the environment, and the tests requested in this decision to clarify the potential risk related to PBT/vPvB properties are justified.

1.4 Further risk management measures

If the properties of the Trioxime Constituent of the Substance are confirmed, the evaluating MSCA will analyse the options to manage the risks and will assess the need for:

- further regulatory risk management in the form of 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

You must follow a tiered-testing strategy encompassing the requests below. The assessment of the results from the requested studies will constitute the first tier in a testing strategy to conclude on the potential risk related to PBT/vPvB properties. 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.

2.2 Request A.1 (Soil simulation testing: Aerobic transformation in soil; test method EU C.23/OECD TG 307))

a) Aim of the study

As detailed in Section 1.1 above, the soil simulation test is required in order to conclude

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on the potential persistency. The requested study will allow to obtain degradation half-lifes of the Trioxime Constituent of the Substance and to identify transformation and/or degradation products.

Testing in soil is considered appropriate for the following reasons:

- Other siloxanes (D4 and D5) reaching rapid hydrolysis rates in water are well known to be P/vP in sediment indicating that strong adsoprtion to particulate matter may slow down or prevent hydrolysis. Since the constituents of the Substance seem to completely hydrolyse very fast in water, it is not clear whether any significant amounts of the constituents can end up in the sediment. However, the presence in soil cannot be excluded especially for the Trioxime Constituent of the Substance due to its high adsorption potential.
- No information is available on the potential for hydrolysis of the Substance's constituents in soils. Hindering of hydrolysis by adsorption cannot be excluded. Therefore, there is a concern that the degradation half-life of the Trioxime Constituent of the Substance may be longer in soil than suggested by the hydrolysis results in pure water.

You commented that there is no exposure of soil due to the uses of the Substance, and hence, you have waived the soil simulation testing in your registration dossier referring to the point 9.2.1.3, column 2 of Annex IX to REACH. As indicated in section 1.2, ECHA highlights that according to the ECHA Guidance Section R.11.4.1.1.1, page 44 (Version 3.0, June 2017), in the persistence assessment, a conclusion needs to be derived for all environmental compartments. The specific concern for persistency is normally present for the environmental compartment for which the P/vP criteria are most likely to be met. Exclusion of certain environmental compartments from the P/vP assessment based on absence of exposure may be acceptable only in very exceptional cases and upon justification. ECHA concludes that based on the available information, exposure of environment, including soil, cannot be excluded.
As indicated in sections 1.1 and 1.2, based on the available data on hydrolysis and considering the physico-chemical properties of the Substance, soil seems to be the environmental compartment where the persistence is most likely to be the highest. Therefore, the requested soil simulation test is necessary in order to conclude on the potential persistency of the Substance.

The OECD TG 307, including the identification of the transformation and/or degradation products, is a standard information requirement at Annex IX, Section 9.2.1.2 of REACH. It could also be a requirement for concluding your PBT assessment according to Annex XIII, Section 2.1 of REACH and could be requested in compliance check under Article 41 of REACH. However, since the information request is based on a potential risk identified for the Trioxime Constituent of the Substance and since the requested test deviates from the standard test design, the substance evaluation is an appropiate process in the present case.

b) Specification of the requested study

Test material and concentration

The test must be performed using the Propan-2-one-O,O',O''-(vinylsilantriyl)trioxime (CAS RN 54948-34-4) constituent of the Substance with ^{14}C-radiolabelling. The radiolabelling must be at the most stable part of the molecule.
You must use a test concentration that is appropriate to also successfully identify and quantify possibly formed transformation and/or degradation products.

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Test temperature

The test must be performed at 12°C to represent the average environmental temperature for the EU.

Test vessel

You must use biometer type test flasks to minimise volatile losses of the test material, and therefore, avoid losses from the test system. Such losses would reduce the recovery rate and impede degradation measurement.

Soil selection

As indicated above, there is a concern that adsorption to particulate matter could possibly slow down or prevent hydrolysis of the Substance. Soils with high organic matter content have higher adsorption capacity, and hence, could potentially represent a worst-case scenario for abiotic hydrolysis. In the OECD TG 307 it is recommended to use a soil with organic carbon content in the range of 0.5-2.5% to determine the transformation pathway and variable organic carbon contents in the additional three soils used to determine transformation rate. In the OECD TG 307 and in the Final Report of the OECD Workshop on Selection of Soils/Sediments (OECD, 1995), referenced in the OECD TG 307, no ranges for organic carbon content are defined for the three additional soils. However, in the Workshop report (OECD, 1995), for soil adsorption/desorption studies seven soils with varying organic carbon content (and other characteristics) are recommended, and the highest organic carbon content range for these soils is > 10%.
Therefore, as per the OECD TG 307 at least four different representative soils varying in their organic carbon content (and other characteristics mentioned in the guideline) should be tested, and you must include at least one soil with high (i.e. > 10%) organic carbon content in the requested simulation study.

Identification of transformation and/or degradation products

Transformation and/or degradation products must be identified and quantified at every sampling time.

Mass balance and quantification of NER

A mass balance calculation must be included in the test. 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. By default, the 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, Chapter R.11). 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].

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

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Sterile controls

Sterile soil 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. volatilization, formation of NER). In addition, as the Substance is known to undergo abiotic hydrolysis in pure water and as adsorption to soil may decrease the rate of hydrolysis, the sterile controls will be useful for estimating the rates of abiotic hydrolysis in the studied soils.

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 test bottles, to ensure comparability.

The OECD TG 307 includes instructions for a sterile control but do not include specific advice on soil sterilization methods. The OECD TG 307 refers to two references for soil sterilization methods (OECD 1993, [redacted] 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 sterilization method strongly depends on the type of study or research questions being asked. For degradation experiments, gamma-sterilized soils are better suited than autoclaving as control soils, because they are physically and chemically less altered by the process of sterilization.

Lees et al (2018) assessed autoclaving, gamma irradiation, and sodium azide as soil sterilization methods for use in adsorption/desorption studies. They reported that autoclaving destroyed the soil structure, therefore potentially affecting its sorption behaviour and 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. It was concluded by Lees et al (2018) that gamma irradiation was the best available method for sterilising soils in preparation for sorption-desorption experiments, but the authors also advocate for a case-by-case basis approach for choosing the best sterilization in other soil types.

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 307 indicates that the microbial biomass must be measured initially, during and at the end of the aerobic studies and mentions methods for that. 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.

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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 for the soil simulation study with the constituent Propan-2-one-O,O',O''-(vinylsilantriyl)trioxime (CAS RN 54948-34-4) is:

- Appropriate, because the test is suitable and necessary to obtain information which will allow clarifying whether the Trioxime Constituent of the Substance has a half-life in soil which fulfils the REACH Annex XIII P or vP criteria and whether transformation and/or degradation products having potential PBT/vPvB properties, are formed under environmental 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 Request A.2 (Bioaccumulation in fish)

a) Aim of the study

As explained in section 1.1., no information is available on the bioaccumulation of the Substance or its constituents. Due to rapid hydrolysis, testing on bioaccumulation was waived for the Substance by you.

However, if the results from the Request A.1 demonstrate that the Trioxime Constituent of the Substance fulfils the criteria for Persistency (P) or very Persistency (vP) according to REACH Annex XIII, the bioaccumulation in fish test is requested in order to obtain a dietary biomagnification factor (BMF), tentative bioconcentration factors (BCFs) and other relevant data to assess the bioaccumulation potential of the Trioxime Constituent of the Substance and to conclude on the potential hazards.

The OECD TG 305 is a standard information requirement at Annex IX, Section 9.3.2 of REACH. It could also be a requirement for concluding your PBT assessment according to Annex XIII, Section 2.1 of REACH and could be requested in compliance check under Article 41 of REACH. However, since the information request is based on a potential risk identified for the Trioxime Constituent of the Substance the substance evaluation is an appropiate process in the present case.

b) Specification of the requested study

The bioaccumulation in fish study under dietary exposure must be conducted following the OECD TG 305. Determination of BMF and tentative BCF values are required to be included in the study. As described in the OECD TG 305, growth corrected and lipid normalised BMF and tentative BCFs must be determined. Identification and quantification of major

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metabolites must be performed.

Exposure route

The Substance and its constituents hydrolyse totally in less than 1 hour. If the Trioxime Constituent of the Substance fulfils the P/vP criteria, this could be an indication that adsorbed Substance has a lower hydrolysis rate and slows the degradation in a significant way. Therefore, significant exposure of fish to the Trioxime Constituent from water is not likely but potential bioaccumulation via dietary exposure route would thus be possible. Hence, the dietary exposure route must be used in the requested OECD TG 305 test.

Test material and concentration

The test must be prerformed using the Propan-2-one-O,O',O''-(vinylsilantriyl)trioxime (CAS RN 54948-34-4) constituent of the Substance with ^{14}C-radiolabelling. The radiolabelling must be at the most stable part of the molecule.
A test concentration appropriate to also successfully identify and quantify possibly formed major metabolites (as indicated in the OECD TG 305 paragraphs 151 and 65) must be used. However, it is important to make sure that the uptake of the applied doses is as complete as possible. For example potential crystallisation of the test material in the spiked food can reduce its bioavailability and must be avoided. Therefore, when selecting the test concentration and spiking method you must ensure that a homogenous distribution of the test material in the food is obtained. Paragraph 119 of OECD TG 305 provides some advice about possible solutions for spiking the test substance to the food.

It is also recommended to follow the instructions on spiking included in section 4.2. of the OECD Guidance Document on Aspects of OECD TG 305 on Fish Bioaccumulation (Series on Testing and Assessment No. 264, OECD, 2017). Use of a reference substance is required to asses whether the food spiking technique is adequate as indicated in the paragraph 114 of the OECD TG 305. You must also provide a scientific justification of the used spiking procedure.

Furthermore, the Substance is susceptible to fast hydrolysis in water with a DT_{50} < 1 hour at different pH conditions and under ambient temperature.

Since the bioaccumulation test is only requested if the Trioxime Constituent of the Substance is previously confirmed to be P/vP based on the outcome of the requested soil simulation test (Request A1), it can be assumed that the adsorption of the Trioxime Constituent to soil impedes or slows down the hydrolysis and similar hindering of hydrolysis could be expected due to adsorption to the spiked food in the bioaccumulation test. However, it cannot be excluded that some hydrolysis of the spiked test material occurs when the food gets into contact with water.

Therefore, the stability of the test material concentration in food after the application of the food into the test medium must be reported, i.e. whether or not concentration losses occurred and if so how these losses were considered. This is necessary in order to ensure that a correct test material concentration is used in the calculation of the assimilation efficiency and BMF value. A similar approach as described in the section 4.3 of the OECD Guidance Document No. 264 (OECD, 2017) for assessing losses due to leaching from the food could be applied to assess potential losses due to hydrolysis.

Request for the full study report

You must submit the full study report which includes:

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- 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 of the Substance.

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

The request for the bioaccumulation study with the constituent Propan-2-one-O,O',O''-(vinylsilantriyl)trioxime (CAS RN 54948-34-4) is:

- Appropriate, because the test is suitable and necessary to obtain information which will allow clarifying whether the Trioxime Constituent of the Substance fulfils the Annex XIII to REACH, B or vB criteria;
- The least onerous measure , because there is no equally suitable alternative methodology available to obtain the information that would clarify the potential hazard.

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

Berns, A.E., Philipp, H., Narres, H.-D., Burauel, P., Vereecken, H. and Tappe, W. (2008), Effect of gamma-sterilization and autoclaving on soil organic matter structure as studied by solid state NMR, UV and fluorescence spectroscopy. European Journal of Soil Science, 59: 540-550. https://doi.org/10.1111/j.1365-2389.2008.01016.x

ECHA 2015. Member State Committee (MSC) Opinion on persistency and bioaccumulation of Octamethylcyclotetrasiloxane (D4) EC Number: 209-136-7 CAS Number: 556-67-2 And Decamethylcyclopentasiloxane (D5) EC Number: 208-764-9 CAS Number: 541-02-6 according to a MSC mandate Adopted on 22 April 2015.

Katherine Lees, Mark Fitzsimons, Jason Snape, Alan Tappin, Sean Comber. Soil sterilisation methods for use in OECD 106: How effective are they?, Chemosphere, Volume 209, 2018, Pages 61-67, ISSN 0045-6535, https://doi.org/10.1016/j.chemosphere.2018.06.073."

OECD 1995. Final Report of the OECD Workshop on Selection of Soils/Sediments. Belgirate, Italy, 18-20 January 1995.

OECD 2017. Guidance Document on Aspects of OECD TG 305 on Fish Bioaccumulation.

Series on Testing & Assessment No. 264. Environment Directorate, Organisation for Economic Co-operation and Development, OECD, Paris 2017

SPIN 2020. Record for the substance 2-Propanone, oxime, reaction products with ethenyltrimethoxysilane and trichloroethenylsilane (CAS RN 797751-44-1) in the SPIN Substances in Products in the Nordic Countries Database. Available at http://www.spin2000.net/spinmyphp/. (Accessed on 1 December 2020)

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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 suspected PBT/vPvB and exposure of environment, the Member State Committee agreed to include the Substance (EC number 458-680-3, CAS RN 797751-44-1) in the Community rolling action plan (CoRAP) to be evaluated in 2019. Spain 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.

- In the course of the evaluation, the evaluating MSCA identified an additional concern for the potential risk related to Carcinogenicity of the hydrolysis product acetone oxime (EC number 202-820-1).

- The evaluating MSCA completed its evaluation considering that further information is required to clarify the following concerns: suspected PBT/vPvB. Therefore, it submitted a draft decision (Article 46(1) of REACH) to ECHA on 27 February 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 requests were not amended.

(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 .

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.

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(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.

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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[5].

Test material

Before generating new data, you must agree within the joint submission on the chemical composition of the material to be tested (propan-2-one-O,O',O''-(vinylsilantriyl)trioxime (CAS 54948-34-4)) which must be relevant for all the registrants of the Substance.

1. *Selection of the Test material*
   The Test Material (propan-2-one-O,O',O''-(vinylsilantriyl)trioxime (CAS 54948-34-4), referred to as the "Trioxime Constituent of the Substance") 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*
   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"[6].

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