ECHA
EUROPEAN CHEMICALS AGENCY

Helsinki, 19 July 2018

Addressee: [redacted]

Decision number: TPE-D-2114428716-44-01/F
Substance name: Silsesquioxanes, phenyl
EC number: 939-487-8
CAS number: 70131-69-0
Registration number: [redacted]
Submission number: [redacted]
Submission date: 28.06.2017
Registered tonnage band: [redacted]

DECISION ON A TESTING PROPOSAL

Based on Article 40 of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA examined your testing proposal(s) and decided as follows.

Your testing proposal is accepted and you are requested to carry out:

1. **Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: Daphnia magna reproduction test, EU C.20./OECD TG 211) using the registered substance.**

You are additionally requested to perform:

2. **Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method: Fish, early-life stage (FELS) toxicity test, OECD TG 210) using the registered substance.**

Your testing proposal is accepted and you are requested to carry out:

3. **Long-term toxicity on terrestrial invertebrates (Annex IX, Section 9.4.1 column 2.; test method: Earthworm reproduction test, OECD TG 222) using the registered substance;**
4. **Long-term toxicity to terrestrial plants (Annex IX, Section 9.4.3., column 2; test method: Terrestrial plant test: seedling emergence and seedling growth test, OECD TG 208 with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species) 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 April 2020**. You shall also update the chemical safety report, where relevant. The timeline has been set to allow for sequential testing.

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 silsesquioxanes, phenyl, CAS No 70131-69-0 (EC No 939-487-8) taking into account the updated dossier.

ECHA notes that in the dossier with submission number [redacted] based on which the initial Draft Decision was prepared, you proposed long-term aquatic toxicity testing of invertebrates and fish on the registered substance without a tiered testing strategy. ECHA accepted the testing as proposed.

You also proposed terrestrial macroorganism and plant testing on analogue substance dodecamethylpentasiloxane (CAS No 141-63-9; EC No 205-492-2). ECHA rejected the read-across proposed and required testing on the registered substance. ECHA also requested you to conduct a terrestrial microorganism study on the registered substance.

In the updated dossier (submission number [redacted]) you have changed your testing strategy with respect to the environmental endpoints. ECHA has assessed your changed strategy in respect to these endpoints in requests 1 to 5 of this decision.

1. **Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)**

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

"Long-term toxicity testing on aquatic invertebrates" is a standard information requirement as laid down in Annex IX, Section 9.1.5. 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.

In your dossier, under IUCLID section 6.1.4. Long-term toxicity to aquatic invertebrates you have submitted endpoint study records for supporting studies on analogue substances Decamethyltetrasiloxane (L4, EC No 205-491-7, CAS No 141-62-8) and dodecamethylcyclohexasiloxane (D6, EC No 208-762-8, CAS No 540-97-6).

In the endpoint summary of IUCLID section 6.1.4. Long-term toxicity to aquatic invertebrates you indicate the following: "
No data are available for the long-term toxicity of Silsesquioxanes, Phenyl to aquatic invertebrates.

However, the constituents of the registration substance have very high log Kow values (9.0) and long-term toxicity is unlikely to be expressed. This is supported by read-across from decamethyltetrasiloxane (L4, log Kow8.2) and dodecamethylcyclohexasiloxane (D6, log Kow9) where no effects have been reported at the limit of solubility with aquatic invertebrates. A 21-day NOEC of ≥ 4.6 µg/l was obtained for the effects of dodecamethylcyclohexasiloxane (D6) on the survival, reproduction and growth ofDaphnia magna. In a study with the read-across substance decamethyltetrasiloxane (L4), a 21-day NOEC of ≥ 4.9 µg/l was obtained based on reproduction of Daphnia magna.The read-across data from surrogate substances having similar physico chemical properties indicate no toxicity at the limit of solubility (<6.6E-03mg/l)."

Concerning the predictions from L4 and D6, in the read-across justification in your CSR you indicate that for these substances the high adsorption potential is the main driver for their behaviour and toxicity in the environment. ECHA notes that no further read-across justification is provided.

ECHA notes that you consider read-across from L4 and D6 to the registered substance as acceptable based on physico-chemical similarity between the source and registered substances. However, physico-chemical similarity does not necessarily lead to predictable or similar ecotoxicological properties. Thus physico-chemical similarity per se is not sufficient to enable the prediction of ecotoxicological properties of a substance. While in the updated dossier you seem to consider that the read-across from L4 and D6 could cover the whole multiconstituent registered substance you also state that the *"the surrogate substance and the constituents cannot be considered as close structural analogues"*. ECHA acknowledges that the analogue substances are structurally different to the constituents of the registered substance and you do not explain what is the consequence of such structural differences in the predicted property. On that basis, the requirement of Annex XI, Section 1.5., that environmental effects may be predicted from data for reference substance(s) within the group, has not been met. ECHA considers that the information present in the technical dossier is insufficient to fulfil the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

Indeed you have recognised this by submitting a testing proposal for testing the registered substance for long-term toxicity on aquatic invertebrates *Daphnia magna* reproduction test, EU C.20/OECD TG 211. In your discussion submitted under IUCLID section 6.1. Aquatic toxicity you discuss the data submitted on L4 and D6 and conclude that *"These long-term no observed effect concentrations for aquatic organisms are subject to some uncertainty in terms of equivalent NOECs for the registration substance in an experimental test.This is key for concluding on classification and labelling; therefore, testing proposals are put forward for OECD TG 210 (Fish, Early-Life Stage Toxicity Test) and OECD TG 211 (Daphnia magnaReproduction Test) with the registration substance. A tiered approach to testing is proposed, starting with the OECD TG 211. The need to conduct the OECD 210 will be re-assessed when the results of the OECD TG 211 are available."*
ECHA agrees with you that it is necessary to generate further data on this endpoint.

ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 9.1.5 of the REACH regulation.

ECHA notes that your proposed tiered approach for long-term aquatic toxicity testing is discussed fully in the request for long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.), request 2. below.

Therefore, pursuant to Article 40(3)(a)of the REACH Regulation, you are requested to carry out the proposed test using the registered substance subject to the present decision: Long-term toxicity testing on aquatic invertebrates (test method: *Daphnia magna* reproduction test, EU C.20/OECD TG 211).

2. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.)

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

"Long-term toxicity testing on fish" is a standard information requirement as laid down in Annex IX, Section 9.1.6. 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.

ECHA notes that in the dossier with submission number [redacted] based on which the initial Draft Decision was prepared you had included as an Endpoint study record (ESR) a testing proposal for testing the registered substance for long-term toxicity on fish according to Fish, early-life stage toxicity test, OECD TG 210. In the udpated technical dossier you have submitted a "placeholder"(even though in the CSR (page 86) and the Endpoint summary of 6.1 Aquatic toxicity you still indicate that a Testing proposal for the present endpoint has been submitted) as you indicate that "*The need to conduct the OECD 210 will be re-assessed when the results of the OECD TG 211 are available.*" ECHA considers that in your new strategy you propose to carry out the long-term aquatic tests in a tiered approach.

You have provided the following justification for testing under IUCLID section 6.1. Aquatic toxicity: "*These long-term no observed effect concentrations for aquatic organisms are subject to some uncertainty in terms of equivalent NOECs for the registration substance in an experimental test.This is key for concluding on classification and labelling; therefore, testing proposals are put forward. However, the assumption that toxicity would be expressed and the use of the read-across and predicted NOECs for PNEC derivation and risk characterisation is a worst-case and is sufficient for the chemical safety assessment.*"

Additionally, under the Endpoint summary of 6.1.2. Long-term toxicity to fish you provide the following arguments for your changed strategy, advocating for tiered testing for long-term aquatic endpoints. You indicate that "An OECD TG 210 FELS test was originally proposed to be conducted with the registration substance, and was provisionally accepted by ECHA (draft decision) (TPE-D-2114331695-46-01). However, *in light of the following factors it will need to be carefully reconsidered whether such a study can still be justified*":

- *The registrants' understanding of the composition of the substance has changed and it is now clear that all constituents have log Kow above 8. As such chronic aquatic effects are not anticipated for any constituents of the registration substance.*
- *An OECD 211 study is planned and is expected to provide further evidence.*
- *Suitable read-across evidence for the long-term fish endpoint is already available within an established Category Approach.*
- *The value of conducting a vertebrate study is in doubt and so there are also ethical considerations.*

Accordingly, this study is not actively proposed in this submission pending further evidence; this TP will be reinstated if the registrants consider it justifiable taking into account observations in the OECD 211 study once it is completed."

ECHA addresses your arguments below.

Firstly, you have provided updated information on the composition of the substance and the supporting analytical information. You indicate that all constituents have Log Kow of above 8 and due to this you consider chronic aquatic effects unlikely. ECHA however notes that "*log Kow above 8"* is not a valid waiver for the present endpoint so this argument is of no relevance to the need for testing for long-term fish. To the contrary, ECHA considers that due to the physicochemical properties of the constituents, high adsorption and low water solubility, chronic testing is indicated, as already noted in the initial draft decision and as

further discussed in the sections below. Additionally ECHA notes also that the KOWWIN v.1.68 QSAR information provided by you for Log Kow is not sufficient to fulfil the requirements of an adaptation of Annex XI, section 1.3. Therefore, the QSAR predictions made cannot be considered valid due to the predictions being outside of the applicability domain of the model due to the very high values calculated, and the presence of more occurrences of one fragment than allowed by the model used.

Secondly, you argue that the OECD 211 Daphnia long-term study to be conducted will provide further evidence on chronic toxicity. ECHA understands that by this you consider to adapt the long-term testing on fish based on results from invertebrates, and hence to apply the aquatic Integrated Testing Strategy (ITS) given in *ECHA Guidance on information requirements and chemical safety assessment*, Chapter R.7b (version 4.0, June 2017, Section R.7.8.5.3.). ECHA however notes that in order to apply the ITS you would need to predict relative differences (or lack of) in species sensitivity in order to provide evidence that the risks for fish are not underestimated by the data on aquatic invertebrates. You have not provided sufficient data to compare the relative species sensitivity for the registered substance, as discussed further below.

Thirdly, you argue that "*Suitable read-across evidence for the long-term fish endpoint is already available within an established Category Approach*". ECHA notes that in your dossier, under IUCLID section 6.1.2. Long-term toxicity to fish you have submitted as a key study an OECD TG 210 study on analogue substance decamethyltetrasiloxane (L4, EC No 205-491-7, CAS No 141-62-8). In addition you have submitted as supporting studies three fish bioaccumulation studies (OECD TG 305): one on a constituent of the registered substance 1,1,1,5,5,5-hexamethyl-3-phenyl-3-[(trimethylsilyl)oxy]trisiloxane) (CAS 2116-84-9, EC 218-320-6), two on the analogue substances L4 and dodecamethylcyclohexasiloxane (D6, EC No 208-762-8, CAS No 540-97-6).

ECHA does not agree with you that the information submitted is a suitable read-across evidence to predict the long-term fish property of the registered substance. Indeed, it is not appropriate to fulfil the standard information requirement of Annex IX, Section 9.1.6.1. for the registered substance, for the following reasons:
(i) the mortality data from OECD 305 fish bioaccumulation studies submitted on the constituent 1,1,1,5,5,5-hexamethyl-3-phenyl-3-[(trimethylsilyl)oxy]trisiloxane and on L4 and D6 are not appropriate to fulfil the standard information requirement of a chronic fish study required under the current endpoint of Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.). Furthermore, as discussed in request 1 above the conditions to predict the ecotoxicological properties of the registered substance from data for reference substance L4 and D6 have not met the requirement of Annex XI, Section 1.5; (ii) the key study on analogue substance L4 is an OECD 210 study which in principle could fulfill the standard information requirement for this endpoint, can also not be used to predict the properties of registered substance as the read-across is similarly not considered acceptable.

Finally, you question the value of conducting a vertebrate study. However, this is contrary to the REACH requirements relevant for your registered substance. Long-term data on fish is a standard information requirement, and there is no such data in your dossier nor sufficient information to adapt it, as already addressed above. ECHA notes that for the derivation of the $PNEC_{aquatic}$, data on three trophic levels(aquatic invertebrates, fish and aquatic plants) is required (ECHA Guidance on information requirements and chemical safety assessment, version 4.0, June 2017, Chapter R7b, Section R.7.8.5.3). ECHA notes that you have waived the requirement for short-term toxicity on fish based on the read-across approach applied to the current endpoint, however, as discussed above ECHA does not consider the read-across approach justified. Therefore, currently no adequate data on

the toxicity to fish is available for the registered substance. ECHA also notes that Annex VIII 9.1.3. and Annex VII 9.1.1. of the REACH Regulation explicitly recommend that long-term aquatic toxicity tests be considered if the substance is poorly water soluble (e.g. water solubility below 1 mg/L or below the detection limit of the analytical method of the test substance based on *ECHA Guidance on information requirements and chemical safety assessment*, Chapter R.7b (version 4.0, June 2017), Section R.7.8.5.). Therefore, in this case long-term data for the three trophic levels are required to accurately assess the effects of the registered, low water solubility, substance on aquatic organisms.

For the reasons stated above, the aquatic ITS (*ECHA Guidance on information requirements and chemical safety assessment*, Chapter R.7b (version 4.0, June 2017), Section R.7.8.5.3.) is not applicable and it is necessary to provide long-term data on both aquatic invertebrates and on fish.

Furthermore, as an overall conclusion of the currently available information submitted under IUCLID section 6.1 Aquatic toxicity, you consider that "*long-term no observed effect concentrations for aquatic organisms are subject to some uncertainty in terms of equivalent NOECs for the registration substance in an experimental test*". You have hence considered it necessary to conduct an experimental study on the registered substance to study its effects on fish and have hence submitted a testing proposal for the current endpoint. In the updated dossier you have changed your conclusion, based on the existing information, advocating for the tiered approach to aquatic testing. However as discussed above, none of your arguments is valid, no tiered testing is possible in this case and chronic testing for both aquatic invertebrates and fish is required.

ECHA considers that the study according to OECD TG 210 with the registered substance is appropriate to fulfil the information requirement of Annex IX, Section 9.1.6 of the REACH Regulation.

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, you are required to carry out the additional study using the registered substance subject to the present decision: Fish, early-life stage (FELS) toxicity test (test method: Fish, early-life stage toxicity test, OECD TG 210).

Notes for your consideration in relation to sections 1 and 2 above

Due to the low solubility of the substance in water you should consult OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA Guidance, Chapter R7b, table R. 7.8-3 summarising aquatic toxicity testing of difficult substances for choosing the design of the requested long-term ecotoxicity tests and for calculation and expression of the result of this test. Furthermore, ECHA notes that if the registered substance is likely to be unstable in the aquatic environment, a decision to test the registered substance and/or the relevant constituents of the registered substance and/or its possibly identified degradation product(s) should be based on a consideration of the half-life of the registered substance under test and real-life conditions. It is your responsibilty to design the test in such a way that the effects on aquatic organisms are adequately assessed.

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

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

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX and X, Section 9.4. of the REACH Regulation. The Registrant must address the standard information requirements set out in Annex IX and X, Section 9.4., for different taxonomic groups: short-term toxicity testing on invertebrates (Annex IX, Section 9.4.1.), long-term toxicity testing on invertebrates (Annex X, section 9.4.4.), short-term toxicity testing on plants (Annex IX, section 9.4.3.) and long-term toxicity testing on plants (Annex X, section 9.4.6.). Column 2 of section 9.4 of Annex IX 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 are ionisable or have a log K_{ow}/K_{oc} >5 are considered highly adsorptive, whereas substances with a half-life >180 days are considered very persistent in soil. According to the evidence presented within the Registration dossier, the substance has a high potential to adsorb to soil (logK_{ow} 6.7 - 9 (QSAR)) and therefore ECHA agrees that long-term testing is indicated (Column 2 of Section 9.4. of Annex IX).

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 the updated dossier, you have submitted a testing proposal for a long-term toxicity test on terrestrial invertebrates (OECD 222) with the registered substance with the following justification: "*There are no data describing the long-term toxicity of the registration substance to soil macroorganisms except arthropods. However, data are available for the siloxane decamethylcyclopentasiloxane (D5, CAS: 541-02-6). A 28-day LC50value of >4074 mg/kg dry weight and a 56-day NOEC of ≥4074 mg/kg dry weight have been determined for the effects of the test substance on mortality and reproduction and growth respectively ofEisenia andrei.*

This approach is an interim approach to risk assessment.
Earthworm reproduction studies are proposed for the registration substance."

In the justification for testing submitted in the Endpoint Summary of Terrestrial toxicity (IUCLID 6.3.) you discuss the potential feasibility of conducting terrestrial studies with the registered substance due to its physicochemical properties. For the registered substance you consider that "*A stability/recovery test under OECD TG 222 conditions performed with the structurally-related substance (L4) demonstrated significant loss of test item from the test system over a five-week period (37% remaining radioactivity after 35 days), ascribed to volatilisation losses. However, it is considered that it is possible that measurable concentrations will remain in the soil at the end of the eight-week test period for the definitive OECD TG 222 study. Silsesquioxanes, phenyl is expected to be more stable in soil, therefore an OECD TG 222 study is proposed".*

ECHA notes that in your justification for testing you refer to several points and ECHA addresses them below.

Firstly, you discuss the potential feasibility of conducting terrestrial studies with the registered substance due to its physicochemical properties. ECHA notes that while you refer to stability test results on what you consider a "*structurally related substance*" L4 you have not attempted to read-across the stability tests results of L4 to the registered substance.

Nevertheless, as already addressed in request 1. above, such prediction, based on provided information, would not be possible.

ECHA notes based on the physicochemical properties of the registered substance, you have considered it feasible to conduct the OECD 222 study proposed. 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*". According to the information provided in the technical dossier the registered substance has a vapour pressure of 0.23 Pa (IUCLID section 4.6.) while no Kair/soil value is provided. ECHA agrees that based on the reported substance properties testing according to the OECD TG 222 guideline is feasible.

Secondly, you discuss the use of a study performed on an analogue substance for the purpose of an interim hazard and risk assessment for the registered substance. For that purpose in section 6.3.1. of IUCLID you have submitted a study for long-term toxicity to soil macroorganisms study on analogue substance Decamethylcyclopentasiloxane (D5, CAS No 541-02-6, EC No 208-764-9). In the CSR you discuss that "*Even though the surrogate substance and the constituents cannot be considered as close structural analogues, the property that will dominate the behaviour of the substance in the environment is the high adsorption potential (log Kow and Koc)*".

ECHA acknowledges that you intend to use the data available on D5 only as "*an interim hazard and risk assessment*", however you have not provided any justification as to why you consider this read-across possible, even as an interim measure. Nevertheless, ECHA notes the following.

ECHA agrees that the registered substance and the analogue substance D5 are not close structural analogues and it is unclear how the structural differences would be covered by the read-across, as already discussed in the initial DD. ECHA notes that in the dossier you provide no explanation on how these differences in structure affect their terrestrial toxicities. Nevertheless, you consider read-across from D5 to the registered substance as acceptable based on physico-chemical similarity between the source and registered substance. However, physico-chemical similarity does not necessarily lead to predictable or similar ecotoxicological properties. Thus physico-chemical similarity per se is not sufficient to enable the prediction of ecotoxicological properties of a substance. On that basis, the requirement of Annex XI, Section 1.5., that environmental effects may be predicted from data for reference substance(s) within the group, has not been met. Therefore ECHA concludes that the data on D5 could not be used to fulfill the current information requirement for the registered substance.

Furthermore, ECHA considers that by submitting the testing proposals you have deemed it necessary to generate further data on this endpoint. ECHA agrees that the information present in the technical dossier is insufficient to fulfil the information requirement.

The earthworm reproduction test (OECD TG 222) proposed is considered capable of generating information appropriate for the fulfilment of the information requirements for long-term toxicity testing to terrestrial invertebrates.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed study using the registered substance subject to the present decision: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) OECD 222)

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

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

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX and X, Section 9.4. of the REACH Regulation. The Registrant must address the standard information requirements set out in Annex IX and X, Section 9.4., for different taxonomic groups: short-term toxicity testing on invertebrates (Annex IX, Section 9.4.1.), long-term toxicity testing on invertebrates (Annex X, section 9.4.4.), short-term toxicity testing on plants (Annex IX, section 9.4.3.) and long-term toxicity testing on plants (Annex X, section 9.4.6.). Column 2 of section 9.4 of Annex IX 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 are ionisable or have a log K_{ow}/K_{oc} >5 are considered highly adsorptive, whereas substances with a half-life >180 days are considered very persistent in soil. According to the evidence presented within the Registration dossier, the substance has a high potential to adsorb to soil (logK_{ow} 6.7 - 9 (QSAR). Therefore ECHA agrees that a 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 the updated dossier, you have submitted a testing proposal for a long-term toxicity test on terrestrial plants (OECD 208) with the registered substance with the following justification: "*There are no data describing the long-term toxicity of the registered substance to terrestrial plants. However, data are available for the siloxane decamethylcyclopentasiloxane (D5, CAS: 541-02-6). A short-term (14-day) IC50value of 209 mg/kg dry weight has been determined for the effects of the test substance on root dry mass ofHordeum vulgare. IC50/EC50values for effects on seedling emergence, root and shoot length and shoot dry mass determined in the same test were ≥248 mg/kg dry weight. 14-day EC50values of >4054 mg/kg dry weight have been determined for the effects of the test substance on seedling emergence, root and shoot length and root and shoot dry mass ofTrifolium pratense. NOECs were not determined in the tests.*

An OECD TG 208 toxicity to terrestrial plants study is proposed for the registration substance. The need for this study will be re-assessed once the results of the OECD TG 222 with the registration substance are available. If there is no indication of risk from the OECD TG 222 study, the OECD TG 208 will not be conducted.
Read-across of the terrestrial toxicity data for D5 to Silsesquioxanes, phenyl is considered to be suitable to derive an interim hazard and risk assessment under REACH".

As indicated above in request 3., in the justification for testing submitted in the Endpoint Summary of Terrestrial toxicity (IUCLID 6.3.) you discuss the potential feasibility of conducting terrestrial studies with the registered substance due to its physicochemical properties.

ECHA notes that in your justification for testing you refer to several points and ECHA addresses them below.

Firstly, you refer to a testing strategy for terrestrial organisms. ECHA has already addressed this adaptation possibility under the notes for your consideration following request No 5 below.

Secondly, you discuss the use of a study performed on an analogue substance for the purpose of an interim hazard and risk assessment for the registered substance. For that purposein IUCLID section6.3.3. Toxicity to terrestrial plants you have submitted a study for short-term toxicity to plants on analogue substance Decamethylcyclopentasiloxane (D5, CAS No 541-02-6, EC No 208-764-9). ECHA notes that as already discussed in request 2. above, you have not justified, as per the requirements of Annex XI, Section 1.5., that environmental effects may be predicted from data for reference substance(s) within the group. Furthermore, ECHA notes that as only two species were tested in the OECD TG guideline 208 study (Terrestrial plants, growth test) submittedon D5, the study cannot be considered a long-term study. Therefore ECHA concludes that the data on D5 could not be used to fulfill the current information requirement for the registered substance.

Thirdly, while you discuss the potential feasibility of terrestrial testing overall due to the physicochemical properties of the substance, as discussed above in request 3 you have considered it feasible to conduct tererstrial testing on the registered substance.

ECHA considers that by submitting the terrestrial testing proposals on the registered substance you have deemed it necessary to generate further data on the registered substance for this endpoint. ECHA agrees that the information present in the technical dossier is insufficient to fulfil 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 required to carry out one of the following studies using the registered substance subject to the present decision: Terrestrial plants, growth test (OECD 208), with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species).

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

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

"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 and long-term toxicity testing on invertebrates (Annex IX, Section 9.4.1., column 2), effects on soil micro-organisms (Annex IX, Section 9.4.2.), and short-term and long-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 the udpated dossier you have submitted a testing proposal to study the effects of the registered substance on soil microorganisms (*Soil Microorganisms: Nitrogen Transformation Test*, OECD TG 216) with the following justification: *"An OECD TG 216 study is proposed with the registration substance"*.

As fully discussed in request 3. above, while in the justification for testing submitted in the Endpoint Summary of Terrestrial toxicity (IUCLID 6.3.) you discuss the potential feasibility of conducting terrestrial studies with the registered substance you have considered it feasible to conduct terrestrial testing on the registered substance.

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 3.0, June 2017), 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.

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)(a) of the REACH Regulation, you are requested to carry out the proposed test using the registered substance subject to the present decision: Soil microorganisms: nitrogen transformation test, EU C.21/OECD TG 216.

Notes for your consideration in relation to sections 3, 4 and 5 above

ECHA notes that you have also proposed a toxicity test on fish and aquatic invertebrates (requests 1 and 2 in this decision) and the results of these tests may subsequently allow the derivation of PNECwater. If the results of the proposed toxicity test on fish and aquatic invertebrates allow the subsequent derivation of a PNECwater, you may consider the ITS as recommended in section R.7.11.6., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, June 2017), and determine the need for further testing on terrestrial organisms. If you include a justified proposal for adaptation of Annex IX, 9.4.3. in the registration dossier you will not be required to perform the toxicity test on plants. If no effects are observed in the chronic aquatic studies to be conducted Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, June 2017) advocates that absence of aquatic toxicity can be used as part of a *Weight-of-Evidence* argument to modify/waive the data requirements of Annex IX and X and a single soil test on a suitable species could be adequate to meet the requirements of Annex IX. Where the substance is highly adsorptive (log Kow/Koc >5), and/or the substance is very persistent in soil, this single test should be a long-term test. ECHA emphasises that the intrinsic properties of soil microbial communities are not addressed through the EPM extrapolation method and therefore the potential adaptation

possibility outlined for the information requirement of Annex IX, Section 9.4.3. does not apply for the present endpoint.

Appendix 2: Procedural history

ECHA received your registration containing the testing proposal(s) for examination pursuant to Article 40(1) on 21 May 2013.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

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 **6 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.

You updated your registration on 28 June 2017. ECHA took the information in the updated registration 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 carrying out the test(s) required by the present decision it is important to ensure that the particular sample of substance tested 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. If the registration of the substance covers different grades, the sample used for the new test(s) must be suitable to assess these. Furthermore, 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.