ECHA
EUROPEAN CHEMICALS AGENCY

Helsinki, 19 July 2018

Addressee: [redacted]

Decision number: TPE-D-2114423791-51-01/F
Substance name: dodecamethylpentasiloxane
EC number: 205-492-2
CAS number: 141-63-9
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 examined your testing proposals and decided as follows.

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

1. **Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EU B.31./OECD TG 414) in a first species (rat or rabbit), oral route using the analogue substance decamethyltetrasiloxane (CAS No 141-62-8, EC No 205-491-7).**

2. **Long-term toxicity on terrestrial invertebrates (test method: Earthworm reproduction test, OECD TG 222) using the registered substance.**

3. **Long-term toxicity testing on plants (test method: Terrestrial plants, growth test, OECD TG 208) using the registered substance.**

4. **Effects on soil micro-organisms (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 to the REACH Regulation. 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 have to submit the requested information in an updated registration dossier by **26 July 2019**. You also have to 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 dodecamethylpentasiloxane, CAS No 141-63-9 (EC No 205-492-2) (hereafter referred to as "target substance" or L5), taking into account the updated dossier.

The initial draft decision was based on the dossier with the submission number [redacted] registered at the tonnage band of 10 to 100 tpa. Therein you proposed pre-natal developmental toxicity study, oral route (Annex IX, Section 8.6.2.)) on analogue substance decamethyltetrasiloxane CAS no 141-62-8, EC No 205-491-7). ECHA rejected the testing proposed as not necessary for the tonnage band of the substance registered.

In the updated dossier (submission number [redacted]) you upgraded the tonnage band of the registered substance to 100-1000 tpa. ECHA has assessed your dossier update in respect to the PNDT endpoint in request 1. of this decision.

With regards to the environmental testing proposals, 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 the registered substance, but 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 in all cases on the registered substance. ECHA has assessed your changed strategy in respect to these endpoints in requests 2 to 4 of this decision. In the following ECHA has considered first the scientific validity of the proposed read-across and grouping approaches, relevant for the pre-natal developmental toxicity study, before assessing the testing proposed (Sections 1-4 below).

0 Grouping of substances and read-across approach

Legal Background on ECHA's assessment of the grouping of substances and read-across hypothesis

The evaluation by ECHA of testing proposals submitted by registrants aims at ensuring that generation of information is tailored to real information needs. To this end, it is necessary to consider whether programmes of testing proposed by you are appropriate to fulfil the relevant information requirements and to guarantee the identification of health and environmental hazards of substances. In that respect, the REACH Regulation aims at promoting wherever possible the use of alternative means, where equivalent results to the prescribed test are provided on health and environmental hazards.

Article 13(1) of the REACH Regulation provides that information on intrinsic properties of substances may be generated whenever possible by means other than vertebrate animal tests, including information from structurally related substances (grouping of substances and read-across), "*provided that the conditions set out in Annex XI are met*".

The first Recital and the first Article of the REACH Regulation establish the "*promotion of alternative methods for assessment of hazards of substances*" as an objective pursued by the Regulation. In accordance with that objective, ECHA considers whether a prediction of the relevant properties of the substance subject to the present decision by using the results of the proposed tests is plausible based on the information currently available.

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0.1 Description of the grouping approach and read-across approach for the human health endpoint

You have proposed to cover the standard information requirements for a pre-natal developmental toxicity study (Annex IX, Section 8.7.2.) by performing the test with an analogue substance decamethyltetrasiloxane (L4, CAS no 141-62-8, EC no 205-491-7), (hereafter referred to as "source substance").

You have provided the following arguments to justify the read-across approach:

"L5 and L4 are closely related substances, consisting of chains of 5 and 4 Si-O groups, with 12 and 10 methyl groups respectively".

And

"The read-across of data from decamethyltetrasiloxane to dodecamethylpentasiloxane is justified by the similarities in structure and physicochemical properties of the two substances."

and

"Both substances belong to the structural class of siloxanes (alkyl, vinyl, aryl or hydrogen substituted) and both substances hydrolyse slowly at pH 7 (see Table 5.6.3) therefore hydrolysis is not of relevance in terms of toxicological studies by the inhalation route. For the oral route, the hydrolysis rate is predicted to be fast at pH2 and 37.5°C (half-life 90 seconds), and both substances share common ultimate hydrolysis products, trimethylsilanol and dimethylsilanediol.

Repeated sub-acute oral toxicity studies are available for decamethyltetrasiloxane and dodecamethylpentasiloxane, in which both substances led to fatty changes in the liver (25, 250 and 1000 mg/kg bw/day for both substances), and decamethyltetrasiloxane caused protoporphyrin accumulation in the bile ducts (250 and 1000 mg/kg bw/day), but other relevant findings were unremarkable and there were no apparent effects on the reproductive organs examined at necropsy. The observed effects with L5 were not considered to be adverse with respect to setting a NOAEL and deriving DNEL for human hazard assessment purposes, whereas for L4 protoporphyrin accumulation was considered to be adverse. A 90-day inhalation study is also available with L4 in which no adverse effects were observed at the highest achievable test concentration of 400 ppm.

Since L4 represents the worst-case in respect of effects observed in the oral toxicity studies, reading across to L5 can therefore also be considered as a worst case.

Overall, these two substances have similar toxicological profiles. After considering all of the above factors it is deemed appropriate to read-across data from L4 to L5 for the inhalation route".

Information submitted to support the grouping and read-across approach

You have provided several documents as separate attachments in IUCLID, Section 13:

[redacted]

[redacted]

The provided [redacted] is an overview of the grouping and read-across methods of Reconsile REACH submissions. The document describes the general principles applied but does not provide any substance-specific information. According to the report, "*each CSR needs to describe clearly whether Category, Analogue or QSAR methods have been applied, and which endpoints they are applied to, and the IUCLID entries must be consistent with this*".

Based on this document, ECHA understands that you intend to apply analogue approach as a basis for data gap filling which are further justified in each registration dossier and CSR.

You have provided a matrix report ("[redacted]") as a separate attachment in IUCLID, Section 13. The document is summarising the available physico-chemical and toxicological data on related siloxanes.

The document "[redacted]" (13th August 2015) in ECHA´s understanding "*sets out the analogue methods applicable to linear/branched and cyclic siloxanes*" and presents the substances within the analogue group of siloxanes (alkyl, vinyl, aryl or hydrogen substituted). In addition, in ECHA's understanding, the document describes the existing data, intended and proposed analogue methods regarding physicochemical, degradation, bioaccumulation and ecotoxicological properties in pelagic, benthic and terrestrial compartments.

The attachment [redacted] *(8 February 2013)* does not provide information on the read-across approach used for the endpoint subject to the present decision.

In the updated dossier you provided the following documents in IUCLID, Section 13:

[redacted]

In addition, you have provided the following human health studies on the registered substance:

- acute dose toxicity via dermal route (OECD 402, [redacted] 2009),
- skin irritation study (OECD 404, [redacted] 2009),
- *in vitro* mammalian chromosome aberration test (OECD 473, [redacted] 2014), and
- a sub-acute oral repeated dose toxicity study (OECD 407, [redacted], 2010).

The following data has been provided for the source substance:

- eye irritation study ([redacted], 2000);
- bacterial reverse mutation assay (OECD 471, [redacted], 2005);
- mammalian cell gene mutation assay (OECD 476, [redacted], 2010);
- sub-chronic toxicity (90-day) (OECD 413)

- combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test conducted via, inhalation route (vapour, whole body; OECD 422, [redacted], 2007b).

In the updated dossier, you did not provide any new studies for human health endpoints.

ECHA analysis of the grouping approach and read-across hypothesis in light of the requirements of Annex XI, 1.5.

ECHA notes that the registrants of siloxanes (alkyl, vinyl, aryl or hydrogen substituted) have grouped the substances in 'Analogue group', including the substance subject to the current decision, but the category approach is not proposed. Based on the substance specific justification for read-across approach and supporting information provided by you, ECHA understands that no category hypothesis /justification has been included and the proposed prediction is based on the analogue approach using decamethyltetrasiloxane ("L4") (CAS no 141-62-8, EC No 205-491-7) as a source substance.

Based on the information provided, ECHA understands that the proposed read-across hypothesis is based on the structural similarity, the similar physico-chemical and the similar toxicological profiles of the target and source substances.

In the following, ECHA examines whether the substances have indeed similar properties or that they would follow a regular pattern in their properties, before assessing the scientific validity of your hypothesis.

(i) Structural (dis)similarities and their impact on prediction

Structural similarity is a prerequisite for applying the grouping and read-across approach, but ECHA does not accept in general or this specific case that structural similarity *per se* is sufficient to enable the prediction of human health properties of a substance, since structural similarity does not always lead to predictable or similar human health properties. It has to be justified why such prediction is possible in view of the identified structural differences and the provided evidence has to support such explanation. In particular, the structural similarities must be linked to a scientific explanation of how and why a prediction is possible.

You have described the structural similarities between target and source substances by stating that "*L4 is a linear siloxane chain with four silicon atoms, connected by three oxygen atoms, in which the Si-O bonds are susceptible to hydrolysis. All silicon atoms present are fully substituted with methyl groups. L5 is a structurally related linear siloxane, with five silicon atoms and four oxygen atoms*".

ECHA notes that you have identified the structural basis for the prediction, i.e. you have identified a common structure consisting of five or four chains of Si-O groups, with twelve and ten methyl groups, for the target and source substances, respectively. Furthermore, ECHA notes that you have concluded that despite the one Si-O group and two methyl groups difference in the chain the substances are sufficiently similar to support the read-across. ECHA notes based on the experimental data provided, structural differences do not seem to impact the toxicity profile of the substances as discussed in detail in toxicological data section below.

(ii) Similar properties or regular pattern as a result of structural similarity

Annex XI, Section 1.5. provides that *"substances whose physicochemical, toxicological and eco-toxicological properties are likely to be similar or follow a regular pattern as result of structural similarity may be considered as a group or 'category' of substances"*. One prerequisite for a prediction based on read-across therefore is that the substances involved are structurally similar and are likely to have similar properties. One important aspect in this regard is the analysis of the data matrix to compare the properties of source and target substances and to establish whether indeed they are similar or follow a regular pattern.

Regarding physico-chemical parameters, in your read-across justification you state that physico-chemical parameters/properties of target and source substances are similar. You have proposed that similar physico-chemical properties of the target and source substances support the read across approach between the substances. ECHA observes that the physico-chemical properties of target and source substances are in the same/similar range.

Regarding toxicokinetics, you claim that *"The read-across of data from decamethyltetrasiloxane to dodecamethylpentasiloxane is justified by the similarities in structure and physicochemical properties of the two substances. They both have extremely low water solubility (0.0067 and 0.000070 mg/l at 23°C, respectively) and high octanol-water partition coefficients (log Kow8.09 and 9.4, respectively). These properties indicate that absorption of parent is likely to be low via oral and dermal routes of exposure. Absorption following dermal exposure is unlikely for both substances. Once absorbed these substances are likely to distribute into tissues, particularly fatty tissues"*.

You have provided toxicokinetic assessments, which are based on the physicochemical properties of the target and source substances. Furthermore, you have provided a pharmacokinetics study that investigated the oral absorption, distribution and elimination of the target substance. ECHA notes that no metabolites were measured in that study. ECHA observes that based on similar physico-chemical properties, the toxicokinetic behaviour of the substances can be assumed to be similar.

Regarding hydrolysis, you claim that *"Both substances belong to the structural class of siloxanes (alkyl, vinyl, aryl or hydrogen substituted), and both substances hydrolyse slowly at pH 7 therefore hydrolysis is not of relevance in terms of toxicological studies by the inhalation route. For the oral route, the hydrolysis rate is predicted to be fast at pH 2 and 37.5°C (half-life 90 seconds), and both substances share common ultimate hydrolysis products, trimethylsilanol and dimethylsilanediol. "*

ECHA observes that hydrolysis half-life rate at pH 2 of both target and source substances is based on assumptions which are not substantiated by data and the formation of the proposed silanol hydrolysis products is not supported by data.

However, ECHA considers that in this particular case the hydrolysis does not seem to impact the toxicity of the substances as the results of the sub-acute toxicity studies conducted with the target and source substance show similar effects as discussed in toxicological data section below.

You claim further that based on the repeated sub-acute oral toxicity studies on the target and source substances *"L4 represents the worst-case in respect of effects observed in the oral toxicity studies, reading across to L5 can therefore also be considered as a worst case."*

ECHA notes that based on the NOAEL and LOAEL values and the severity of the effects observed in the 28-day studies, indeed the source substance (L4) seems to be more potent at producing liver effects (protoporphyrin accumulation in the liver, which was not seen in

the study conducted with L5), as claimed by you. Similar effects to L4 were observed also with another substance (L3) belonging to the same structural class. ECHA notes that these results indicate that the toxicity of the substances may decrease with the increasing molecular weight.

ECHA further observes that in the inhalation studies (OECD 413 and OECD 422) conducted with L3, similar liver effects were observed as in the oral sub-acute studies conducted with L3 and L4. Based on the similar liver effects observed in the oral and inhalation studies conducted with L3 ECHA considers that hydrolysis does not seem to impact the toxicity of this substance.

ECHA observes that in the inhalation studies (OECD 413 and OECD 422) conducted with the source substance (L4) no adverse liver effects were observed. However, the highest dose used in these studies was 400 ppm, whereas the highest dose used in the studies with L3 were 3200 ppm. ECHA therefore considers that due to lower doses used in the L4 studies (compared to the L3 studies) it cannot be ruled out that L4 may have similar effects both via oral and inhalation routes with higher doses.

ECHA considers that due to similar and/or decreasing oral toxicity of the substances, the read-across approach is considered plausible for the repeated-dose toxicity.

ECHA notes that the results of the 28-day studies do not provide information about reproductive organs or any indication of the (mechanism of) pre-natal developmental toxicity, which may mediate via different mechanism of action than repeated dose toxicity.

ECHA however considers that although no screening study is available on the target substance, read-across can be considered plausible also for the pre-natal developmental toxicity. The proposed pre-natal developmental toxicity study should be conducted via oral route and the read-across is considered plausible based on oral studies. In addition, it cannot be ruled out that the substances have similar effects both via oral and inhalation routes as discussed above. Furthermore, the reproductive effects were observed with the source substance (L4) and ECHA considers it important to conduct further studies with this substance to confirm the severity/nature of the observed effects.

Therefore ECHA concludes that based on the presented information there is an adequate basis for predicting the properties of the target substance from the data obtained with the source substance.

Conclusion on the read-across approach for the human health endpoint

Based on the above considerations ECHA concludes that you have provided adequate and reliable information to demonstrate that the proposed read-across approach is plausible for the pre-natal developmental toxicity (PNDT) endpoint in consideration.

ECHA therefore concludes that the criteria of Annex XI, Section 1.5, are met, and consequently the testing proposed on the read-across substance is principally appropriate to fulfil the information requirement(s) of the substance subject to the present 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 pre-natal developmental toxicity study for a first species is a standard information requirement for the tonnage band of 100 to 1000 tonnes per year 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 proposed to conduct a pre-natal developmental toxicity study with the analogue substance decamethyltetrasiloxane (L4, CAS no 141-62-8, EC No 205-491-7). ECHA notes that you have provided the following justification for your proposal to conduct the study: "*Developmental toxicity data will be read-across from the proposed OECD 414 developmental toxicity study with decamethyltetrasiloxane (CAS 141-62-8).*"

ECHA has evaluated your proposal to perform the test with the analogue substance decamethyltetrasiloxane (L4, CAS no 141-62-8, EC No 205-491-7). As explained in the Section 0 above, ECHA concludes that the criteria of Annex XI, 1.5. are met, and the read-across approach, as presented by you, can be considered plausible to meet 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) Chapter R.7a, Section 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.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed study with the analogue substance decamethyltetrasiloxane (L4, CAS no 141-62-8, EC No 205-491-7): 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} 6.3) 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.

You have submitted a testing proposal for testing the registered substance for long-term toxicity testing on terrestrial invertebrates (*Earthworm Reproduction Test (Eisenia fetida/Eisenia andrei)*, OECD TG 222) with the following justification provided in the updated dossier: "*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.*"

Furthermore, "*Read-across of the terrestrial toxicity data for D5 to L5 is considered to be suitable to derive an interim hazard and risk assessment under REACH for L5.*"

ECHA notes that in your justification 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 real 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.

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 (OECD TG 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.

"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} 6.3) Therefore ECHA agrees that a need for long-term testing is indicated.

You have submitted a testing proposal for testing the registered substance for long-term toxicity test to plants (*Terrestrial Plants Test: Seedling Emergence and Seedling Growth Test* OECD TG 208) with the following justification provided in the updated dossier: "
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 L5 is considered to be suitable to derive an interim hazard and risk assessment under REACH for L5."

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

Firstly, you propose a tiered testing strategy for terrestrial organisms. In the endpoint summary of IUCLID section 6.3. Terrestrial toxicity you indicate that "*The registration substance, L5, falls within soil hazard category 3 as defined in REACH R.7; high absorption (log Kow>5) but no indication that the substance is very toxic to aquatic organisms. Aquatic toxicity data show no effects at concentrations that are close to or above the limit of water solubility of the substance*". ECHA acknowledges that no effects up to the water solubility limit were observed in the chronic *Daphnia* study available on the registered substance.

ECHA notes that if no effects are observed in chronic or long-term effects in aquatic organisms up to the substance solubility limit it is unfeasible to derive a PNEC for aquatic organisms. Consequently, the Equilibrium Partitioning Method (EPM) is not applicable and ECHA considers it not possible to allocate a 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)). Therefore the tiered testing strategy proposed by you is not accepted by ECHA with current information and it is necessary to generate data for this endpoint. However, for your future considerations ECHA refers you to the *Note for your consideration* at the end of this request.

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) submitted on 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 requested to carry out the proposed test using the registered substance subject to the present decision: 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)

Note for your consideration

As explained in the request above, in absence of PNECaquatic it is not possible to use the hazard category approach described in ECHA Guidance (Section R.7.11.6., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, November 2017)). ECHA notes however that *Guidance on information requirements and chemical safety assessment* Chapter R.7c (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 hence considers that if based on the results of the long-term terrestrial toxicity test on terrestrial invertebrates you consider that you have sufficient data to assess the risks to the terrestrial environment and no further testing of terrestrial organisms is required you should update your technical dossier by clearly stating the reasons for adapting the information requirements of long-term toxicity test on terrestrial plants (Annex IX, section 9.4. of the REACH Regulation).

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: 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 long-term toxicity testing on plants (Annex IX, Section 9.4.3., column 2).

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, June2017), 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.

Appendix 2: Procedural history

ECHA received your registration containing the testing proposal for examination pursuant to Article 40(1) on 30 April 2015.

ECHA held a third party consultation for the testing proposals from 25 June 2015 until 10 August 2015. ECHA did not receive information from third parties.

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

You were notified that the draft decision does not take into account any updates after 06 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 amended 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.