ECHA
EUROPEAN CHEMICALS AGENCY

Helsinki, 19 July 2018

Addressee: [redacted]

Decision number: TPE-D-2114422684-49-01/F
Substance name: decamethyltetrasiloxane
EC number: 205-491-7
CAS number: 141-62-8
Registration number: [redacted]
Submission number: [redacted]
Submission date: 19.06.2017
Registered tonnage band: 100-1000T

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

1. **Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: OECD TG 414) in a rat using the registered substance.**

2. **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.**

3. **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.**

4. **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 January 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 proposals submitted by you for the registered substance decamethyltetrasiloxane (CAS No 141-62-8, EC No 205-491-7), 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 terrestrial macroorganism and plant testing on analogue substances dodecamethylpentasiloxane (CAS No 141-63-9; EC No 205-492-2) and octamethyltrisiloxane (CAS No 107-51-7; EC No 203-497-4); and terrestrial microorganisms testing on octamethyltrisiloxane and decamethylcyclopentasiloxane (CAS No 541-02-6; EC No 208-764-9). ECHA rejected the read-across proposed and required testing on the registered substance. In the updated dossier you have changed your testing strategy with respect to the environmental endpoints and you have proposed testing to be conducted on the registered substance. ECHA has assessed your changed strategy in respect to these endpoints in requests 2 to 4 of this decision.

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

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

a) Examination of the testing proposal

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

You proposed testing with the rat as a first species. 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 the rat or rabbit 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 referred to an earlier testing proposal for the same endpoint to be conducted with the analogue substance octamethyltrisiloxane (EC No 203-497-4) and proposed to consider a read-across approach for prenatal developmental toxicity.

ECHA acknowledges that the third party has proposed a read across approach for you to consider.

ECHA notes that it is your responsibility to consider and justify any adaptation of the information requirements in accordance with the relevant conditions as established in Annex XI, Section 1.5. Therefore, you may assess whether you can justify a read-across as suggested by the third party. If the information requirement can be met by way of adaptation, you may include the adaptation argument with all necessary documentation according to Annex XI, Section 1.2. in an updated registration.

ECHA notes that the information provided by the third party is currently insufficient for demonstrating that the conditions of Annex XI, Section 1.2 of the REACH Regulation are met. As the third party points out, you made use of the read-across approach with analogue substance for acute oral toxicity, skin sensitisation and genetic toxicity endpoints. However, you did not make use of such approach for repeated dose toxicity and toxicity to reproduction endpoints neither you submitted a read-across justification for these endpoints nor pre-natal developmental study results conducted on the analogue substance.

Based on that, ECHA concludes at the present stage that the information provided by the third party in itself would not be sufficient to adapt the standard information requirement.

c) Outcome

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* (version 6.0, July 2017), Chapter R.7a, section R.7.6.2.3.2.

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).

2. 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, 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 (logK_{ow} 8.21) 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. Consequently there is an information gap and it is necessary to provide information for this endpoint.

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 registered substance to soil macroorganisms. However, data are available for the siloxane decamethylcyclopentasiloxane (D5, CAS: 541-02-6). A 28-day LC50 value 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 of Eisenia andrei. The read-across is considered to be reliability 2.*

Earthworm reproduction studies are proposed for the registration substances. A preliminary stability study under OECD 222 conditions has been carried out and demonstrates significant losses due to volatilisation over a five week period (37% remaining radioactivity after 35 days). 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 222 study, and therefore testing is proposed.

Read-across of the terrestrial toxicity data for D5 to L4 is considered to be suitable to derive an interim hazard and risk assessment under REACH for L4."

ECHA notes that in your justification 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. In IUCLID section 6.3.1. Toxicity to soil macroorganisms you have submitted an endpoint study record for a "*stability study under OECD 222 conditions without test organism*", also referred to in your justification for

the testing proposal quoted above. ECHA acknowledges the data and notes that while you have considered that maintaining concentrations of the registered substance in the terrestrial test medium may be an issue you have considered it feasible to conduct the OECD 222 study proposed. ECHA notes also that 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 73 Pa (IUCLID section 4.6.) and a Kair/soil value of 0.2 (Siloxane category report attached to section 13 of IUCLID technical dossier). ECHA hence agrees that based on 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 on analogue substance Decamethylcyclopentasiloxane (D5, CAS No 541-02-6, EC No 208-764-9). Under the Endpoint summary of terrestrial toxicity you note that "*The registered substance and the surrogate substance share similar physico-chemical properties but are not close structural analogues (linear and cyclic siloxanes)".*

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 as the registered substance is a linear siloxane while the source substance D5 is a cyclic siloxane, the target and source substance are not close structural analogues. 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 environmental properties. Thus physico-chemical similarity per se is not sufficient to enable the prediction of environmental 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 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 invertebrates" for the registered substance and it is necessary to provide information on this endpoint.

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 required to carry out the proposed study using the registered substance subject to the present decision: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) (OECD 222).

3. 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 under modified conditions.

"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 (logK_{ow} 8.21) 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. Consequently there is an information gap and it is necessary to provide information for this endpoint.

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) IC50 value of 209 mg/kg dry weight has been determined for the effects of the test substance on root dry mass of Hordeum vulgare. IC50/EC50 values 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 EC50 values 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 of Trifolium pratense. NOECs were not determined in the tests. The read-across is considered to be reliability 2.*

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 L4 is considered to be suitable to derive an interim hazard and risk assessment under REACH for L4."

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 4 below and refers you therein.

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 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.

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)(a) of the REACH Regulation, you are required to carry out the proposed study using the registered substance: Terrestrial plants, growth test (OECD 208), with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species)

4. 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 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 the updated dossier you have submitted a testing proposal to study the effects of the registered substance on soil micro-organisms (*Soil Microorganisms: Nitrogen Transformation Test*, OECD TG 216) with the following justification: *"An OECD TG 216 study is proposed with the registration 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. 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: Soil microorganisms: nitrogen transformation test, EU C.21/OECD TG 216.

Notes for your consideration

Due to absence of chronic or long-term effects in aquatic organisms up to the substance solubility limit you have considered that it is unfeasible, with the currently available information, to derive a PNEC for aquatic organisms. Consequently, the Equilibrium Partitioning Method (EPM) is not applicable in this case and it is not possible to allocate the substance to a soil hazard category (Section R.7.11.6., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, June 2017)). However, 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 would 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 hence considers that you may start testing by performing one of the long-term terrestrial toxicity tests, the long-term toxicity to invertebrates as proposed. Once the results of the long-term toxicity to invertebrates test are available, you should consider whether there is a need to investigate further the effects on terrestrial organisms in order to fulfil the information requirements of section 9.4 of Annex IX, and if necessary, to carry out the long-term toxicity to plant test requested above. If you conclude that no further investigation of effects on terrestrial organisms is required, you should update your technical dossier by clearly stating the reasons for adapting the information requirements of Annex IX, section 9.4. of the REACH Regulation.

ECHA emphasises that the intrinsic properties of soil microbial communities are not addressed through the aquatic data on invertebrates and/or fish and an adaptation provided for invertebrates/plants may not be applicable for the information requirement of Annex IX, Section 9.4.2.

Appendix 2: Procedural history

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

ECHA held a third party consultation for the testing proposal from 16 October 2014 until 1 December 2014 based on the information provided in the registration dossier submitted on 22 September 2015, [redacted]. ECHA received information from third parties (see Appendix 1). You updated your registration dossier on 18 April 2016, dossier submission [redacted], and no modifications to the initial testing proposals were included in that dossier update.

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 19 June 2017. ECHA took the information in the updated registration into account, and modified the draft decision (requests 2, 3 and 4).

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.