EUROPEAN CHEMICALS AGENCY

Helsinki, 19 July 2018

Addressee: [redacted]

Decision number: TPE-D-2114422682-53-01/F
Substance name: 3,3-bis[(dimethylvinylsilyl)oxy]-1,1,5,5-tetramethyl-1,5-divinyltrisiloxane
EC number: 262-061-1
CAS number: 60111-54-8
Registration number: [redacted]
Submission number: [redacted]
Submission date: 04/07/2017
Registered tonnage band: [redacted]

DECISION ON A TESTING PROPOSAL

Based on Article 40 of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA has taken the following decision.

Your following two testing proposals are accepted and you are requested to carry out:

1. **Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method: EU B.26./OECD TG 408) in rats using the registered substance.**

2. **Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EU B.31./OECD TG 414) in a first species (rats or rabbits), oral route using the registered substance.**

While your originally proposed tests for

- **Long-term toxicity on terrestrial invertebrates (Annex IX, Section 9.4.1., Column 2; test method: Earthworm reproduction test, OECD TG 222) using the analogue substances 2,4,6,8-tetramethyl-2,4,6,8-tetravinylcyclotetrasiloxane (CAS No 2554-06-5, EC No 219-863-1) and dodecamethylpentasiloxane (CAS No 141-63-9; EC No 205-492-2);**

- **Long-term toxicity testing on plants (Annex IX, Section 9.4.3., Column 2; test method: Terrestrial plants, growth test, OECD TG 208) using the analogue substances dodecamethylpentasiloxane (CAS No 141-63-9; EC No 205-492-2) and 2,4,6,8-tetramethyl-2,4,6,8-tetravinylcyclotetrasiloxane (CAS No 2554-06-5, EC No 219-863-1); and**

- **Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD TG 216) using the analogue substances octamethyltrisiloxane (CAS No 107-51-7; EC No 203-497-4) and decamethylcyclopentasiloxane (CAS No 541-02-6; EC No 208-764-9)**

are rejected, you are requested to perform:

3. **Long-term toxicity on terrestrial invertebrates (Annex IX, Section 9.4.1., Column 2; test method: Earthworm reproduction test, OECD TG 222) OR Long-term toxicity on terrestrial invertebrates (Annex X, Section 9.4.4.; test method: Enchytraeid reproduction test, OECD TG 220) OR Long-term toxicity on terrestrial invertebrates (Annex X, Section 9.4.4.; test method: Collembolan reproduction test in soil, OECD TG 232) using the registered substance.**

4. **Long-term toxicity testing on plants (Annex IX, Section 9.4.3., Column 2; test method: Terrestrial plants, growth test, OECD TG 208) using the registered substance.**

5. **Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD TG 216) using the registered substance.**

You may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring and conforming to the appropriate rules in the respective Annex, and an adequate and reliable documentation.

You are required to submit the requested information in an updated registration dossier by ***27 July 2020***. You shall also update the chemical safety report, where relevant.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2. Advice and further observations are provided in Appendix 3.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, shall be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under http://echa.europa.eu/regulations/appeals.

Authorised[1] by Ofelia Bercaru, Head of Unit, Evaluation E3

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

Appendix 1: Reasons

The decision of ECHA is based on the examination of the testing proposal(s) submitted by you for the registered substance Tetra(dimethylvinylsiloxy)silane, CAS No 60111-54-8 (EC No 262-061-1) (hereafter referred to as "target substance" or ViM4Q) and the submitted third party comments, taking into account an updated dossier (submission number [redacted]).

1. Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.)

a) Examination of the testing proposalPursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

A sub-chronic toxicity study (90 day) is a standard information requirement as laid down in Annex IX, Section 8.6.2. of the REACH Regulation. The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

You have submitted a testing proposal for a sub-chronic toxicity study (90 day) in rats by the oral route according to EU B.26/OECD TG 408.

ECHA notes that in the updated dossier you provided your considerations for alternative methods to fulfil the information requirement for Sub-chronic toxicity (90-day): oral. You concluded that there were no alternative methods which could be used to adapt the information requirement(s) for which testing is proposed. ECHA has taken these considerations into account.

You proposed testing by the oral route. Based on the information provided in the technical dossier and/or in the chemical safety report, ECHA agrees that the oral route - which is the preferred one as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 6.0, July 2017) Chapter R.7a, section R.7.5.4.3.2 - is the most appropriate route of administration. More specifically, the substance is a liquid of very low vapour pressure and no uses with spray application are reported that could potentially lead to aerosols of inhalable size.

Therefore, ECHA considers that the proposed study performed by the oral route with the registered substance is appropriate to fulfil the information requirement of Annex IX, Section 8.6.2. of the REACH Regulation.

Hence, the test shall be performed by the oral route using the test method EU B.26./OECD TG 408.

You proposed testing in rats. According to the test method EU B.26/OECD TG 408 the rat is the preferred species. ECHA considers this species as being appropriate and testing should be performed with the rat.

b) Consideration of the information received during third party consultation

ECHA received third party information concerning the testing proposal during the third party consultation. For the reasons explained further below the information provided by third parties is not sufficient to fulfil this information requirement.

A third party has indicated that : *"The substance seems to display a low toxicity profile. Repeated dose and reproductive toxicity data are not available but the chemical proved to be practically non-toxic in acute and local tests. These findings combined with the physico-chemical properties (insolubility in water, log Pow of 9, molecular weight of 433) raise the possibility that the substance may not be significantly absorbed from the gastro-intestinal tract, and consequently systemic exposure is low. We therefore suggest the conduct of in vitro bioavailability studies which may provide data on toxicokinetics and help to make an informed decision on the need of the proposed oral sub-chronic toxicity study."*

ECHA notes that it is your responsibility to consider and justify in the registration dossier any adaptation of the information requirements in accordance with Annex IX, Section 8.6.2., column 2, fourth indent. This adaptation specifies that a sub-chronic toxicity study (90-day) does not need to be conducted if "*the substance is unreactive, insoluble and not inhalable and there is no evidence of absorption and no evidence of toxicity in a 28-day study, particularly if such a pattern is coupled with limited human exposure*". ECHA notes that all criteria need to be met.

ECHA observes that the third party comment addressed only the criterion concerning absorption. However, the third party did not provide sufficient evidence of no absorption. Furthermore, an adaptation would also need to demonstrate that the other conditions of the adaptation possibility are fulfilled.

Therefore the criteria listed in Column 2 of Annex IX, section 8.6.2., fourth indent are not met and the information requirement for the sub-chronic toxicity study (90-day) cannot be adapted on this basis.

c) Outcome

In your comments to the draft decision, you did not provide considerations to this specific endpoint.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed study with the registered substance subject to the present decision: Sub-chronic toxicity study (90-day) in rats, oral route (test method: EU B.26/OECD TG 408).

Notes for your consideration

ECHA notes that a revised version of OECD TG 408 was adopted this year by the OECD. This revised version contains enhancements of certain endocrine disrupting relevant parameters. You should test in accordance with the revised version of the guideline as published on the OECD website for adopted test guidelines (https://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals-section-4-health-effects_20745788).

2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.) in a first species

a) Examination of the testing proposal

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

A pre-natal developmental toxicity study for a first species is a standard information requirement as laid down in Annex IX, Section 8.7.2. of the REACH Regulation. The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

You have submitted a testing proposal for a pre-natal developmental toxicity study in rats according to EU B.31/OECD TG 414.

ECHA notes that in the updated dossier you provided your considerations for alternative methods to fulfil the information requirement for Reproductive toxicity (pre-natal developmental toxicity). You concluded that there were no alternative methods which could be used to adapt the information requirement(s) for which testing is proposed. ECHA has taken these considerations into account.

ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 8.7.2. of the REACH Regulation.

According to the test method EU B.31/OECD TG 414, the rat is the preferred rodent species and the rabbit the preferred non-rodent species. On the basis of this default consideration, ECHA considers testing should be performed with rats or rabbits as a first species.

You did not specify the route for testing.

ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 6.0, July 2017) R.7a, chapter R.7.6.2.3.2. Since the substance to be tested is a liquid, ECHA concludes that testing should be performed by the oral route.

b) Consideration of the information received during third party consultation

ECHA received third party information concerning the testing proposal during the third party consultation. For the reasons explained further below the information provided by third parties is not sufficient to fulfil this information requirement.

A third party has indicated that *the substance "seems to display a low toxicity profile. Repeated dose and reproductive toxicity data are not available but the chemical proved to be practically non-toxic in acute and local tests. These findings combined with the physico-chemical properties (insolubility in water, log Pow of 9, molecular weight of 433) raise the possibility that the substance may not be significantly absorbed from the gastro-intestinal tract, and consequently systemic exposure is low. We therefore suggest the conduct of in vitro bioavailability studies which may provide data on toxicokinetics and help to make an informed decision on the need of the proposed pre-natal developmental toxicity study".*

ECHA notes that it is your responsibility to consider and justify in the registration dossier any adaptation of the information requirements in accordance with Annex IX, Section 8.7., column 2, third indent. This adaptation specifies that a pre-natal developmental toxicity study does not need to be conducted if "the substance is of low toxicological activity (no evidence of toxicity seen in any of the tests available), it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure (e.g. plasma/blood concentrations below detection limit using a sensitive method and absence of the substance

and of metabolites of the substance in urine, bile or exhaled air) and there is no or no significant human exposure." ECHA notes that all three criteria need to be met.

ECHA observes that the third party comment addressed only the criterion concerning absorption. However, the third party did not prove that no systemic absorption occurs via relevant routes of exposure. Furthermore, an adaptation would also need to demonstrate that the other conditions of the adaptation possibility are fulfilled.

Consequently the criteria listed in column 2 of Annex IX, Section 8.7., third indent are not met and the information requirement for the pre-natal developmental toxicity study cannot be adapted on this basis.

c) Outcome

In your comments to the draft decision, you did not provide considerations to this specific endpoint.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed study with the registered substance subject to the present decision: Pre-natal developmental toxicity study in a first species (rats or rabbits), oral route (test method: EU B.31/OECD TG 414).

Notes for your consideration

For the selection of the appropriate species you are advised to consult ECHA *Guidance on information requirements and chemical safety assessment* R.7a, chapter R.7.6.2.3.2 (version 6.0, July 2017).

ECHA notes that a revised version of OECD TG 414 was adopted this year by the OECD. This revised version contains enhancements of certain endocrine disrupting relevant parameters. You should test in accordance with the revised version of the guideline as published on the OECD website for adopted test guidelines (https://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals-section-4-health-effects_20745788).

3. Long-term toxicity to terrestrial invertebrates (Annex IX, Section 9.4.1., column 2)

Pursuant to Article 40(3)(d) and (c) of the REACH Regulation, ECHA may reject a proposed test and require the Registrant to carry out other tests in cases of non-compliance of the testing proposal with Annexes IX, X or XI.

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX, Section 9.4. of the REACH Regulation. The Registrant must address the standard information requirements set out in Annex IX, Section 9.4., for different taxonomic groups: short-term toxicity testing on invertebrates (Annex IX, Section 9.4.1.), effects on soil micro-organisms (Annex IX, Section 9.4.2.), and short-term toxicity testing on plants (Annex IX, Section 9.4.3.). Furthermore, Annex IX, Section 9.4., column 2 specifies that long-term toxicity testing shall be considered by the Registrant instead of short-term, in particular for substances that have a high potential to adsorb to soil or that are very persistent.

According to Section R.7.11.5.3., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, June 2017), substances that have a log K_{ow}/K_{oc} >5 are considered highly adsorptive, in soil. According to the evidence presented within the Registration dossier, the substance has a high potential to adsorb to soil . Therefore ECHA agrees that a need for long-term testing is indicated.

The information on "long-term toxicity to invertebrates" is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements.

In your dossier with submission number [redacted], based on which the initial draft decision was prepared, you have submitted two testing proposals for a long-term toxicity test to invertebrates (*Earthworm Reproduction Test (Eisenia fetida/Eisenia andrei), OECD TG 222)* with the following justification: (TP 1) *"An earthworm reproduction study is planned for the related test substance 2,4,6,8-tetramethyl-2,4,6,8-tetravinylcyclotetrasiloxane (Vi4D4, CAS 2554-06-5, EC 219-863-1) . The registrant plans to read across the results of this study to 3,3-bis[(dimethylvinylsilyl)oxy]-1,1,5,5-tetramethyl-1,5-divinyltrisiloxane (ViM4Q). Justification for planned read-across is given in the Endpoint Summary for Ecotoxicological information"* and (TP 2) *"An earthworm reproduction study is planned for the related test substance dodecamethylpentasiloxane (L5, CAS 141-63-9, EC 205-492-2). The registrant plans to read across the results of this study to 3,3-bis[(dimethylvinylsilyl)oxy]-1,1,5,5-tetramethyl-1,5-divinyltrisiloxane (ViM4Q). Justification for planned read-across is given in the Endpoint Summary for Ecotoxicological information."*

ECHA has evaluated your proposal to perform the test with the analogue substances 2,4,6,8-tetramethyl-2,4,6,8-tetravinylcyclotetrasiloxane (Vi4-D4, CAS No 2554-06-5, EC No 219-863-1) and dodecamethylpentasiloxane (L5, CAS No 141-63-9; EC No 205-492-2) and concluded that you did not provide adequate and reliable information to demonstrate that the proposed read-across approach is plausible for the endpoint in consideration. Consequently the testing proposed on the read-across substances was rejected and ECHA requested you to perform an Earthworm reproduction test (OECD TG222) with the registered substance.

The major reasons for rejecting the read-across approach as proposed in the dossier with the submission number [redacted] have been thoroughly addressed in the initial draft decision and are briefly summarised below. Based on the provided data, the read-across hypothesis and justification, ECHA concluded that you did not sufficiently demonstrate

- that the differences in structures and different physicochemical properties would not impact the possibility to predict the properties of the target substance from the data obtained with the source substances;
- that the substances would behave similarly in soil and their fate in both the aquatic and the terrestrial environments would be similar;
- that their bioavailability and thus their toxic potential is similar
- and due to lack of relevant ecotoxicity data did not show that the ecotoxic potential of the substances is in the same range.

In your comments to the draft decision you did not provide considerations to the specific endpoint, subject to the current decision.

After receiving the draft decision you updated your registration with the submission number [redacted].

In your updated dossier you have attempted to adapt the current information requirements using new arguments, all based on existing information. You argue that:

"A stability test under OECD TG 222 conditions with the related substance L3 demonstrated significant loss of test item from the test system. ViM4Q has a higher air-soil partition coefficient than L3, and consequently is expected to behave similarly in soil. Additionally, in OECD TG 216 (Soil Microorganisms: Nitrogen Transformation Test) for the effects of the related substances L2 and L3 on nitrate formation rate of soil microflora, analysis of the test substance concentrations show that test material was lost by day three of the test (see Section 6.3.4). Based on these experimental findings, the registrants believe it is not technically feasible to conduct an OECD TG 222 test for the registration substance on the basis that the test substance is too volatile to maintain adequate concentrations in the test system."

In the Endpoint Summaries of IUCLID 6.3.1. and 6.3 you discuss further the potential feasibility of conducting terrestrial studies with the registered substance, ViM4Q, due to its physicochemical properties and due to its similarities with octamethyltrisiloxane (L3; EC No 203-497-4; CAS No 107-51-7) which has been shown to be unstable in a stability test conducted under OECD TG 222 test conditions without test organisms (stability test submitted as an ESR in IUCLID 6.3.1). You also refer to results from OECD 216 soil microorganisms studies on L3 and another analogue, L2 (hexamethyldisiloxane; CAS No 107-46-0; EC No 203-492-7), where issues with test material stability were identified (ESRs submitted under IUCLID 6.3.4.). You indicate that "*it is considered valid to read-across the results of the soil stability study with L3*" due to both having a Kair-soil value of above 1 and that "*ViM4Q has a higher air-soil partition coefficient that L3*". You acknowledge that "*Although the vapour pressure for this substance is quite low (<10 Pa at 25°C), the substance is very poorly water soluble (<1.0E-05 mg/l (<10 ng/l) at 20°C). Therefore the behaviour of this substance in the soil test systems is expected to be similar to L2 and L3, i.e. losses due to volatilisation would be expected*". You indicate that the registered substance and the source substances are "*structurally related*".

ECHA notes that in your new adaptation you refer to several points and ECHA addresses them below.

Firstly, you claim that based on the physicochemical properties of the registered substance testing is techinically not feasible. According to the OECD TG 222 guideline (paragraph 5) the method may not "*be applicable to substances for which the air/soil partition coefficient is greater than one, or to substances with vapour pressure exceeding 300 Pa at 25°C*". You have reported that the registered substance has a vapour pressure of < 10 Pa and a Kair/soil value of 2.3 (given in the CSR). However, ECHA considers the Kair-soil value you provided as not reliable for the following reasons:

You have calculated Kair-soil value using the approach given in ECHA guidance on information requirements and chemical safety assessment (Chapter R. 16., version 3, February 2016). As input values on partitioning (Kow, Koc) you indicated a Log Kow value of 9 and a Log Koc value of 6 based on QSAR predictions. However, ECHA has compared the QSAR information provided for Log Kow and Log Koc with the requirements set in the general rules for adaptation of the information requirements by Qualitative or Quantitative structure-activity relationship, (Q)SAR (Annex XI, section 1.3). and concludes that it does not fulfil those requirements. Specifically: For the model predicting Koc, you state in the QMRF that "*There were insufficient data points of sufficient quality to allow the splitting of the data into training and test sets*". Since no external validation for the Koc model is

provided, appropriate measures of predictivity have not been provided and the Koc model cannot be considered scientifically valid. In addition, both the Kow and Koc predictions are outside the parametric and structural domains of the models since silane compounds with a vinyl substituent, such as the registered substance, are not covered by the models. The predicted values are also higher than the maximum values of the parametric domains (LogKow domain: -04 to 9.4; predicted logKow of 11, logKoc domain log Koc: 1.09 – 5.26, predicted logKoc 6). Lastly, while the predicted Log Kow value is 11, you have used logKow of 9 as an input value for the prediction of logKoc. Therefore, the values predicted are not reliable and are likely underestimates of the true values.

Therefore, the QSAR information submitted for Log Kow and Log Koc cannot be considered valid.

Consequently, the Kair-soil used as the basis of your claim is also not reliable and thus cannot be used to justify that ViM4Q has a Kair-soil of above 1 and that testing is not feasible. In contrast, ECHA notes that the predicted logKoc is likely an underestimation of the true adsorption potential, and therefore the Kair-soil is likely overpredicted by the use of these model predictions.

Secondly, you refer to existing terrestrial data on L2 and L3 where the test material was shown to be unstable in soil. You consider that also the registered substance would be unstable in soils due to structural and physicochemical similarity to the two substances. With regards to your claim of the registered substance, L3 and L2 having similar structural and physicochemical properties ECHA notes that structural and physico-chemical similarity does not necessarily lead to predictable or similar environmental behaviour of the substances and are not per se sufficient to enable the prediction of environmental behaviour of a substance. Furthermore, there are obvious structural differences not addressed by you in your justification and the physicochemical properties of the substances are not similar. The properties are indeed very different (specifically vapour pressure and partitioning, that are relevant for terrestrial testing), as also identified by you and quoted above. Therefore, no prediction of relevant properties of the registered substance is possible based on data on L2 and L3.

In summary, ECHA considers that your claim that *"it is not technically feasible to conduct an OECD TG 222 test for the registration substance on the basis that the test substance is too volatile to maintain adequate concentrations in the test system"* is not justified based on the physicochemical properties of the registered substance.

ECHA concludes that your new arguments do not provide any valid information to fulfil or waive the information requirement of "long-term toxicity to terrestrial invertebrates" for the registered substance and it is necessary to provide information for this endpoint.

ECHA notes that the earthworm reproduction test (OECD TG 222) or Enchytraeid reproduction test (OECD TG 220) or Collembolan reproduction test in soil (OECD TG 232) are considered capable of generating information appropriate for the fulfilment of the information requirements for long-term toxicity testing to terrestrial invertebrates. ECHA is not in a position to determine the most appropriate test guideline/method, since this decision is dependent upon species sensitivity and substance properties. You are to apply the most appropriate and suitable test guideline among those listed above. However ECHA notes that when log Kow >5 and log Koc >4, as with the registered substance, the test OECD TG 232 may not be the most appropriate test guideline/method as the dominant route of exposure for Collembolans is via pore water.

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, you are requested to carry out one of the following studies with the registered substance: the Earthworm reproduction test (OECD TG 222) or Enchytraeid reproduction test (OECD TG 220) or Collembolan reproduction test in soil (OECD TG 232) with the registered substance while your originally proposed Earthworm reproduction test (OECD TG 222), using analogue substances 2,4,6,8-tetramethyl-2,4,6,8-tetravinylcyclotetrasiloxane (Vi4-D4, CAS No 2554-06-5, EC No 219-863-1) and dodecamethylpentasiloxane (L5, CAS No 141-63-9; EC No 205-492-2) are rejected according to Article 40(3)(d) of the REACH Regulation.

4. Long-term toxicity to terrestrial plants (Annex IX, Section 9.4.3., column 2)

Pursuant to Article 40(3)(d) and (c) of the REACH Regulation, ECHA may reject a proposed test and require the Registrant to carry out other tests in cases of non-compliance of the testing proposal with Annexes IX, X or XI.

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX, Section 9.4. of the REACH Regulation. The Registrant must address the standard information requirements set out in Annex IX, Section 9.4., for different taxonomic groups: short-term toxicity testing on invertebrates (Annex IX, Section 9.4.1.), effects on soil micro-organisms (Annex IX, Section 9.4.2.), and short-term toxicity testing on plants (Annex IX, Section 9.4.3.). Furthermore, Annex IX, Section 9.4., column 2 specifies that long-term toxicity testing shall be considered by the Registrant instead of short-term, in particular for substances that have a high potential to adsorb to soil or that are very persistent.

According to Section R.7.11.5.3., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), substances that have a log K_{ow}/K_{oc} >5 are considered highly adsorptive, in soil. According to the evidence presented within the Registration dossier, the substance has a high potential to adsorb to soil. Therefore ECHA agrees that a need for long-term testing is indicated.

The information on "long-term toxicity to plants" is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements.

In your dossier with submission number [redacted], based on which the initial draft decision was prepared, you have submitted two testing proposals for long-term toxicity test to plants (*Terrestrial Plants Test: Seedling Emergence and Seedling Growth Test* OECD TG 208) with the following justifications: (TP 1) "*A Terrestrial plants study is planned for the related test substance dodecamethylpentasiloxane (L5, CAS 141-63-9). The registrant plans to read across the results of this study to 3,3-bis[(dimethylvinylsilyl)oxy]-1,1,5,5-tetramethyl-1,5-divinyltrisiloxane (ViM4Q). Justification for planned read-across is given in the Endpoint Summary for Ecotoxicological information*" and (TP 2) "*A terrestrial plants study is planned for the related test substance 2,4,6,8-tetramethyl-2,4,6,8-tetravinylcyclotetrasiloxane (Vi4D4). The registrant plans to read across the results of this study to 3,3-bis[(dimethylvinylsilyl)oxy]-1,1,5,5-tetramethyl-1,5-divinyltrisiloxane (ViM4Q). Justification for planned read-across is given in the Endpoint Summary for Ecotoxicological information*".

ECHA has evaluated your proposal to perform the test with the analogue substances dodecamethylpentasiloxane (L5, CAS No 141-63-9; EC No 205-492-2) and 2,4,6,8-tetramethyl-2,4,6,8-tetravinylcyclotetrasiloxane (Vi4D4, CAS No 2554-06-5, EC No 219-863-1)and concluded that you did not provide adequate and reliable information to demonstrate that the proposed read-across approach is plausible for the endpoint in consideration. Consequently the testing proposed on the read-across substances was rejected and ECHA requested you to perform Terrestrial plants, growth test (OECD 208)with the registered substance.

The major reasons for rejecting the read-across approach as proposed in the dossier with the submission number [redacted] have been thoroughly addressed in the initial draft decision and briefly summarised in request 3 above.

In your comments to the draft decision you did not provide considerations to the specific endpoint, subject to the current decision.

After receiving the draft decision you updated your registration with the submission number [redacted].
In your updated dossier you have attempted to adapt the current information requirements using a new arguments, all based on existing information. You argue that:

"Soil stability studies using the source substances L2 and L3 under test conditions relevant to this endpoint have demonstrated that the test substance is likely to be too volatile to maintain adequate concentrations in the test system. This is demonstrated by recoveries of the related substance L2 <LOQ by day 3 of the OECD TG 216 test (please refer to Section 6.3.3) and also very poor recoveries in a stability / recovery pre-test with the related substance L3 under conditions of OECD TG 222 (please refer to Section 6.3.1) . ViM4Q has a higher air-soil partition coefficient than L3, therefore testing in accordance with OECD TG 208 or similar guidelines to fulfil this REACH endpoint can be expected to show similar volatilisation losses, meaning that test organisms cannot be exposed to test material for long enough or at high enough concentrations to assess its toxicity. Testing of this endpoint is therefore waived because the study is technically not feasible."

As fully discussed in request 3. above, in the Endpoint Summary of IUCLID 6.3. you provide further argument on why terrestrial testing is not feasible due to substance stability issues. However, for the reasons given in request 3. above, ECHA considers it not justified to adapt the terrestrial testing requirements based on the physicochemical properties of the registered substance. In addition to the general discussion, ECHA notes that you have provided no specific considerations as to why testing in the set up of the standard terrestrial plant test (OECD TG 208) would not be possible. ECHA notes also that while the limitation of testing substances with vapour pressure of above 300 and of Kair-soil of above 1 is given in the OECD TG 222, no such specific limits for infeasibility of testing due to volatility of the substance are provided in the OECD TG 208.

In summary, ECHA considers that your claim that testing of terrestrial plants is not feasible due to issues with the stability of the substance is not justified.

ECHA concludes that your new arguments do not provide any valid information to fulfil or waive the information requirement of "long-term toxicity to plants" for the registered substance and it is necessary to provide information for this endpoint.

OECD guideline 208 (Terrestrial plants, growth test) considers the need to select the number of test species according to relevant regulatory requirements, and the need for a reasonably broad selection of species to account for interspecies sensitivity distribution. For long-term toxicity testing, ECHA considers six species as the minimum to achieve a reasonably broad selection. Testing shall be conducted with species from different families, as a minimum with two monocotyledonous species and four dicotyledonous species, selected according to the criteria indicated in the OECD TG 208 guideline. You should consider if testing on additional species is required to cover the information requirement.

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, you are requested to carry out the study with the registered substance: Terrestrial plants, growth test (test method: OECD TG 208), with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species). while your originally proposed Terrestrial plants, growth test (test method: OECD TG 208), using analogue substances dodecamethylpentasiloxane (L5, CAS No 141-63-9; EC No 205-492-2) and 2,4,6,8-tetramethyl-2,4,6,8-tetravinylcyclotetrasiloxane (Vi4D4, CAS No 2554-06-5, EC No 219-863-1) are rejected according to Article 40(3)(d) of the REACH Regulation.

5. Effects on soil micro-organisms (Annex IX, Section 9.4.2.)

Pursuant to Article 40(3)(d) and (c) of the REACH Regulation, ECHA may reject a proposed test and require the Registrant to carry out other tests in cases of non-compliance of the testing proposal with Annexes IX, X or XI.

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX, Section 9.4. of the REACH Regulation. The Registrant must address the standard information requirements set out in Annex IX, Section 9.4., for different taxonomic groups: short-term toxicity testing on invertebrates (Annex IX, Section 9.4.1.), effects on soil micro-organisms (Annex IX, Section 9.4.2.), and short-term toxicity testing on plants (Annex IX, Section 9.4.3.).

The information on "effects on soil micro-organisms" is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

In your dossier with submission number [redacted], based on which the initial draft decision was prepared, you have submitted two testing proposals to study the effects on soil micro-organisms (*Soil Microorganisms: Nitrogen Transformation Test*, OECD TG 216) with the following justifications: (TP 1) "*A soil microorganisms study is planned for the related test substance octamethyltrisiloxane (CAS 107-51-7; EC 203-497-4). Should no toxicity be observed in this test, no microbial assay with 3,3-bis[(dimethylvinylsilyl)oxy]-1,1,5,5-tetramethyl-1,5-divinyltrisiloxane (ViM4Q) will be proposed. The approach will be reconsidered once the relevant stability and toxicity studies are complete*" and (TP 2) "*A soil microorganisms study is planned for the related test substance decamethylcyclopentasiloxane (CAS 541-02-6; EC 208-764-9). Should no toxicity be observed in this test, no microbial assay with 3,3-bis[(dimethylvinylsilyl)oxy]-1,1,5,5-tetramethyl-1,5-divinyltrisiloxane (ViM4Q) will be proposed. The approach will be reconsidered once the relevant stability and toxicity studies are complete..*

ECHA has evaluated your proposal to perform the test with the analogue substances octamethyltrisiloxane (L3, CAS No 107-51-7; EC No 203-497-4) and decamethylcyclopentasiloxane (D5, CAS No 541-02-6; EC No 208-764-9) and concluded that you did not provide adequate and reliable information to demonstrate that the proposed read-across approach is plausible for the endpoint in consideration. Consequently the testing proposed on the read-across substances was rejected and ECHA requested you to perform Soil microorganisms: nitrogen transformation test (EU C.21/OECD TG 216) with the registered substance.

The major reasons for rejecting the read-across approach as proposed in the dossier with the submission number [redacted] have been thoroughly addressed in the initial draft decision and briefly summarised in request 3 above.

In your comments to the draft decision you did not provide considerations to the specific endpoint, subject to the current decision.

After receiving the draft decision you updated your registration with the submission number [redacted].

In your updated dossier you have attempted to adapt the current information requirements using a new arguments, all based on existing information. You argue that:
"OECD TG 216 (Soil Microorganisms: Nitrogen Transformation Test) for the effects of the related substances L2 and L3 on nitrate formation rate of soil microflora, analysis of the test substance concentrations show that test material was lost by day three of the test. Additionally, as discussed in Section 6.3.1 a stability test under OECD TG 222 conditions with the related substance L3 demonstrated significant loss of test item from the test system. ViM4Q has a higher air-soil partition coefficient than L3, meaning that similar losses from the test system would be expected under equivalent test conditions. Based on these experimental findings, the registrants believe it is not technically feasible to conduct an OECD TG 222 test for the registration substance on the basis that the test substance is too volatile to maintain adequate concentrations in the test system".

As fully discussed in request 3. above, in the Endpoint Summary of IUCLID 6.3. you provide further argument on why terrestrial testing is not feasible due to substance stability issues. However, for the reasons given in request 3. above, ECHA considers it not justified to adapt the terrestrial testing requirements based on the physicochemical properties of the registered substance.

ECHA concludes that your new arguments do not provide any valid information to fulfil or waive the information requirement of "Effects on terrestrial organisms" for the registered substance and it is necessary to provide information for this endpoint.

To address this endpoint, either a nitrogen transformation test (test method: EU C.21/OECD TG 216) or a carbon transformation test (test method: EU C.22/OECD TG 217) could be performed. According to Section R.7.11.3.1, Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), ECHA considers the nitrogen transformation test (EU C.21/OECD TG 216) suitable for non-agrochemicals. For agrochemicals the carbon transformation test (EU: C.22/OECD TG 217) is also required.

ECHA notes that no agrochemical uses have been identified for this substance in the technical dossier. Therefore, the proposed test *Soil Microorganisms: Nitrogen Transformation Test*, OECD TG 216 is suitable to address the information requirement of Annex IX, section 9.4.2.

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, you are requested to carry out the study with the registered substance: Soil microorganisms: nitrogen transformation test (EU C.21/OECD TG 216). while your originally proposed Soil microorganisms: nitrogen transformation test (EU C.21/OECD TG 216), using analogue substances octamethyltrisiloxane (L3, CAS No 107-51-7; EC No 203-497-4) and decamethylcyclopentasiloxane (D5, CAS No 541-02-6; EC No 208-764-9) are rejected according to Article 40(3)(d) of the REACH Regulation.

Appendix 2: Procedural history

ECHA received your registration containing the testing proposals for examination pursuant to Article 40(1) on 12 May 2014.

ECHA held a third party consultation for the testing proposals from 16 October 2014 until 1 December 2014. ECHA received information from third parties (see Appendix 1).

ECHA notified you of the draft decision and invited you to provide comments.

You were notified that the draft decision does not take into account any updates after 11 July 2016, 30 calendar days after the end of the commenting period. However, following your request and justification provided (including interlinked read-across testing strategy on several supposedly related registered substances), ECHA has exceptionally granted you additional time until 30 June 2017 for the update of the IUCLID dossier.

You submitted an updated dossier on 20 June 2017, which failed completeness check, and then successfully resubmitted it on 4 July 2017. ECHA took information in the updated dossier into account and modified the draft decision.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

As no amendments were proposed, ECHA took the decision according to Article 51(3) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. This decision does not imply that the information provided in your registration dossier is in compliance with the REACH requirements. The decision does not prevent ECHA from initiating a compliance check on the registration at a later stage.

2. Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the Enforcement Authorities of the Member States.

3. In relation to the information required by the present decision, the sample of the substance used for the new test(s) must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is suitable to fulfil the information requirement for the range of substance compositions manufactured or imported by the joint registrants. It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition. In addition, it is important to ensure that the particular sample of the substance tested in the new test(s) is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured or imported by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new test(s) must be suitable to assess these grades. Finally there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the test(s) to be assessed.