EUROPEAN CHEMICALS AGENCY

Helsinki, 19 May 2017

Addressee: [redacted]

Decision number: CCH-D-2114359638-34-01/F
Substance name: 1,1,1,3,5,5,5-heptamethyl-3-[(trimethylsilyl)oxy]trisiloxane
EC number: 241-867-7
CAS number: 17928-28-8
Registration number: [redacted]
Submission number: [redacted]
Submission date: 03.02.2014
Registered tonnage band: 100-1000T

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. **In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method: OECD TG 476 or TG 490) with the registered substance;**

2. **Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.; test method: OECD [421/422]) in rats, oral route with the registered substance;**

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

4. **Robust study summary for Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.; test method: Bioaccumulation in fish: aqueous and dietary exposure, OECD TG 305, [aqueous exposure/dietary exposure]);**

5. **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;**

6. **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;**

7. **Soil simulation testing (Annex IX, Section 9.2.1.3.; test method: Aerobic and anaerobic transformation in soil, EU C.23./OECD TG 307) at a temperature of 12 °C with the registered substance;**

8. **Identification of degradation products (Annex IX, Section 9.2.3.)**

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 information requested for endpoints 1-3 in an updated registration dossier by **26 November 2019** and the information requested for endpoints 4-8 in an updated registration dossier by **26 November 2018**. You shall also update the chemical safety report, where relevant. The timeline has been set to allow for sequential testing

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

Appeal

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

Authorised[1] by 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 toxicological standard information requirements subject to the current decision. The proposed read-across for the endpoints Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.) and Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.) is discussed in section 0 of this decision because it is based on similar justifications. The corresponding section 2 and section 3 analyse the need for further data to meet the respective information requirements.

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 (Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.) and Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.)) by applying a read-across adaptation following REACH Annex XI, Section 1.5. with the following substances:

- Decamethyltetrasiloxane CAS 141-62-8; EC 205-491-7 (hereafter referred to as source substance or as L4)
- 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 built your hypothesis on structural similarity as well as physical-chemical and basic toxicological parameters being in the same range. You analyzed structural similarities and dissimilarities between parent substances and the substances used for read-across and explained that all the substances have high lipophilicity and low water solubility. You also explained that they are all susceptible to hydrolysis, but the hydrolysis rate is slow at pH 7. At pH 2 and 37.5°C, all three substances were predicted to hydrolyse very rapidly forming either dimethylsilanediol and trimethylsilanol (for L3 and L4, respectively) or trimethylsilanol and methylsilanetriol (for M3T). Therefore, the hypothesis also is based on the production of similar hydrolysis products.

In the CSR you have provided the following arguments relevant to justify the read-across approach:

"In the case of repeated dose toxicity and reproductive toxicity relevant properties are structural similarity as well as physical-chemical and basic toxicological parameters in the same range. In the following paragraphs the read-across approach for M3T is evaluated point by point.

(a) Structural similarity

The registered substance (M3T) and read-across substances (L3 and L4) are all methylated siloxanes containing Si atoms linked by oxygen. L3 and L4 are linear chains of 3 and 4 Si-O units respectively, whereas M3T is a tertiary branched structure of four Si atoms, with a central Si (see Section 1 for chemical structure). None of the substances contains any reactive functional groups.

(b) Physicochemical properties

The substances all have high lipophilicity and low water solubility. They are all susceptible to hydrolysis, but the hydrolysis rate is slow at pH 7. At pH 2 and 37.5°C, relevant for oral exposure, all three substances hydrolyse very rapidly, forming either dimethylsilanediol and trimethylsilanol (L3 and L4) or trimethylsilanol and methylsilanetriol (M3T).[...] *However, in view of the high lipophilicity and poor water solubility of the parent substances it is likely that some unhydrolysed material is absorbed onto food present in the stomach and thus the true rate of degradation in the stomach is difficult to predict."*

"For the inhalation and dermal routes, since hydrolysis at pH 7 is slow, distribution relates mainly to parent substance. Although L4 is the closest analogous structure in respect of solubility and partitioning of the parent, they hydrolysis rate of L3 is more comparable to that of M3T and it is therefore appropriate to take into consideration data for both L3 and L4."

"By both oral and inhaled routes of administration, a generally similar toxicological profile is observed for L3 and L4 . As L4 is noted to result in slightly fewer changes, L3 is selected as worst-case and there appropriate for chemical safety assessment. [...] *These results indicate that there is no reason to suspect that the hydrolysis product would contribute any additional effects not seen with L3 and L4.*

L3 and L4 both hydrolyse to produce dimethylsilanediol which is not generated by M3T. A 28-day sub-acute oral toxicity with that substance ([redacted], 2009), reported a NOAEL of 250 mg/kg bw/day. Hepatic brown pigment accumulation was observed in males at the higher dose level of 500 mg/kg bw/day. Lower dose levels of L3 and L4 caused a similar effect, but since the amount of dimethylsilanediol produced at the dose levels where effects were seen with L3 and L4 are much lower (250 mg/kg bw/day parent, equivalent to 97 and 148 mg/kg bw/day dimethylsilanediol), it can be concluded that the hydrolysis product is not the only contributor to the effects and reading across the results for these substances can be considered as a reasonable worst case for M3T.

Reproductive toxicity (fertility)

Neither of the available screening studies for L3 and L4 showed any evidence of adverse effects on reproductive parameters up to the highest concentrations tested.(...) "

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

You have provided a read-across justification in the CSR (please see section 0.0.b). Furthermore, you have provided several documents as separate attachments in IUCLID, Section 13, relevant to the current decision:

[redacted]

The provided matrix report ("[redacted]") is summarising the available physico-chemical and toxicological data on related alkoxysilanes.

The document [redacted] *"sets out the analogue methods applicable to linear and cyclic siloxanes"* and presents a list of substances within the analogue group of siloxanes (alkyl, vinyl, aryl or hydrogen substituted).

[redacted] document 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, substance specific information regarding which methods (i.e. category, analogue or QSAR) have been applied will be provided in the CSR and IUCLID.

Apart from the above general information you have provided the substance specific read-across hypothesis and justification, in the technical dossier, under the endpoint study summary for repeated dose toxicity, in Section 7.5 and in the Chemical Safety Report (CSR) in section 5.

This information includes the read-across hypothesis and justification, the identification of the source and target substances; comparison of the structural features, physico-chemical properties, predicted toxicokinetics properties and acute dose toxicity of the source and target substances. In the same place you also discuss the repeated systemic toxicity and conclude on your read-across approach.

In addition you have provided in the technical dossier of the target substance the following toxicological studies.
For the target substance:

- an acute oral toxicity study (non guideline, performed according to Guidance on Safety Assessment of New Cosmetics (Japan Cosmetic Industry Association, technical materials No.92, 1991) 2001);
- Ames test (according to Guidelines for Screening Mutagenicity Testing Of Chemicals, Japanese ministry of health and welfare ordinance No. 1604: November 1, 1999) 2001);
- In vitro mammalian cytogenicity (according to Guidelines for Screening Mutagenicity Testing Of Chemicals, Japanese ministry of health and welfare ordinance No. 1604: November 1, 1999) 2001);
- skin and eye irritation studies (non guideline, performed according to Guidance on Safety Assessment of New Cosmetics (Japan Cosmetic Industry Association, technical materials No.92, 1991) 2001);

- Sensitization (non guideline, performed according to Guidance on Safety Assessment of New Cosmetics (Japan Cosmetic Industry Association, technical materials No.92, 1991) 2001);

For the source substance decamethyltetrasiloxane:
- results of an acute dermal toxicity study (OECD 402, GLP, [redacted], 2009)
- results of an oral repeated dose toxicity (OECD 407, GLP, [redacted], 2010) in Section 7.5.1. as key study
- results of inhalation repeated dose toxicity study (OECD 413, GLP, [redacted], 2010) in Section 7.5.1. as key study
- results of combined repeated dose toxicity with reproduction developmental toxicity screening test via inhalation route (OECD 422, GLP, [redacted] 2007) in Sections 7.8.1. and 7.8.2. as key study and in Section 7.5.2. as supporting study.

For the source substance octamethyltrisiloxane:
- results of inhalation repeated dose toxicity study (OECD 413, GLP, [redacted] 2011) in Section 7.5.1. as key study
- results of combined repeated dose toxicity with reproduction developmental toxicity screening test via inhalation route (OECD 422, GLP, [redacted] 2008) in Sections 7.8.1. and 7.8.2. as key study and in Section 7.5.2. as supporting study.

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 linear and cyclic siloxanes with alkyl, aryl, vinyl, hydrogen or hydroxy attached to Si 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 CAS 141-62-8; EC 205-491-7 (L4), and Octamethyltrisiloxane CAS 107-51-7 ; EC 203-497-4 (L3) as source substances.

According to ECHA's understanding you suggest that target and source substances have similar properties based on:
- structural similarities
- similar physico-chemical properties of the substances leading to similar toxicokinetic profiles and hence the toxicological properties of the substances would be similar
- the justification for the read-across approach is also based on rapid and complete hydrolysis of the parent substances at pH 2 and 37.5°C, leading to the formation of the proposed structurally same and similar silanol hydrolysis products (either dimethylsilanediol and trimethylsilanol (for L3 and L4) or trimethylsilanol and methylsilanetriol (for M3T).

(i) Substance characterisation of source and target 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 substances has solely been characterised by their chemical name and CAS No and no information on the composition or impurities has been provided in the technical dossier of the target substance.

ECHA considers that currently the composition and the impurity profile of the source and target substances cannot be compared using the information provided in the registration dossier. Therefore, ECHA cannot reach conclusion whether the source substances can be used to predict properties for the registered substance.

(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 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 and differences between target and source substances by indicating that they *"are all methylated siloxanes containing Si atoms linked by oxygen"* and *"The registration substance, M3T, is a branched siloxane with four silicon atoms linked by three oxygen atoms; the longest siloxane chain contains three silicons and two oxygens. It is fully substituted by methyl groups. The read-across substance octamethyltrisiloxane is a linear siloxane with three silicon atoms linked by two oxygen atoms; it is fully substituted by methyl groups. The read-across substance 1,1,1,3,5,5,5-heptamethyltrisiloxane is a linear is otherwise substituted by methyl groups. The read-across substance decamethyltetrasiloxane is a linear siloxane with four silicon atoms linked by three oxygen atoms; it is fully substituted by methyl groups."*
ECHA observes that the source substances are linear while the target substance has a branched structure. ECHA notes that you have not addressed how the above differences may impact the toxicokinetic properties, hydrolysis and toxicity of the target substance.

ECHA observes that due to the described structural differences of target and source substances the silanol hydrolysis products formed from the parent substances are different. You have provided experimental data on the hydrolysis products trimethylsilanol and dimethylsilanediol. ECHA notes that the dimethylsilanediol - formed from the source substance - and methylsilanetriol –formed from the target substance - differ in the number of the hydroxyl groups. You have not explained or provided data to address the toxicity of methylsilanetriol.

ECHA notes that you have not provided sufficient information on how the structural differences in the parent substances and consequently in the silanol hydrolysis products 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 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.

In your read-across justification you state that physico-chemical parameters/properties of target and source substances are same range and thus support the similar toxicokinetic behaviour of the substances. ECHA observes that the physico-chemical properties of target and source substances are in the same/similar range.

Toxicokinetics

ECHA observes that you have provided toxicokinetic assessments, which are based on the physico-chemical properties of the substances. You claim that the physico-chemical properties of the substances "*indicate that absorption of parent is likely to be low via all routes of exposure. Once absorbed these substances are likely to distribute into tissues, particularly fatty tissues*", and "*although L4 is the closest analogous structure in respect of solubility and partitioning of the parent, they hydrolysis rate of L3 is more comparable to that of M3T and it is therefore appropriate to take into consideration data for both L3 and L4. For the oral route, the hydrolysis rate is predicted to be very rapid at pH 2 and 37.5°C. However, in view of the high lipophilicity and poor water solubility of the parent substances it is likely that some unhydrolysed material is absorbed onto food present in the stomach and thus the true rate of degradation in the stomach is difficult to predict*".

ECHA understands that you assume that the toxicokinetic behaviour of the substances is similar. ECHA notes, as pointed out in section "Hydrolysis" below, that there is insufficient evidence supporting the formation and presence of the proposed silanol hydrolysis products and fast hydrolysis at pH 2 and 37.5°C.

ECHA considers that on the basis of the above mentioned it is not possible to verify whether the proposed source substances and the target substance are likely to have similar toxicity profiles as a result of similar toxicokinetic profile.

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.

Hydrolysis

ECHA notes that based on data provided by you, the hydrolysis at pH 7 is slow. ECHA notes that there are marked differences in the hydrolysis rate at pH 7 and 20-25°C: 12.5 days (target substance, based on prediction), 30.3 days (L4) and 13.7 days (L3). You further claim that hydrolysis at pH 2 and 37.5°C is very rapid.

Firstly, ECHA observes that hydrolysis half-life rate at pH 2 is based on assumptions which are not substantiated by data. ECHA notes that there is no hydrolysis data available in the registration dossier for pH 2 for the target and source substances but instead you have postulated that the rate of the hydrolysis reaction is dependent on hydronium ion concentration and that there will be a 100 fold increase in hydrolysis rate on going from pH 4 to pH 2. ECHA accepts that the hydrolysis is catalysed by the hydronium ion, however there is no evidence provided to suggest such a dependence on the hydronium ion concentration and consequently ECHA considers the assumption of a 100 fold increase in hydrolysis rate on going from pH 4 to pH 2 as not supported by scientific evidence.

Secondly, ECHA considers that the formation of the proposed silanol hydrolysis products which is supporting of the hypothesis is not supported by data. In the data provided in the registration dossier there is no evidence of the formation of the proposed silanol hydrolysis products so it is not possible to verify that ultimate hydrolysis of both target and source substances has indeed occurred within the timeframe of the test.
Furthermore, you have not substantiated your assumption of a complete hydrolysis. In fact, the hydrolysis process which involves several steps may produce also other substances, whose possible presence and effects on your hypothesis you have not addressed.

ECHA therefore considers that you have not provided reliable data to support the rapid hydrolysis at pH 2 and 37.5°C, and formation of the claimed hydrolysis products. Consequently, the impact of the parent substances and other possible hydrolysis products on toxicity in oral studies cannot be excluded.

Experimental data

ECHA notes that the dossier contains only an acute oral toxicity study with the target substance, and an acute dermal study with the source substance L4.

You have summarised repeated dose toxicity studies conducted with the source substances L3 and L4 and conclude that "*by both oral and inhaled routes of administration, a generally similar toxicological profile is observed for L3 and L4. As L4 is noted to result in slightly fewer changes, L3 is selected as worst-case and there appropriate for chemical safety assessment*".

ECHA notes that based on the NOAEL and LOAEL values and the severity of the effects observed in the oral 28-day studies, toxicity profile of L3 and L4 seems to be similar. In addition, in the sub-chronic and screening inhalation studies (OECD 413 and 422) conducted with L3, similar liver effects were observed as in the 28-day study. However, in the sub-chronic and screening inhalation studies (OECD 413 and OECD 422) conducted with the source substance L4 no adverse liver effects were observed, which may support your claim of L3 being the worst-case. However, ECHA notes that the highest dose used in the studies conducted with L4 was 400 ppm, whereas the highest dose used in the studies with L3 was 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. Therefore, it cannot be concluded with sufficient certainty that L3 is the worst-case scenario.

You further state that based on the experimental study conducted with trimethylsilanol (hydrolysis product of all three substances) *"there is no reason to suspect that the hydrolysis product would contribute any additional effects not seen with L3 and L4".* In addition, based on the experimental study conducted with dimethylsilanol (hydrolysis product of L3 and L4) it *"can be concluded that the hydrolysis product is not the only contributor to the effects and reading across the results for these substances can be considered as a reasonable worst case for M3T".* ECHA notes that liver effects were observed with dimethylsilanol (hydrolysis product of L3 and L4) at 500 mg/kg bw/day, but no liver effects were seen in the study conducted with trimethylsilanol (hydrolysis product of all three substances) at 700 mg/kg bw/day. ECHA further notes that no experimental data on methylsilanetriol (hydrolysis product of the target substance) has been provided and thus, it cannot be concluded on its contribution to the toxicity of the target substance.

ECHA notes that the data provided indicates that the source substances L3 and L4 have similar toxicological profile in oral studies. However, comparison of the toxicological profiles of the target and source substances cannot be made as no higher tier studies are available for the target substance, i.e. your claim *"basic toxicological parameters in the same range"* cannot be verified.
ECHA concludes that based on the information provided it is not possible to confirm that the substances would have similar properties or they would follow a regular pattern in their properties. 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 substances.

d. Conclusion

For the reasons explained above, ECHA does not consider the read-across approach as proposed in the dossier to be a reliable basis to predict the relevant properties of the registered substance by interpolation. As the proposed read-across approach does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5, it cannot be approved to adapt standard information requirements for Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.) and Sub-chronic toxicity study (90-day)(Annex IX, Section 8.6.2.).

1. In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.)

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 X of the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

An "*In vitro* gene mutation study in mammalian cells" is an information requirement as laid down in Annex VIII, Section 8.4.3. of the REACH Regulation, "if a negative result in Annex VII, Section 8.4.1. and Annex VIII, Section 8.4.2." is obtained.
ECHA notes that the registration dossier contains negative results for both these information requirements. Therefore, adequate information *on in vitro* gene mutation in mammalian cells 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 with the following justification:

"The registration substance, M3T, is a branched siloxane with four silicon atoms linked by three oxygen atoms; the longest siloxane chain contains three silicons and two oxygens. It is fully substituted by methyl groups. The read-across substance 1,1,1,3,5,5,5-heptamethyltrisiloxane is a linear siloxane with three silicon atoms linked by two oxygen atoms; it has a single Si-H bond and is otherwise substituted by methyl groups. For both the ultimate products of hydrolysis are trimethylsilanol and methylsilanetriol.

The registered substance and the read-across substance both hydrolyse slowly (300 hours and 50 hours respectively). Neither of these two substances includes structural groups that are associated with genotoxicity. It is concluded that read-across between the substances is scientifically justified. Additional information is given in a supporting report [redacted] *attached in Section 13 of the IUCLID 5 dossier.*

1,1,1,3,5,5,5-heptamethyltrisiloxane was chosen as read-across substance as it has similar hydrolysis products to the registered substance and neither substance has any functional groups that are associated with genetic toxicity.

Information on mutagenicity to mammalian cells is available for the structural analogue, 1,1,1,3,5,5,5 -heptamethyltrisiloxane from an in vitro study for mutagenicity to mammalian cells conducted according to OECD TG 476 and in compliance with GLP ([redacted] *(2012)). The original study was considered reliability 1. Read-across to the registered substance is considered scientifically justified and is reliability 2. No evidence for test-substance induced increase in mutant factor was observed when tested in mouse lymphoma L5178Y cells with and without metabolic activation. Appropriate positive and solvent controls were included and gave expected results. It is concluded that the test substance is negative for mutagenicity to mammalian cells under the conditions of the test".*

You provided a study record for an In vitro Mammalian Cell Gene Mutation Test (OECD TG 476) with the analogue substance 1,1,1,3,5,5,5-heptamethyltrisiloxane (EC no 217-496-1).You also provided the document [redacted], which is a generic document for the whole analogue group The document "*outlines the approach to genetic toxicity for all the organosilicone substances, and other Si-containing substances which are not organic*". A hypothesis for analogue approach regarding genotoxicity is described. An overview of the genotoxic potential of the analogue groups, and data matrix is provided. It is concluded that "*Read-across between organosilicone substances with similar functional groups is scientifically justified*". ECHA notes however, that no substance-specific information regarding the read-across approach has been provided.

The reason for choosing the analogue to be tested for this endpoint is summarized by you as: "*1,1,1,3,5,5,5-heptamethyltrisiloxane was chosen as read-across substance as it has similar hydrolysis products to the registered substance and neither substance has any functional groups that are associated with genetic toxicity.*"

ECHA has following observations on your prediction:

Firstly, it must be noted that since the hydrolysis rate claimed by you of both the registered substance and the analogue substance are so slow, the possible similarity of the hydrolysis products loses the relevance.

Secondly, there are structural differences between the registered substance and the analogue. In particular, M3T is branched and the analogue substance 1,1,1,3,5,5,5-heptamethyltrisiloxane is a linear substance. You have not provided any justification why these differences would not affect the prediction. ECHA considers that structural similarity alone is not sufficient to conclude that the genetic toxicity of M3T can be predicted from the data for the reference substance in the context of read-across approach. 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.

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.
ECHA considers that the *in vitro* mammalian cell gene mutation tests using the *Hprt* and *xprt* genes (OECD TG 476) and the *in vitro* mammalian cell gene mutation tests using the thymidine kinase gene (OECD TG 490) are appropriate to address the standard information requirement of Annex VIII, Section 8.4.3.
In your comments on the draft decision, you indicated your willingness to conduct this test.

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: *In vitro* mammalian cell gene mutation test (test method: OECD TG 476 *or* OECD TG 490).

2. Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.)

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 X of the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

"Screening for reproductive/developmental toxicity" (test method OECD TG 421 or 422) is a standard information requirement as laid down in Annex VIII, Section 8.7.1. of the REACH Regulation if there is no evidence from available information on structurally related substances, from (Q)SAR estimates or from *in vitro* methods that the substance may be a developmental toxicant. No such evidence is presented in the dossier. Therefore, adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have not provided any study record of a screening for reproductive/developmental toxicity in the dossier that would meet the information requirement of Annex VIII, Section 8.7.1.

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing study records for a Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test (OECD TG 422) with the analogue substance(s) Octamethyltrisiloxane (CAS no 107-51-7) and Decamethyltetrasiloxane (CAS no 141-62-8).

However, as explained above in Appendix 1, section 0 of this decision, your adaptation of the information requirement is rejected.

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 the test methods OECD TG 421/422, the test is designed for use with rats. On the basis of this default assumption ECHA considers testing should be performed with 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.

You provided comments on the draft decision, in which you proposed to waive this requirement on the basis of Annex VIII, Column 2 adaptation, 8.7.1. '*This study does not need to be conducted if a pre-natal developmental toxicity study (Annex IX, 8.7.2) or a two-generation reproductive toxicity study (Annex IX, Section 8.7.3) is available.*'
You further explained that "*The following test was requested in ECHA's 'decision on a test proposal' for 1,1,1,3,5,5,5-heptamethyl-3-[(trimethylsilyl)oxy]trisiloxane (CAS number: 17928-28-8) and will be conducted accordingly. 1. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EUB.31./OECD TG 414) in a first species (rat or rabbit), oral route using 1,1,1,3,5,5,5-heptamethyl-3-[(trimethylsilyl)oxy]trisiloxane (CAS number: 17928-28-8).*"

ECHA notes that a testing proposal is not equivalent to an available study. As long as there is no data for a prenatal developmental toxicity study available in the dossier, there is a data gap for reproductive toxicity screening study endpoint. If the prenatal developmental toxicity study should become available before the deadline set in the final decision of the current compliance check, you may then use the appropriate adaptation possibility.

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:
- Reproductive/developmental toxicity screening test (test method: OECD TG 421) *or*
Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (test method: OECD TG 422) in rats by the oral route.

Notes for your considerations

For the selection of the appropriate test, please consult ECHA *Guidance on information requirements and chemical safety assessment*, Chapter R.7a, section R.7.5 and 7.6 (version 4.1, October 2015).

3. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.)

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 X of the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

A "sub-chronic toxicity study (90 day)" is a standard information requirement as laid down in Annex IX, Section 8.6.2. of the REACH Regulation. 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 study records for a Repeated Dose 28-Day Oral Toxicity in Rodents (OECD TG 407) with the analogue substance Decamethyltetrasiloxane (CAS no 141-62-8) and two Subchronic Inhalation Toxicity: 90-Day (OECD Guideline 413) studies with the analogue substances Octamethyltrisiloxane (CAS 107-51-7) and Decamethyltetrasiloxane (CAS 141-62-8). However, as explained above in Appendix 1, section 0 of this decision, your adaptation of the information requirement is rejected.

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.

ECHA has evaluated the most appropriate route of administration for the study. Based on the information provided in the technical dossier and/or in the chemical safety report, and as explained above in Appendix 1, section 0 of this decision, ECHA considers that the oral route - which is the preferred one as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 4.1, October 2015) Chapter R.7a, section R.7.5.4.3 - is the most appropriate route of administration. More specifically, even though the information indicates that human exposure to the registered substance by the inhalation route is likely, the registered substance is a liquid with a vapor pressure of 40 Pa at 25 C, and it is used in formulations and as laboratory reagent. Hence, the test shall be performed by the oral route using the test method EU B.26./OECD TG 408.

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

In your comments on the draft decision, you indicated your willingness to conduct this test.

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: Repeated dose 90-day oral toxicity study (test method: EU B.26./OECD TG 408) in rats.

4. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.)

"Bioaccumulation in aquatic species, preferably fish" is a standard information requirement as laid down in Annex IX, Section 9.3.2.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.

In the technical dossier you have provided a study record for a non-GLP study "*Bioconcentration of methyltris(trimetylsiloxy)silane in rainbow trout*", the protocol of which is claimed to be comparable to the OECD 305 test guideline. However, the summary of this study does not fulfil the conditions for a robust study summary, according to Article 3(28), as it is not sufficiently detailed to allow ECHA to make an independent assessment of the study.

In particular, the reporting detail provided is not sufficient to enable ECHA to conclude whether the provided bioconcentration factor (BCF) value is correct. It is not clear whether the value has been normalised for lipid content or whether growth correction has been applied. Additionally, the range of BCF values reported is between 1500 and 9600 L/kg and so the reason for the selection of the value of 3500 L/Kg as an appropriate value for PBT assessment is not sufficiently clear.

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.

In your comments on the draft decision, you indicate your intention to address this issue by presentation of additional data on the existing bioaccumulation study and by addition of read across data on the analogue substance L4. You note that some of the study details requested in the draft decision are not available in the original study report e.g. concentrations in fish and water, lipid values and growth rates. Consequently, you propose to supplement the available data with the read across study. You based the read-across to L4 on "*close similarity in physicochemical properties, molecular size, structural features, and hydrolysis rate under equivalent conditions* " and on a similar mode of action, and you discussed these arguments in your read-across justification provided in your comments. Furthermore, the kinetic BCF value of 6840 L/Kg for L4, indicates that the vB criterion is met (i.e. BCF >5000). Therefore, the read-across to L4 would also appear a worst-case scenario for this endpoint.

ECHA notes that you intend to improve the study summary for the existing bioaccumulation study on the registered substance.

With regard to the proposed read-across, ECHA notes that the read across can only be evaluated in full once the study and the read across justification are included in the registration dossier. Nevertheless, in principle, ECHA considers this to be a reasonable approach to fulfil bioaccumulation endpoint on the basis of the information provided in your comments.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit a robust study summary of the "Bioconcentration of methyltris(trimetylsiloxy)silane in rainbow trout" study.

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

"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.

In the technical dossier you have provided a study record for an OECD 305 study entitled "*14C-Decamethyltetrasiloxane (14C-L4): Bioconcentration in the Fathead minnow (Pimephales promelas) under flow-through test conditions*". However, this study record has not been generated with appropriate test method for this particular information requirement as it does not provide the information required by Annex IX, Section 9.1.6.1.

In particular, in accordance with Annex XI, Section 1.1.2., data generated by another than the corresponding test methods referred to in Article 13(3) of the REACH Regulation shall be considered equivalent if the following conditions are met:

(1) adequacy for the purpose of classification and labelling and/or risk assessment;
(2) adequate and reliable coverage of the key parameters foreseen to be investigated in the corresponding test methods referred to in Article 13(3);
(3) exposure duration comparable to or longer than the corresponding test methods referred to in Article 13(3) if exposure duration is a relevant parameter; and
(4) adequate and reliable documentation of the study is provided.

With regard to the above conditions, ECHA notes that the current study is not appropriate for the purpose of classification and labelling and neither can it be considered to provide adequate and reliable coverage of the key parameters foreseen to be investigated in a long-term toxicity to fish test as the study did not determine whether there were any sub-lethal effects and the NOEC was set based on mortality only. Additionally, aquatic toxicity study can only be regarded as long-term when sensitive life stages (e.g. juveniles, eggs, larvae) are exposed (ECHA Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 3.0, February 2016). Thus, test performed according to OECD 305 cannot be considered as long-term toxicity test.

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

In your comments on the draft decision, you propose to address this issue by inclusion of read across data, namely an OECD 210 study on the analogue substance L4. You have provided an overview of the read across and of the study to be included. You based the read-across to L4 on "*close similarity in physicochemical properties, molecular size, structural features, and hydrolysis rate under equivalent conditions* " and on a similar mode of action, and you discussed these arguments in your read-across justification provided in your comments.

ECHA acknowledges that the source and target substances have similar physicochemical properties and that mode of action (non-polar narcosis) is likely to be the same due to the presence of the same functional groups. Additionally there are no effects in aquatic toxicity studies for the target and source siloxanes with similar high log Kow (~8).
However, ECHA notes that the read across can only be evaluated in full once the study and the read across justification are included in the registration dossier. Nevertheless, in principle, ECHA considers this a reasonable approach for this endpoint based on the information provided in your comments.

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).

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

"Sediment simulation testing" is a standard information requirement as laid down in Annex IX, section 9.2.1.4. of the REACH Regulation. Column 2 of Section 9.2.1.4 of Annex IX further indicates that the study needs to be conducted if the chemical safety assessment (CSA) according to Annex I indicates the need to investigate further the degradation of the substance and its degradation products and that the choice of the appropriate test(s), which may include simulation degradation tests in appropriate media, depends of the results of the CSA. Column 2 indicates that the study does not need to be conducted if the substance is readily biodegradable or if direct and indirect exposure of soil is unlikely. 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 2. You provided the following justifications 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 "*Simulation tests (water and sediments) are not considered necessary because the risk characterisation ratios (RCRs) for the aquatic and sediment compartment, even with the conservative 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 there is a vPvB/PBT concern for this substance. .

Characteristics of other siloxanes suggest that this group of substances has the potential to be persistent in sediment as a result of adsorption processes preventing hydrolysis. You have indicated that the substance may be P/vP in the sediment compartment and that it does not meet the criteria for P/vP in the aquatic compartment stating that "*Based on the data available for the submission substance, along with the siloxane analogue group considerations, it is concluded that the substance does not meet the criteria for persistence (P/vP) in the aquatic compartment, may meet the criteria for persistence (P/vP) in the sediment compartment and may meet the criteria for persistence (P/vP) in the soil compartment".*

Additionally, you have concluded in your PBT assessment that "*BCF data available for the submission substance (steady-state BCF 3500 l/kg) indicates that the substance meets the criteria for B*". ECHA has requested further information on the bioaccumulation study provided in the registration dossier to clarify the bioaccumulation status.

Furthermore, ECHA notes that the registered substance has low water solubility (0.00189 mg/L), high partition coefficient (log Kow 8.2) and high adsorption coefficient (log Koc 5.3), indicating adsorptive properties. In addition, based on the uses reported in the technical dossier, ECHA considers that certain uses are reported for which sediment exposure cannot be excluded e.g. ERC 8c: Wide dispersive indoor use resulting in inclusion into or onto a matrix and ERC 8f: Wide dispersive outdoor use resulting in inclusion into or onto a matrix and also that the exposure estimations that you provided in the Chemical Safety Report (CSR) indicate that there is exposure to sediment in number of your exposure scenarios. ECHA therefore considers that you have not demonstrated that sediment exposure is unlikely.

In conclusion, ECHA notes that with the current information gaps, the Chemical safety Assessment (CSA) is not complete and cannot be used to justify why there is no need to investigate further the degradation of the substance and its degradation products. Furthermore, ECHA considers that the information is needed for the PBT/vPvB assessment and for the identification of the degradation products in relation to the PBT/vPvB assessment as the PBT/vPvB status of the registered substance is unclear. Therefore, your adaptation of the information requirement cannot be accepted.

In your comments on the draft decision, you set out a step-wise strategy to address this information requirement. You indicate that a stability study is ongoing with L2 to determine whether sediment simulation testing is feasible for branched and linear siloxanes. You propose to await the results of the studies with L2 before determining the appropriate action for the registered substance.

If L2 proves to be vP then you intend to read-across the result to the registered substance. If L2 proves not to be vP a testing strategy will be developed to address data gaps for other branched and linear siloxanes. This may include testing of the registered substance or read across from an analogue.

ECHA notes that you have not indicated a specific timeline to implement such a strategy nor given sufficient details to justify your proposal. Therefore, the request in the decision is maintained as originally notified to you.

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 "*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.

Simulation tests performed in sediment or in soil possibly imply the formation of non-extractable residues (NER). These residues (of the parent substance and/or transformation products) are bound to the soil or 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. The amount and kind of NER is operationally defined by the extraction method employed. Strong extractions methods, for example soxhlet-extraction with apolar solvents, should be used in order to qualify the remaining NER as irreversibly bound residues. You are therefore requested to justify scientifically that the extraction method you will apply is appropriate to identify non-extractable residues (NER) as residues irreversibility bound to the sediment.

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 tests 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 to determine the sequence in which the simulation tests are to be conducted and the necessity to conduct all of them.
The order in which the simulation biodegradation tests are performed needs to take into account the intrinsic properties of the registered substance and the identified use and release patterns which could significantly influence the environmental fate of the registered substance .

In accordance with Annex I, Section 4, of the REACH Regulation you should revise the PBT assessment when results of the tests 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.

7. Soil simulation testing (Annex IX, Section 9.2.1.3.)

"Soil simulation testing" is a standard information requirement as laid down in Annex IX, section 9.2.1.3. of the REACH Regulation. Column 2 of Section 9.2.1.3 of Annex IX further indicates that the study needs to be conducted if the chemical safety assessment (CSA) according to Annex I indicates the need to investigate further the degradation of the substance and its degradation products and that the choice of the appropriate test(s), which may include simulation degradation tests in appropriate media, depends of the results of the CSA. Column 2 indicates that the study does not need to be conducted if the substance is readily biodegradable or if direct and indirect exposure of soil is unlikely. 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 9.2.1.3., column 2 You provided the following justifications for the adaptation

"*In accordance with Column 2 of REACH Annex IX, the soil simulation test does not need to be conducted as the chemical safety assessment according to Annex I indicates that this is not necessary*" and "*The chemical safety assessment according to Annex I indicates that it is not necessary to conduct the soil simulation test. Simulation test (soil) is not considered necessary because the risk characterisation ratios (RCRs) for the terrestrial compartment, even with the conservative 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 there is a vPvB/PBT concern for this substance.

Characteristics of other siloxanes suggest that this group of substances has the potential to be persistent in soil as a result of adsorption processes preventing hydrolysis. You have indicated that the substance may be P/vP in the soil compartment and that it does not meet the criteria for P/vP in the aquatic compartment stating that "*Based on the data available for the submission substance, along with the siloxane analogue group considerations, it is concluded that the substance does not meet the criteria for persistence (P/vP) in the aquatic compartment, may meet the criteria for persistence (P/vP) in the sediment compartment and may meet the criteria for persistence (P/vP) in the soil compartment under conditions of very high humidity and in closed systems, but under normal environmental conditions, is unlikely to persist in soil environments due to the simultaneous action of both degradation and volatilisation*".

Additionally, you have concluded in your PBT assessment that "*BCF data available for the submission substance (steady-state BCF 3500 l/kg) indicates that the substance meets the criteria for B*". ECHA has requested further information on the bioaccumulation study provided in the registration dossier to clarify the bioaccumulation status.

Furthermore, ECHA notes that the registered substance has low water solubility (0.00189 mg/L), high partition coefficient (log Kow 8.2) and high adsorption coefficient (log Koc 5.3), indicating adsorptive properties. In addition, based on the uses reported in the technical dossier, ECHA considers that certain uses are reported for which soil exposure cannot be excluded e.g. ERC 8c: Wide dispersive indoor use resulting in inclusion into or onto a matrix and ERC 8f:

Wide dispersive outdoor use resulting in inclusion into or onto a matrix and also that the exposure estimations that you provided in the Chemical Safety Report (CSR) indicate that there is exposure to sediment in number of your exposure scenarios. ECHA therefore considers that you have not demonstrated that soil exposure is unlikely.

In conclusion, ECHA notes that with the current information gaps, the Chemical safety Assessment (CSA) is not complete and cannot be used to justify why there is no need to investigate further the degradation of the substance and its degradation products. Furthermore, ECHA considers that the information is needed for the PBT/vPvB assessment and for the identification of the degradation products in relation to the PBT/vPvB assessment as the PBT/vPvB status of the registered substance is unclear. Therefore, your adaptation of the information requirement cannot be accepted.

In your comments on the draft decision, you indicate your intention to provide read across data to address this information requirement. You proposes to read-across soil simulation test data from the structurally related substance L4. You have provided an overview of the read across and of the study to be included.

ECHA notes that the read across can only be evaluated in full once the study and the read across justification are included in the registration dossier. Nevertheless, based on the information provided in your comments, ECHA already observes certain shortcomings that would need to be addressed.

You refer to a half-life$_{soil}$ of 10days at 20 °C for the read across substance (L4) and report information on transformation rates based on removal of parent substance derived by chemical analysis. You also indicate that CO_2 release was not investigated.

ECHA highlights that if degradation half-life is available from existing studies performed at temperatures other than 12 °C, it is recommended to normalised the half-life to 12 °C using the Arrhenius equation (ECHA Guidance on information requirements Chapter 7b (version 3.0 2016), section R.7.9.4).

In addition, ECHA Guidance on information requirements and chemical safety assessment (version 2.0, November 2014), Chapter R.11, Section R.11.4.1.1. specifies that in persistence assessment, it is insufficient to consider removal of the parent substance alone when deriving degradation half-life. Removal may simply represent the transfer of a substance from one environmental compartment to another. Degradation may be biotic and/or abiotic (e.g. hydrolysis) and result in complete mineralisation, or simply in the transformation of the parent substance (primary degradation). In case primary degradation is observed, it is necessary to identify the degradation products and to assess their PBT/vPvB properties.

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 soil (test method EU C.23. / OECD TG 307) is the preferred test to cover the standard information requirement of Annex IX, Section 9.2.1.3.

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 "*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 307. Therefore, the test should be performed at the temperature of 12°C.

Simulation tests performed in sediment or in soil possibly imply the formation of non-extractable residues (NER). These residues (of the parent substance and/or transformation products) are bound to the soil or 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. The amount and kind of NER is operationally defined by the extraction method employed. Strong extractions methods, for example soxhlet-extraction with apolar solvents, should be used in order to qualify the remaining NER as irreversibly bound residues. You are therefore requested to justify scientifically that the extraction method you will apply is appropriate to identify non-extractable residues (NER) as residues irreversibility bound to the soil.

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 soil (test method: EU C.23./OECD TG 307).

Notes for your consideration

Before conducting the requested tests 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 to determine the sequence in which the simulation tests are to be conducted and the necessity to conduct all of them. The order in which the simulation biodegradation tests are performed needs to take into account the intrinsic properties of the registered substance and the identified use and release patterns which could significantly influence the environmental fate of the registered substance .

In accordance with Annex I, Section 4, of the REACH Regulation you should revise the PBT assessment when results of the tests 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.

8. Identification of degradation products (Annex IX, Section 9.2.3.)

The identification of the degradation products is a standard information requirement according to column 1, Section 9.2.3. of Annex IX of the REACH Regulation. Column 2 of Section 9.2.3. of Annex IX further states that the information does not need to be provided if the substance is readily biodegradable.

You consider that identification of the degradation products does not need to be conducted using the following justification: "*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*".

ECHA considers that exposure of the sediment and soil compartments cannot be excluded because the substance is used in professional and consumer applications where the environmental release is likely e.g. ERC 8c: Wide dispersive indoor use resulting in inclusion into or onto a matrix and ERC 8f: Wide dispersive outdoor use resulting in inclusion into or onto a matrix.

The registered substance has low water solubility (0.00189 mg/L), high partition coefficient (log Kow 8.2) and high adsorption coefficient (log Koc 5.3), indicating adsorptive properties.

As explained fully in sections (6) and (7) above, ECHA considers that with the current information the CSA cannot be used to justify that there is no need to investigate further the degradation of the substance and its degradation products. ECHA notes further that the information requested here may be needed for the PBT/vPvB assessment and for the identification of the degradation products in relation to the PBT/vPvB assessment.

The justification for waiving provided does not meet the criteria of either the specific adaptation rules of Column 2 of Annex IX, section 9.2.3, or the general adaptation rules of Annex XI. Therefore, the adaptation cannot be accepted.

In your comments on the draft decision, you indicate that for any sediment simulation test carried out, the study will include the identification of degradation products. Regarding the information on degradation products from soil simulation testing, you indicated your intention to provide read across data to address this information requirement. You proposes to read-across soil simulation test data from the structurally related substance L4. You have provided an overview of the read across and of the study to be included. ECHA has already outlined under request 7 above the considerations related to this adaptation.

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.

Regarding appropriate and suitable test method, the methods will have to be substance specific. When analytically possible, identification, stability, behaviour, molar quantity of metabolites relative to the parent compound should be evaluated. In addition, degradation half-life, log Kow and potential toxicity of the metabolite may be investigated.

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:

Identification of the degradation products (Annex IX, Section 9.2.3.) by using an appropriate and suitable test method, as explained above in this section.

Notes for your consideration

Before providing the above information you are advised to consult the ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, February 2016), Chapter R.7b., Sections R.7.9.2.3 and R.7.9.4. These guidance documents explain that the data on degradation products is only required if information on the degradation products following primary degradation is required in order to complete the chemical safety assessment. Section R.7.9.4. further states that when substance is not fully degraded or mineralised, degradation products may be determined by chemical analysis.

Appendix 2: Procedural history

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 31 March 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 took into account your comments and did not amend the requests.

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

ECHA received proposals for amendment and modified the draft decision.

ECHA invited you to comment on the proposed amendment(s).

ECHA referred the draft decision to the Member State Committee.

Your comments on the proposed amendment(s) were taken into account by the Member State Committee

The Member State Committee reached a unanimous agreement on the draft decision in its MSC-52 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 2017.

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 requirement(s) with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State.

4. In carrying out the tests required by the present decision it is important to ensure that the particular sample of substance tested is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured or imported. If the registration of the substance covers different grades, the sample used for the new tests must be suitable to assess these. Furthermore, there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the tests to be assessed.