EUROPEAN CHEMICALS AGENCY

Helsinki, 19 July 2017

Addressee: [redacted]

Decision number: CCH-D-2114362615-47-01/F
Substance name: 1,1,1,3,5,5,5-heptamethyltrisiloxane
EC number: 217-496-1
CAS number: 1873-88-7
Registration number: [redacted]
Submission number: [redacted]
Submission date: 30.09.2015
Registered tonnage band: 10-100T

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA requests you to submit information on

1. **Extended one-generation reproductive toxicity study (Annex IX, Section 8.7.3.; test method: EU B.56./OECD TG 443) in rats, oral route with the registered substance specified as follows:**
   - **Ten weeks premating exposure duration for the parental (P0) generation;**
   - **Dose level setting shall aim to induce some toxicity at the highest dose level;**
   - **Cohort 1A (Reproductive toxicity);**
   - **Cohort 1B (Reproductive toxicity) without extension to mate the Cohort 1B animals to produce the F2 generation;**

2. **Sediment simulation testing (Annex IX, Section 9.2.1.4.; test method: Aerobic and anaerobic transformation in aquatic sediment systems, EU C.24./OECD TG 308) at a temperature of 12 °C with the registered substance;**

3. **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) with the registered substance;**

4. **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) with 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 requested for the endpoint 1 in an updated registration dossier by **26 July 2019** and the information requested for endpoints

2-4 in an updated registration dossier by **28 January 2019**. 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 Claudio Carlon, Head of Unit, Evaluation E2

[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

You have applied read-across adaptations for several environmental standard information requirements subject to the current decision. The proposed read-across for the endpoints Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.) and Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.) is discussed in section 0 of this decision because it is based on similar justifications.

0. Grouping of substances and read-across approach

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

In the registration, you have adapted the standard information requirements, relevant to the current decision for Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.) and Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.) by applying a read-across adaptation following REACH Annex XI, Section 1.5. with Octamethyltrisiloxane CAS 107-51-7 ; EC 203-497-4 (hereafter referred to as source substance or as L3).

Annex XI, Section 1.5. requires a structural similarity among the substances within a group or category such that relevant properties of a substance within the group can be predicted from the data on reference substance(s) within the group by interpolation. The following analysis presents your justification for the proposed grouping approach and read-across hypothesis, together with ECHA's analysis concerning the justification in both a generic and a property-specific context.

a. Description of the grouping and read-across approach proposed by the Registrant

You have provided the following arguments to justify the read-across approaches in general terms:
"The registration substance belongs to the structural class of siloxanes (alkyl, vinyl, aryl or hydrogen substituted), assigned structural class I-3 in [redacted]*."* (Section 1.4 Analogue group approach, CSR)

The registered substance is further categorised as I-3-3 which is characterised as follows: *"I-3-3: Substances with hydrolysis half-life at pH 7 and 25°C >1 hour and log Kow greater than 4. Although these substances could hydrolyse in theory, they may be absorbed into compartments in which the reaction is slower. This would apply to absorption in the gastro-intestinal tract, or to sediment in water, for example."* (Section 7.3, Reconsile Category/Analogue/QSAR strategy)

You further described in the CSR that the data gaps for the registered substance may be filled using read-across of measured data from *"Other substances from the structural class shown in Table 1.4.1."* (i.e., Table 1.4.1. Substances in the structural class of siloxanes (alkyl, vinyl, aryl or hydrogen substituted) and from *"substance trimethoxysilane (CAS 2487-90-3) (supporting data), for ecotoxicology, as a substance containing a Si-H bond"*.

In your read-across justification provided for above endpoints, you proposed octamethyltrisiloxane (L3, CAS 107-51-7) for testing, *"which is also a linear siloxane made*

up of a chain of 3 silicon atoms linked by oxygen. In both substances methyl groups form the silicon side groups, however the difference is that in H-L3 the middle silicone has a Si-H bond in place of one of the methyl groups."

You further states that "*HL3 and L3 are part of the siloxanes grouping of substances. They have low water solubility (0.02 and 0.034 mg/l respectively), high log Kow (6.2 and 6.6 respectively) and slow hydrolysis rate (2.15 days at pH 7 and 20-25°C and 13.7 days at pH 7 and 25°C, respectively). Both substances also are not readily biodegradable and have high adsorption to sediment potential. Therefore read-across between the two substances is considered to be valid."*

In addition to read-across to L3, data have been read-across from another substance that contains a Si-H bond (trimethoxysilane CAS 2487-90-3) to "*exclude the possibility that by-products of this Si-H reaction might bring unpredicted toxicity to aquatic organisms*".

b. Information submitted to support the grouping and read-across approach

The following justification documents are provided to support the proposed read-across (IUCLID section 13):

[redacted]

The provided Siloxane analogue report ([redacted]) 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.

Apart from the above general information in ECHA's understanding you have provided the substance specific read-across justification for environmental hazard assessment, in the technical dossier, under the endpoint study summary for Ecotoxicological information, in Section 6 and in the Chemical Safety Report (CSR) in section 7.0.

This information includes a description of the properties of substances in the class of siloxanes in general terms, followed by specific information regarding the read-across approaches from the source substances to the target substance, taking into account structure, hydrolysis rate, physico-chemical properties and ecotoxicological properties.

In addition you have provided in the technical dossier of the target substance the following ecotoxicological studies for the source substance L3:

- Fish, Early-Life Stage Toxicity Test (OECD TG 210, GLP, [redacted] 2010) in Section 6.1.2 as key study
- Daphnia magna Reproduction Test (OECD TG 211, GLP, [redacted] 2010) in Section 6.1.4 as key study

The technical dossier of the target substance does not include long-term aquatic studies performed with the target substance.

This information encompasses the read-across hypothesis and justification, where *"the read-across approach for H-L3 is assessed for the surrogate substance taking into account structure and physico-chemical properties".* The justification includes the following sections:

- Table 1 Summary of physico-chemical and ecotoxicological properties for the registered and surrogate substances (i.e., Octamethyltrisiloxane (L3) CAS 107-51-7; Trimethoxysilane CAS 2487-90-3).
- Read-across from L3 to H-L3
- Read-across from trimethoxysilane to H-L3

c. 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 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 one-to-one analogue approach using octamethyltrisiloxane (L3, CAS 107-51-7; EC 203-497-4) as the source substance.

According to ECHA's understanding you suggested that due to structural similarities, similar physicochemical properties, comparable slow hydrolysis rates and expected mode of action, the ecotoxicological properties of the target substance L4 can be predicted from the source substance L3.

In the following, ECHA examines whether the substances have indeed similar properties or that they would follow a regular pattern in their properties resulting from structural similarity.

(i) Substance identity information (including level of purity and impurities) for the target and source substances

The substance characterisation of the source substance(s) need to be sufficiently detailed in order to assess whether the attempted prediction is not compromised by the composition and/or impurities. In the ECHA practical guide 6 "How to report on Read-Across" it is recommended to follow the ECHA Guidance for identification and naming of substances under REACH and CLP (version 1.3, February 2014) also for the source substances. This ensures that the identity of the source substance and its impurity profile allows an assessment of the suitability of the substances for read-across purposes.

ECHA notes that the source substance has solely been characterized by its chemical name and CAS No and no information on the composition or impurities has been provided in the technical dossier of the target substance. As there are several registrations for the source substances, it is not possible to perform substance specific analysis of the possible differences in the composition and impurity profiles of the source and target substances and the impact they may have on the proposed prediction.

(ii) 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 ecotoxicological properties of a substance, since structural similarity does not always lead to predictable or similar ecotoxicological 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 as follows: "*The registration substance, 1,1,1,3,5,5,5-heptamethyltrisiloxane (H-L3) is a siloxane of three silicon atoms linked by oxygen atoms. The structurally analogous substance proposed for read-across is octamethyltrisiloxane (L3, CAS 107-51-7), which is also a linear siloxane made up of a chain of 3 silicon atoms linked by oxygen. In both substances methyl groups form the silicon side groups, however the difference is that in H-L3 the middle silicone has a Si-H bond in place of one of the methyl groups*".

ECHA notes that in addition to the structural similarities, structural differences can be observed. The target and source substances are linear siloxanes containing 3 methylated silicon atoms - however, in the target substance the middle silicone has a Si-H bond in place of one of the methyl group.

ECHA acknowledges that the target substance and the proposed source substance belong to a class of compounds called *siloxanes*. ECHA notes that you acknowledged structural differences between the target and source substances, i.e., existence of Si-H bond in the target substance in place of one methyl group in the source substance. In order to justify this structural difference, i.e., Si-H bond versus methyl group, you provided data for another substance that contains a Si-H bond (Trimethoxysilane, CAS No 2487-90-3) to exclude the possibility that by-products of this Si-H reaction might bring unpredicted toxicity to aquatic organisms.

While ECHA acknowledges that you intended to "*demonstrate that reaction of the Si-H bond does not cause toxic effects*", ECHA also notes that even if the by-products of this Si-H reaction of the target substance would not produce enhanced effects in toxicity tests when compared to the source substance, you have not addressed in your read-across justification how the absence of an additional methyl group in the target substance may influence the predicted property.

You further intend to support the structural similarity in the Siloxane analogue report. You state that the choice of substances for testing is based on e.g., "*structural similarity, represented by the Tanimoto similarity index using an enhanced MDL fingerprint for the representation of Si-compounds*". ECHA acknowledges that molecular similarity indexes (e.g. the Tanimoto similarity index) can be considered when searching for relevant source chemicals for comparison. However, ECHA considers that such approaches give only an indication regarding potential similarity and do not provide a justification for the structural differences between the target and source substances and how they influence the property to be predicted.

You acknowledged structural differences between the target and source substances. However ECHA notes that you have not fully justified how a structural difference, i.e. an absence of a methyl group, between the target and source substances may impact the toxicity of the substances and thus affect the possibility to predict properties of the target substance from the data obtained with the source substance.

The provided explanation is therefore not sufficient to establish a scientifically credible link between the structural similarity and the prediction.

(iii) 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 structural 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.

You have reported several physico-chemical properties of the target and source substances in your read-across justification and concluded that *"Therefore read-across between the two substances is considered to be valid"*. However, ECHA observes that there are differences in the physicochemical properties between the target and source substances. You report in your read-across justification the log Kow values (6.2 for the target, 6.6 for L3), molecular weight (222.51 for the target, 236.54 for L3), water solubility (0.02 mg/l for the target, 0.034 mg/l for L3), and vapour pressure values (850 Pa for the target, 530 Pa for L3).

ECHA observes that the existing long-term aquatic studies were conducted in flow-through conditions. Therefore, despite of the differences in vapour pressure, there is unlikely to be any concern for substance stability in aqueous media during testing for the source and target substances. However, ECHA notes that you have not explained how the differences in physicochemical properties such as log Kow affect the predicted hazardous property, i.e. toxicity to aquatic organisms in long-term exposure. Lipophilicity has an effect on bioaccumulation potential which in turn influences the concentrations of the substances in the organisms, and in the target sites, and can therefore affect the toxic potential of the substances.

With respect to the structural differences in toxic potential of the substances, you propose that *"To exclude the possibility that by-products of this Si-H reaction might bring unpredicted toxicity to aquatic organisms, data have been read-across from another substance that contains a Si-H bond"*. You do not intend to fulfil any data-gap with the data provided on Trimethoxysilane (CAS 2487-90-3), but only to *"demonstrate that reaction of the Si-H bond does not cause toxic effects"*.

ECHA understands that you propose that the only difference in structure that may produce changes in toxic effects is the *"reaction of the Si-H bond, present in the registration substance but not in L3"*. ECHA agrees that the data provided on trimethoxysilane (CAS 2487-90-3), does not show toxicity in short-term aquatic studies with fish and Daphnia. However, ECHA notes that even if the by-products of this Si-H reaction (hydrogen) of the target substance would not produce enhanced effects in toxicity tests when compared to the source substance, there are other structural differences, e.g. presence of an additional methyl group in the source substance, that may produce differences in hazard properties

between the substances. As described in the previous paragraphs, the substances have differences in both physicochemical properties and degradation (e.g. log Kow of 6.2 for the target substance, 6.6 for L3; vapour pressure of 850 Pa for the target, 530 Pa for L3). Existence of such differences indicates the likelihood of differences in bioavailability and bioaccumulation potential, and consequently in the degree of toxic effects, and you have not provided any evidence to the contrary. ECHA considers that you did not demonstrate similarity in bioavailability and bioaccumulation properties among the substances (and their degradation products), and did not address how the potential differences in these properties do not influence the toxic potential of the substances.

In summary, ECHA concludes that based on the presented information it is not possible to confirm that the substances would have similar properties or they would follow a regular pattern in their properties regarding aquatic toxicity. In the absence of such information there is not an adequate basis for predicting the properties of the target substance from the data obtained with the source substance.

d. Conclusion on the read-across approach for the endpoints related to ecotoxicological properties

Based on the above considerations ECHA concludes that you have not provided adequate and reliable information to demonstrate the validity of the proposed read-across approach for the environmental endpoints under consideration.

ECHA therefore concludes that the criteria of Annex XI, Section 1.5, are not met and the read across is rejected.

1. Extended one-generation reproductive toxicity study (Annex IX, Section 8.7.3.)

Pursuant to Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

The basic test design of an extended one-generation reproductive toxicity study (test method EU B.56./OECD TG 443 with Cohorts 1A and 1B, without extension of Cohort 1B to include a F2 generation, and without Cohorts 2A, 2B and 3) is a standard information requirement as laid down in column 1 of 8.7.3., Annex IX of the REACH Regulation, if the available repeated dose toxicity studies (e.g. 28-day or 90-day studies, OECD TGs 421 or 422 screening studies) indicate adverse effects on reproductive organs or tissues or reveal other concerns in relation with reproductive toxicity. If the conditions described in column 2 of Annex IX are met, the study design needs to be expanded to include the extension of Cohort 1B, Cohorts 2A/2B, and/or Cohort 3. Further detailed guidance on study design and triggers is provided in in ECHA *Guidance on information requirements and chemical safety assessment* R.7a, chapter R.7.6 (version 4.1, October 2015).

Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

a) The information requirement

ECHA considers that other concerns in relation with reproductive toxicity are observed. More specifically, in the OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test) provided in the dossier, a reduced survival of offspring and reduced body weight of offspring were identified. According to ECHA Guidance Chapter R.7a: Endpoint specific guidance Version 4.1 – October 2015 (R.7.6.2.3.2, p.374), the reduced survival of offspring and reduced body weight of offspring independent of litter size are triggers to perform an EOGRTS at Annex IX. Pursuant to Annex IX, Section 8.7.3. an extended one-generation reproductive toxicity study is thus an information requirement.

You did not consider the information requirement for reproductive toxicity in Annex IX, Section 8.7.3., column 1, because no adverse effects on reproductive organs or tissues have been observed in the available repeated dose toxicity studies: "*In accordance with Column 1 of REACH Annex IX, the 2-generation reproductive toxicity study) (required in Section 8.7.2.) does not need to be conducted because there are no adverse reproductive effects in the existing repeated dose toxicity studies and reproductive studies with the registered substance and a relevant surrogate substance*".

However, ECHA points out that the information requirement according to Annex IX, Section 8.7.3. has been changed by Commission Regulation (EU) 2015/282, and that the new information requirement, i.e. the extended one-generation reproductive toxicity study, is an information requirement if adverse effects on reproductive organs or tissues have been observed in the available repeated dose toxicity studies (e.g. a 28-day or 90-day repeated dose toxicity study, OECD 421 or 422 screening studies) or if these studies reveal other concerns in relation with reproductive toxicity. ECHA considers that other concerns in relation with reproductive toxicity is observed from the available OECD 422 screening study.

The reduced survival of offspring and reduced body weight of offspring independent of litter size constitute 'other concerns in relation with reproductive toxicity', and as such act as triggers to perform an EOGRTS at Annex IX. Hence, an extended one-generation reproductive toxicity study is an information requirement.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint. Thus, an extended one-generation reproductive toxicity study according to Annex IX, Section 8.7.3. is required. The following refers to the specifications of this required study.

a) The specifications for the required study

Premating exposure duration and dose-level setting

To ensure that the study design adequately addresses the fertility endpoint, the duration of the premating exposure period and the selection of the highest dose level are key aspects to be considered. According to the ECHA *Guidance on information requirements and chemical safety assessment* R.7a, chapter R.7.6 (version 4.1, October 2015), the starting point for deciding on the length of the premating exposure period should be ten weeks to cover the full spermatogenesis and folliculogenesis before the mating, allowing meaningful assessment of the effects on fertility.

Ten weeks premating exposure duration is required because there is no substance specific information in the dossier supporting shorter premating exposure duration as advised in the

ECHA *Guidance on information requirements and chemical safety assessment* R.7a, chapter R.7.6 (version 4.1, October 2015). Ten weeks exposure duration is supported also by the lipophilicity of the substance to ensure that the steady state in parental animals has been reached before mating.

The highest dose level shall aim to induce some toxicity to allow comparison of effect levels and effects of reproductive toxicity with those of systemic toxicity. The dose level selection should be based upon the fertility effects with the other cohorts being tested at the same dose levels

Species and route selection

According to the test method EU B.56/ OECD TG 443, the rat is the preferred species. On the basis of this default assumption, ECHA considers that testing should be performed in rats.

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 4.1, October 2015) 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) Outcome

Based on the available information, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Extended one-generation reproductive toxicity study (test method EU B.56./OECD TG 443), in rats, oral route, according to the following study-design specifications:

Ten weeks premating exposure duration for the parental (P0) generation;
- Dose level setting shall aim to induce some toxicity at the highest dose level;
- Cohort 1A (Reproductive toxicity);
- Cohort 1B (Reproductive toxicity) without extension to mate the Cohort 1B animals to produce the F2 generation;

Notes for your consideration

The conditions to include the extension of Cohort 1B are currently not met. Furthermore, no triggers for the inclusion of Cohorts 2A and 2B (developmental neurotoxicity) and Cohort 3 (developmental immunotoxicity) were identified. However, you may expand the study by including the extension of Cohort 1B, Cohorts 2A and 2B and/or Cohort 3 if new information becomes available after this decision is issued to justify such an inclusion. Inclusion is justified if the new information shows triggers which are described in column 2 of Section 8.7.3., Annex X and further elaborated in ECHA *Guidance on information requirements and chemical safety assessment* R.7a, chapter R.7.6 (version 4.1, October 2015). You may also expand the study to address a concern identified during the conduct of the extended one-generation reproduction toxicity study and also due to other scientific reasons in order to avoid a conduct of a new study. The justification for the expansion must be documented. The study design must be justified in the dossier and, thus, the existence/non-existence of the conditions/triggers must be documented.

2. Sediment simulation testing (Annex IX, Section 9.2.1.4.)

Pursuant to Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to VIII of the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.
"Sediment simulation testing" is a standard information requirement as laid down in Annex IX, section 9.2.1.4. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex IX, Section 9.2.1.4., column. You provided the following justification for the adaptation:

"*In accordance with Column 2 of REACH Annex IX, the simulation test on ultimate degradation in surface water and the sediment simulation test do not need to be conducted as the chemical safety assessment according to Annex I indicates that these are not necessary. The chemical safety assessment also indicates that identification of degradation products is not necessary*" and

"*The chemical safety assessment according to REACH Annex I indicates that it is not necessary to conduct the simulation test on ultimate degradation in surface water and the sediment simulation test, or to identify degradation products. Simulation tests (water and sediments) are not considered necessary because the risk characterisation ratios (RCRs) for the aquatic and sediment compartment, even with the assumption that the parent substance is not biodegradable, are <1*".

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.2.1.4., column 2 because the substance is not readily biodegradable and the provided information in the dossier leads to potentially P or vP conclusion for sediment. You have yourself indicated that "*The screening criteria for persistence (P/vP) in the sediment compartment are met*" and that "*No data are available for stability in sediment. The substance is not readily biodegradable (based on read-across) and meets the screening criteria for persistence (P/vP) in the sediment compartment. The intermediate siloxane hydrolysis/degradation products, and silanol hydrolysis/degradation product, may also meet the screening criteria for persistence (P/vP) in the sediment compartment*".

Furthermore, ECHA notes that the registered substance has low water solubility (0.02 mg/L), high partition coefficient (log Kow 6.2) and adsorption coefficient (log Koc, soil 3.8) indicating adsorptive properties. In addition, substance is used as a laboratory reagent by professional workers and potential exposure to sediment cannot be excluded. ECHA therefore considers that you have not demonstrated that sediment exposure is unlikely.

In response to a Member State Competent Authority (MSCAs) proposals for amendment (PfA) ECHA clarifies the following. ECHA considers that further information on the degradation of the substance and its degradation products is needed for the PBT/vPvB assessment and for the identification of the degradation products in relation to the PBT/vPvB assessment. ECHA hence considers that at this stage the information in the CSA is not complete due to the data gaps addressed in this decision. On this basis, the CSA cannot be used to justify that there is no need to investigate further the degradation of the substance and its degradation products

Therefore, your adaptation of the information requirement cannot be accepted.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 3.0, February 2016) Aerobic and anaerobic transformation in aquatic sediment systems (test method EU C.24. / OECD TG 308) is the preferred test to cover the standard information requirement of Annex IX, Section 9.2.1.4.
One of the purposes of the simulation test is to provide the information that must be considered for assessing the P/vP properties of the registered substance in accordance with Annex XIII of REACH Regulation to decide whether it is persistent in the environment. Annex XIII also indicates that "*the information used for the purposes of assessment of the PBT/vPvB properties shall be based on data obtained under relevant conditions*".

The Guidance on information requirements and chemical safety assessment R.7b (version 3.0, February 2016) specifies that simulation tests "attempt to simulate degradation in a specific environment by use of indigenous biomass, media, relevant solids [...], and a typical temperature that represents the particular environment". The Guidance on information requirements and chemical safety assessment Chapter R.16 on Environmental Exposure Estimation, Table R.16-9 (version 2.1 October 2012) indicates 12°C (285K) as the average environmental temperature for the EU to be used in the chemical safety assessment. Performing the test at the temperature of 12°C is within the applicable test conditions of the Test Guideline OECD TG 308. Therefore, the test should be performed at the temperature of 12°C.

In response to a MSCAs PfA ECHA clarifies the following. Simulation tests performed in sediment possibly imply the formation of non-extractable residues (NER). These residues (of the parent substance and/or transformation products) are bound to the sediment particles. NERs may potentially be re-mobilised as parent substance or transformation product unless they are irreversibly bound by covalent bonds or incorporated into the biomass. When reporting the non-extractable residues (NER) in your test results you are requested to explain and scientifically justify the extraction procedure and solvent used obtaining a quantitative measure of NER.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Aerobic and anaerobic transformation in aquatic sediment systems (test method: EU C.24./OECD TG 308).

Notes for your consideration

Before conducting the requested test you are advised to consult the ECHA Guidance on information requirements and chemical safety assessment, Chapter R7b, Sections R.7.9.4 and R.7.9.6 (version 3.0, February 2016) and Chapter R.11, Section R.11.4.1.1 (version 2.0, November 2014) on PBT assessment.

In accordance with Annex I, Section 4, of the REACH Regulation you should revise the PBT assessment when results of the test detailed above is available. You are also advised to consult the ECHA Guidance on information requirements and chemical safety assessment

(version 2.0, November 2014), Chapter R.11, Section R.11.4.1.1. and Figure R. 11-3 on PBT assessment for the integrated testing strategy for persistency assessment in particular taking into account the degradation products of the registered substance.

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

Pursuant to Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to VIII of the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

"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. Adequate information on Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1.), or Fish, short-term toxicity test on embryo and sac-fry stages (Annex IX, 9.1.6.2.), or Fish, juvenile growth test (Annex IX, 9.1.6.3.) needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing a study record for a fish early-life stage toxicity test (test method OECD TG 210) performed with the analogue substance Octamethyltrisiloxane (EC No 203-497-4).

However, as explained above in Appendix 1, section 0 of this decision, your adaptation of the information requirement cannot be accepted.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 3.0, February 2016) fish early-life stage toxicity test (test method OECD TG 210), fish short-term toxicity test on embryo and sac-fry stages (test method EU C.15. / OECD TG 212) and fish juvenile growth test (test method EU C.14. / OECD TG 215) are the preferred tests to cover the standard information requirement of Annex IX, Section 9.1.6.

Regarding the long-term toxicity testing on fish pursuant to Annex IX, section 9.1.6.1, ECHA considers that the FELS toxicity test according to OECD TG 210 is the most sensitive of the standard fish tests available as it covers several life stages of the fish from the newly fertilised egg, through hatch to early stages of growth and should therefore be used (see ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, February 2016), Chapter R7b, Figure R.7.8-4). The test method OECD TG 210 is also the only suitable test currently available for examining the potential toxic effects of bioaccumulation (ECHA Guidance Chapter R7b, version 3.0, February 2016). For these reasons, ECHA considers the FELS toxicity test using the test method OECD TG 210 as most appropriate and suitable.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Fish, early-life stage (FELS) toxicity test (test method: OECD TG 210).

Notes for your consideration

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, February 2016), Chapter R7b (Section R.7.8.5., including Figure R.7.8-4) if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both.

Due to the low solubility of the substance in water and the high partition coefficient you should consult OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, February 2016), Chapter R7b, Table R.7.8-3 summarising aquatic toxicity testing of difficult substances for choosing the design of the requested ecotoxicity tests and for calculation and expression of the result of the tests.

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

Pursuant to Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to VIII of the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

"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. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation [by providing (a) study record(s) for a *Daphnia magna* Reproduction Test (OECD TG 211) with the analogue substance Octamethyltrisiloxane (EC No 203-497-4).

However, as explained above in Appendix 1, section 0 of this decision, your adaptation of the information requirement cannot be accepted.

Therefore, your adaptation of the information requirement cannot be accepted.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 3.0, February 2016) *Daphnia magna* reproduction test (test method EU C.20. / OECD TG 211) is the preferred test to cover the standard information requirement of Annex IX, Section 9.1.5.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Daphnia magna reproduction test (test method: EU C.20./OECD TG 211).

Notes for your consideration

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, February 2016), Chapter R7b (Section R.7.8.5., including Figure R.7.8-4) if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both.

Due to the low solubility of the substance in water and the high partition coefficient you should consult OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, February 2016), Chapter R7b, Table R.7.8-3 summarising aquatic toxicity testing of difficult substances for choosing the design of the requested ecotoxicity tests and for calculation and expression of the result of the tests.

Appendix 2: Procedural history

ECHA notes that the tonnage band for several members of the joint submission is 100 to 1000 tonnes per year.

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

The compliance check was initiated on 18 August 2016.

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.

ECHA did not receive any comments by the end of the commenting period.

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

ECHA received a proposal for amendment and modified the draft decision.

ECHA invited you to comment on the proposed amendment.

ECHA referred the draft decision to the Member State Committee.

You did not provide any comments on the proposed amendment(s).

The Member State Committee reached a unanimous agreement on the draft decision in its MSC-53 written procedure and ECHA took the decision according to Article 51(6) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. The substance subject to the present decision is provisionally listed in the Community rolling action plan (CoRAP) for start of substance evaluation in 2018.

2. This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

3. Failure to comply with the requests in this decision, or to fulfil otherwise the information requirements with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State.

4. In relation to the information required by the present decision, the sample of the substance used for the new tests 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 tests 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 tests must be suitable to assess these grades. Finally there must be adequate information on substance identity for the sample tested and the grades registered to enable the relevance of the tests to be assessed.