SUBSTANCE EVALUATION CONCLUSION

as required by REACH Article 48

and

EVALUATION REPORT

for

Dodecamethylpentasiloxane (L5)

EC No 205-492-2

CAS RN 141-63-9

Evaluating Member State(s): Norway, handover from United Kingdom

Dated: December 2021

Evaluating Member State Competent Authority

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Year of evaluation in CoRAP: 2015

Before concluding the substance evaluation a Decision to request further information was issued on: 27 March 2017

Further information on registered substances here:

Dodecamethylpentasiloxane - Registration Dossier - ECHA (europa.eu)

DISCLAIMER

This document has been prepared by the evaluating Member State as a part of the substance evaluation process under the REACH Regulation (EC) No 1907/2006. The information and views set out in this document are those of the author and do not necessarily reflect the position or opinion of the European Chemicals Agency or other Member States. The Agency does not guarantee the accuracy of the information included in the document. Neither the Agency nor the evaluating Member State nor any person acting on either of their behalves may be held liable for the use which may be made of the information contained therein. Statements made or information contained in the document are without prejudice to any further regulatory work that the Agency or Member States may initiate at a later stage.

Foreword

Substance evaluation is an evaluation process under REACH Regulation (EC) No. 1907/2006. Under this process the Member States perform the evaluation and ECHA secretariat coordinates the work. The Community rolling action plan (CoRAP) of substances subject to evaluation, is updated and published annually on the ECHA web site[1].

Substance evaluation is a concern driven process, which aims to clarify whether a substance constitutes a risk to human health or the environment. Member States evaluate assigned substances in the CoRAP with the objective to clarify the potential concern and, if necessary, to request further information from the Registrant(s) concerning the substance. If the evaluating Member State concludes that no further information needs to be requested, the substance evaluation is completed. If additional information is required, this is sought by the evaluating Member State. The evaluating Member State then draws conclusions on how to use the existing and obtained information for the safe use of the substance.

This Conclusion document, as required by Article 48 of the REACH Regulation, provides the final outcome of the Substance Evaluation carried out by the evaluating Member State. The document consists of two parts i.e. A) the conclusion and B) the evaluation report. In the conclusion part A, the evaluating Member State considers how the information on the substance can be used for the purposes of regulatory risk management such as identification of substances of very high concern (SVHC), restriction and/or classification and labelling. In the evaluation report part B the document provides explanation how the evaluating Member State assessed and drew the conclusions from the information available.

With this Conclusion document the substance evaluation process is finished and the Commission, the Registrant(s) of the substance and the Competent Authorities of the other Member States are informed of the considerations of the evaluating Member State. In case the evaluating Member State proposes further regulatory risk management measures, this document shall not be considered initiating those other measures or processes. Further analyses may need to be performed which may change the proposed regulatory measures in this document. Since this document only reflects the views of the evaluating Member State, it does not preclude other Member States or the European Commission from initiating regulatory risk management measures which they deem appropriate.

[1] http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan

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Part A. Conclusion

1. CONCERN(S) SUBJECT TO EVALUATION

The Substance, dodecamethylpentasiloxane (L5) was originally selected for substance evaluation in order to clarify concerns about:

- PBT/vPvB
- Wide dispersive use
- Exposure of environment

During the evaluation no additional concern was identified.

The assessment was targeted to the environmental concerns. Nonetheless, an evaluation of the information available for human health hazard endpoints relevant to the “T” criteria was made.

2. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

A decision on testing proposal was adopted by ECHA in 2018 where the following tests were required:

1. Pre-natal developmental toxicity study in rats or rabbits, oral route using the analogue substance decamethyltetrasiloxane (L3)
2. Long-term toxicity to terrestrial invertebrates on L5
3. Long-term toxicity testing on plants on L5
4. Effects on soil microorganisms on L5

Furthermore, another testing proposal decision was adopted by ECHA in 2020 on

1. Reproductive toxicity (extended one-generation reproductive toxicity study)
2. Reproductive toxicity (pre-natal developmental toxicity)

Dodecamethylpentasiloxane (L5) is part of a group of related linear siloxanes that are subject to substance evaluation for similar concerns. The linear siloxanes are suspected PBT/vPvB substances. The other substances in this group are hexamethyldisiloxane (L2), octamethyltrisiloxane (L3) octamethyltrisiloxane (L4).
Data from these substances and the cyclic siloxanes D4, D5 and D6 (octamethylcyclotetra-siloxane; decamethylcyclopentasiloxane, and dodecamethylcyclohexasiloxane) have been used by the Registrant(s)s to support their registrations and the eMSCAs in their evaluation:

- SVHC on the basis of the criteria in REACH Articles 57(d) and 57(e) (PBT/vPvB): D4, D5 and D6 have been identified as SVHC (ECHA, 2015, 2018b).
- Restriction in wash-off cosmetic products for D4 and D5 entered into force by 31 January 2020, (ECHA, 2016).
- Restriction in leave-on personal care products and other consumer/ professional products is under consideration for D4, D5 and D6. Furthermore, a restriction of D6 in wash off and rinse off cosmetic products is included in the same restriction proposal (ECHA, 2020).

Some uses of the cyclosiloxanes are already or are in the process of being restricted in consumer products and in most professional uses under REACH. However, some of their uses (industrial production of electronics and some professional uses such as dry cleaning in closed systems) are not covered by these restrictions. These uses are in the process of being included into the authorisation list and companies will need to apply for authorisation to continue using them.

A compliance check on D5 is still ongoing in 2021.

3. CONCLUSION OF SUBSTANCE EVALUATION

The evaluation of the available information on the substance has led the evaluating Member State to the following conclusions, as summarised in the table below.

Table 1

CONCLUSION OF SUBSTANCE EVALUATION Conclusions	
Need for follow-up regulatory action at EU level	X
Harmonised Classification and Labelling	
Identification as SVHC	X
Restrictions	X
Other EU-wide measures	
No need for regulatory follow-up action at EU level	

4. FOLLOW UP AT EU LEVEL

4.1. Need for follow-up regulatory action at EU level

4.1.1. Harmonised Classification and Labelling

Not applicable.

4.1.2. Identification as a substance of very high concern, SVHC (first step towards authorisation)

L5 is considered to meet the criteria for very persistent and very bioaccumulative (vPvB) substances according to Article 57(e) of REACH.

According to the REACH Regulation (Annex I), exposure and emissions of PBT/vPvB substances should be minimized throughout the lifecycle of the substance. A first step would be the identification of L5 as a SVHC. In addition to leading to a formal recognition of the PBT/vPvB properties, Candidate Listing of L5 will also imply other legal obligations. Suppliers of substances and mixtures containing L5 have to provide a safety data sheet to their customers. Furthermore, suppliers of articles are obliged to pass on information on the respective substances in the supply chain and upon request provide information to consumers. Producers or importers of articles have to notify ECHA if their article contains a substance being on the Candidate List. The formal recognition of L5 as a PBT/vPvB substance with the subsequent obligations for the supply chain is expected to result in emission reductions of L5.

4.1.3. Restriction

L5 is used by consumers and professional workers mainly in cosmetics and personal care products and automotive care products. The wide dispersive use represents a significant potential for environmental releases.

The eMSCA concludes that L5 is considered to meet the criteria for very persistent and very bioaccumulative (vPvB) substances according to Article 57(e) of REACH.

Therefore, all emissions and environmental releases of L5 should be reduced as much as possible. To avoid regrettable substitution, L5 should be restricted since the substance has been identified as a potential alternative in the restriction of D4 and D5 in wash-off

cosmetic products (ECHA, 2016) and the restriction on D4, D5 and D6 in consumer and professional products (ECHA, 2020).

Since the inclusion of L5 into the CoRAP, an increase in the aggregated tonnage from 10-100 t in 2015 up to 1000-10 000 t in 2021 has been noted, confirming the increased use of L5 as a potential alternative for D4 and D5.

4.1.4. Other EU-wide regulatory risk management measures

Not applicable

5. CURRENTLY NO FOLLOW-UP FORESEEN AT EU LEVEL

5.1. No need for regulatory follow-up at EU level

Not applicable.

5.2. Other actions

Not applicable.

6. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS (IF NECESSARY)

Indication of a tentative plan is not a formal commitment by the evaluating Member State. A commitment to prepare a REACH Annex XV dossier (SVHC, restrictions) and/or CLP Annex VI dossier should be made via the Registry of Intentions.

Table 2

FOLLOW-UP		
Follow-up action	**Date for intention**	**Actor**
Identification as SVHC (authorisation)	-	Not agreed yet
Restriction	-	Not agreed yet
RMOA	-	Not agreed yet

The option of including L5 in other EU-wide regulatory risk management measures will be assessed in the RMOA for the group of linear siloxanes L2, L3, L4 and L5, which are subject to substance evaluation due to PBT/vPvB concern.

Part B. Substance evaluation

7. EVALUATION REPORT

7.1. Overview of the substance evaluation performed

The Substance, dodecamethylpentasiloxane (L5) was originally selected for substance evaluation in order to clarify concerns about:

- PBT/vPvB
- Wide dispersive use
- Exposure of environment

During the evaluation no additional concern was identified. The assessment was targeted to the environmental concerns. Nonetheless, an evaluation of the information available for human health hazard endpoints relevant to the "T" criteria was made.

Table 3 shows a list of evaluated endpoints with corresponding outcomes. More details can be found in the relevant sections below.

Table 3

EVALUATED ENDPOINTS	
Endpoint evaluated	**Outcome / conclusion**
Persistence	Concern confirmed. Conclude L5 as vP based on read-across to currently available information on sediment simulation testing OECD TG 308 for L3 and L2.
Bioaccumulation	Concern confirmed. Conclude L5 is vB based on currently available information on bioaccumulation studies OECD TG 305 for L5.
Toxicity	Concern refuted. Conclude L5 as not T based on currently available information on human and ecotoxicological studies.
Suspected vPvB properties	Concern confirmed. Conclude L5 is vPvB as explained above.
Exposure of environment and wide dispersive use	Concern confirmed. Based on use pattern there is wide dispersive use and exposure of the environment

7.2. Procedure

Dodecamethylpentasiloxane (L5) was included in the Community rolling action plan (CoRAP) for substance evaluation to be performed in 2015.

The initial assessment was initiated on 17 March 2015 by the UK as the eMSCA. Due to the UK's departure from the EU on 31 January 2020, Norway took over the substance evaluation for L5 in the conclusion stage. The evaluation of the available test results relies mainly on the UK's assessment and based on this, regulatory actions have been proposed by the Norwegian eMSCA.

The substance is part of a group of related linear siloxanes being evaluated under substance evaluation for similar concerns that they could be PBT/vPvB substances. The

other substances are hexamethyldisiloxane (L2), octamethyltrisiloxane (L3) and decamethyltetrasiloxane (L4). Data from these substances and the cyclic siloxanes D4, D5 and D6 (octamethylcyclotetrasiloxane; decamethylcyclopentasiloxane, and dodecamethylcyclohexasiloxane) have been used by the Registrant(s) to support their registrations and the eMSCA in their evaluation.

Information was provided in registration dossiers, publicly available information and information provided to the eMSCA by the Registrant(s). Based on the evaluation of the available information, the eMSCA concluded that some uncertainty remained on the degradation of the registered substance, sediment toxicity and on exposure assessment and risk characterisation for the environment. Therefore, it was necessary to request new data and a decision was issued by ECHA on 27 March 2017:

1. Sediment simulation testing; test method: Aerobic and anaerobic transformation in aquatic sediment systems, EU C.24./ OECD TG 308, including the identification of transformation products, at a temperature of 12 °C; OECD TG 218 Sediment-Water Chironomid Toxicity Test Using Spiked Sediment.
2. ASTM E1706-95b (1999) standard test methods for measuring the toxicity of sediment-associated contaminants with freshwater invertebrates: 28-day survival and growth test or 42-day survival, growth and reproduction test using the amphipod *Hyallela azteca*.
   Tests 1, 2 and 3 should be carried out as a tiered testing strategy. Test 2 is required unless the outcome of test 1 is that the substance is not P; Test 3 is required unless the outcome of test 2 indicates the substance is T.
3. Exposure assessment and risk characterisation for environment: Provide further information and justification on the input parameters used for the exposure assessment for ES3: Professional & consumer use of personal care products or alternatively, provide separate scenarios for professional consumer use and household consumer use of personal care products, including clear justification of the environmental emission factors chosen for each.

A dossier update for L5 containing the information from a sediment simulation test (OECD TG 308) for L2 and updated exposure information for L5 was received on 2 July 2020.

In addition, the Registrant(s) provided on 9 February 2021, the final study report for the OECD TG 308 sediment simulation study for L3 and the updated registration has been published at ECHAS disseminated page in June 2021. This sediment simulation study has been used in a read-across to evaluate the persistence of L5.

In May 2021 eMSCA launched a closed written commenting round in the PBT expert group for seeking advice on the properties of L5. The received comments have been taken into account in this document.

7.3. Identity of the substance

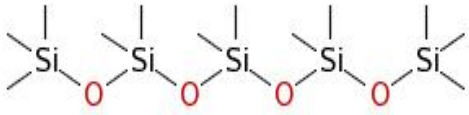
Table 4

SUBSTANCE IDENTITY	
Public name:	Dodecamethylpentasiloxane
EC number:	205-492-2
CAS number:	141-63-9
Index number in Annex VI of the CLP Regulation:	n/a
Molecular formula:	$C_{12}H_{36}O_4Si_5$
Molecular weight range:	384.85 g mol^{-1}

Synonyms:	L5, MD3M

Type of substance ☒ Mono-constituent ☐ Multi-constituent ☐ UVCB

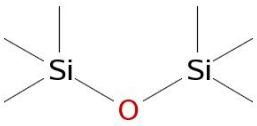
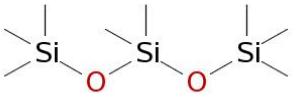
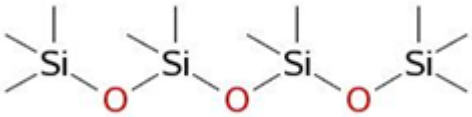
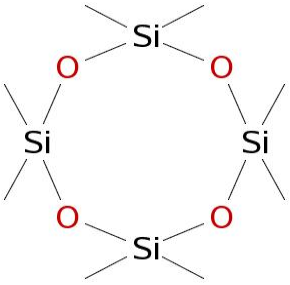
Structural formula:

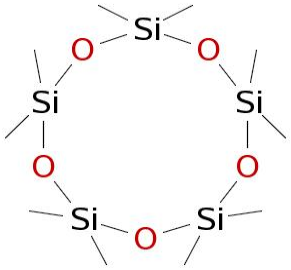
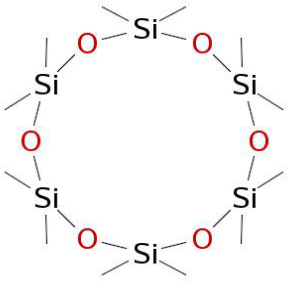


Category information

The following additional substances shown in Table 5 are relevant to consider in the assessment.

Table 5

Chemical	structure
L2, hexamethyldisiloxane EC No. 203-492-7 CAS RN 107-46-0	
L3, octamethyltrisiloxane EC No. 203-497-4 CAS RN 107-51-7	
L4, decamethyltetrasiloxane EC No. 205-491-7 CAS RN 141-62-8	
D4, octamethylcyclotetrasiloxane EC No. 209-136-7 CAS RN 556-67-2	

Chemical	structure
D5, decamethylcyclopentasiloxane EC no. 208-764-9 CAS RN 541-02-6	
D6, dodecamethylcyclohexasiloxane EC No. 208-762-8 CAS RN 540-97-6	

Appendix I to this report details the expected trends in PBT properties across this group.

7.4. Physico-chemical properties

Table 6

OVERVIEW OF PHYSICOCHEMICAL PROPERTIES	
Property	**Value**
Physical state at 20°C and 101.3 kPa	Colourless liquid
Melting/freezing point	-80 °C Publication
Boiling Point	210-232 °C Publication & QSAR
Vapour pressure	7.8 Pa at 25°C QSAR (MPBPVP v1.42 adapted for organosilicons)
Water solubility	$7.0x10^{-5}$ mg/l at 23°C Publication (non-guideline. A non-colloidal, saturated solution prepared by slow-stirring and analysed by GC-MS)
Partition coefficient n-octanol/water (Log Kow)	9.41 at ~25°C OECD 123 (Slow-stirring method)
Flash Point	79 °C at 101.3 kPa Closed cup ASTMD3828
Explosive properties	Data waiving
Oxidising properties	Data waiving
Stability in organic solvents and identity of relevant degradation products	Data waiving
Dissociation constant	Waiver - No ionisable groups
Relative density	0.88-0.94 at 20°C Publication

OVERVIEW OF PHYSICOCHEMICAL PROPERTIES	
Property	**Value**
Auto Flammability	350°C at 101.3 kPa Publication ASTM D286
Surface tension	Data waiving

7.5. Manufacture and uses

7.5.1. Quantities

Table 7 displays information from the ECHA dissemination website. Quantities have increased from 10-100 t in 2015 up to 1000- 10 000 t in 2021.

Table 7

AGGREGATED TONNAGE (PER YEAR)				
☐ 1 – 10 t	☐10 – 100 t	☐ 100 – 1000 t	☒ 1000- 10,000 t	☐ 10,000-50,000 t
☐ 50,000 – 100,000 t	☐ 100,000 – 500,000 t	☐ 500,000 – 1000,000 t	☐ > 1000,000 t	☐ Confidential

7.5.2. Overview of uses

Table 8 lists the different uses stated for L5 on the REACH public dissemination website[2].

Table 8

USES	
	Use(s)
Uses as intermediate	Use as intermediate at industrial sites
Manufacture	Manufacture of substance
Formulation	o Formulation of personal care products, o Formulation of automotive care products o Formulation of release agents o Polymer preparation-formulation of release agent o On-site formulation o Formulation of non-metal surface treatment – in situ treatment at downstream user industrial sites o Formulation of non- aqueous polymer preparations at downstream industrial sites
Uses at industrial sites	o Use as a laboratory reagent o Polymer preparation - use of release agent o Use of release agent o In situ treatment of non-metal surfaces o On site use as an intermediate o Laboratory uses o Use as a non-metal surface treatment agent o Use in binder and release agent o Industrial use, heat transfer fluid

[2] Checked 22 April 2021

USES	Use(s)
Uses by professional workers	o Professional use of personal care products, wash-off o Professional use in cosmetics, personal care products-leave-on o Professional use of personal care products o Professional use of automotive care
Consumer Uses	o Consumer use of personal care products o Consumer use in cosmetics, personal care products-leave-on o Consumer use of personal care products-wash-off o Use of automotive care
Article service life	Not listed

Several new use areas have been registered, including automotive care products for professional and consumer use. These new use areas lead to increased wide dispersal use, professional worker and consumer uses. A restriction on D4 and D5 in wash-off cosmetic products has been adopted, and a further restriction on D4, D5 and D6 for leave-on personal care products and other consumer/professional products is in progress. L5 is mentioned as an alternative replacement for the restricted uses of D4, D5 in cosmetics and personal care products. The supply volume of L5 has already increased from 10-100 t in 2015 up to 1000- 10 000 t in 2021,

An article written by Triest & Alemany (2014) summarises the use of silicone oils as anti-foam additives in drilling fluids used for ice core recovery in very deep exploration in the Antarctic. L5 is specifically listed, as well as polydimethylsiloxanes (PDMS), which can include L5. The use is not listed in the current registrations. This either means that the use area is not relevant in Europe, that it occurs at a tonnage below the current registration trigger, or that it was not realised commercially. The use for ice-drilling may provide a source of L5 in what would normally be considered remote areas.

7.6. Classification and Labelling

7.6.1. Harmonised Classification (Annex VI of CLP)

Not included in Annex VI of the CLP regulation.

7.6.2. Self-classification

Table 9: Notified self-classification and labelling of L5

Number of notifiers	Self-classification
199 (December 2021)	Not classified
39 (December 2021)	H315: Causes skin irritation. H319: Causes serious eye irritation. H335: May cause respiratory irritation.

7.7. Environmental fate properties

7.7.1. **Degradation**

7.7.1.1. Abiotic degradation

7.7.1.1.1. Hydrolysis

The key study in the registration dossier is an OECD Guideline 111 study (to GLP) carried out with the read-across substance decamethyltetrasiloxane (L4, CAS RN 141-62-8, EC No. 205-491-7).

The registration dossier for L4 contains a summary of a hydrolysis study conducted according to OECD Guideline 111, hydrolysis as a function of pH (registration dossier, 2009). The study is given a reliability - score of 1. Radiolabelled substance was used, as the concentration tested was low (3 µg/l, around half of the solubility limit). Precautions were taken to minimise volatilisation in the experiment (sealed test vessels) and the calculation methods used to obtain rate constants were adapted in some cases to allow for substance present in the headspace.

Low recoveries were seen in some of the experiments, 76-90% for the pH 5 and pH 9 studies and 55-70% for the pH 7 studies. These were attributed to losses during the preparation of the reaction tubes, and losses to the headspace in the case of the pH 7 studies.

The half-lives obtained from the study are presented in Table 10. These are for the disappearance of the parent substance.

Table 10: Hydrolysis half-life for L4

pH	Temperature (°C)	Half-life (hours)	Equivalent first order rate constant k_{obs} (day^{-1})
5	10	44.4 (1.9 days)	0.37
	25	14.0	1.19
	35	6.4	2.62
7	10	3,960 **(165 days)**	0.0042
	25	728 (30.3 days)	0.0228
	35	219 (9.1 days)	0.0761
9	10	180 (7.5 days)	0.0926
	25	21.1	0.789
	35	7.3	2.28

The initial products of hydrolysis are also unstable in water. The ultimate products of hydrolysis were dimethylsilanediol (detected) and trimethylsilanol (inferred, not detected due to the position of the radiolabel in the parent substance).
As can be seen from Table 10, the half-life for hydrolysis depends on the temperature and the pH.

The half-life at pH 7 and 10°C is around 165 days. The default environmental temperature assumed in the REACH guidance is typically 12°C for the freshwater environment and 9°C for the marine environment. However, the pH for the marine environment is generally higher (typically around pH 8).
Although not carried out in the registration dossier, it is possible to estimate the approximate hydrolysis half-life for the substance at 12°C and pH 7 and 9°C and pH 8 from the available data using the following approach.

At any given pH the observed first order rate constant (k_{obs}) determined in the study can be expressed in terms of the following equation.

$$k_{obs} = k_0 + k_{H3O+}[H_3O^+] + k_{OH^-}[OH^-] + k_a[acid] + k_b[base]$$

where: k_0 = first order rate constant for the uncatalyzed reaction.
k_{H3O+} = second order rate constant for catalysis by hydronium ions.
$[H_3O^+]$ = concentration of hydronium ions.
k_{OH-} = second order rate constant for catalysis by hydroxide ions.
$[OH^-]$ = concentration of hydroxide ions.
k_a = second order rate constant for catalysis by/reaction with general acids.
[acid] = concentration of acid.
k_b = second order rate constant for catalysis by/reaction with general bases.
[base] = concentration of base.

Assuming that under the conditions of the test, a) general acid or base catalysis was not occurring and b) at pH 5 and pH 9 the rate of the uncatalyzed reaction was negligible compared with the rates catalysis by hydronium (pH 5) and hydroxide (pH 9) ions, the values of k_{H30+} and $k_{[OH-]}$ can be estimated directly from the k_{obs} value measured at pH 5 (here $[H_3O^+] = 1\times10^{-5}$ mole/l) and pH 9 (here $[OH^-] = 1\times10^{-5}$ mole/l). Thus k_{H3O+} = 119,000 l mole^{-1} d^{-1} and k_{OH-} = 78,900 l mole^{-1} d^{-1}, both at 25°C.

At pH 7, $k_{obs} = k_0 + (119{,}000\times1\times10^{-7}) + (78{,}900\times1\times10^{-7})$.
As k_{obs} at pH 7 and 25ºC was determined as 0.0228 d^{-1}, k_0 = 0.003 d^{-1}.

The values of k_0, k_{H30+} and k_{OH-} allow the first order rate constant for hydrolysis (k_{obs}) to be estimated at any pH.

The experiment at pH 7 was carried out at three temperatures. Analysing these data using the Arrhenius equation allows value of k_{obs} at any given temperature to be extrapolated[3]. A plot (not shown) of ln k_{obs} versus 1/T (in K) revealed that the activation energy for the reaction was around 83,500 J/mole. The value of k_{obs} at pH 7 can then be estimated to be around 0.00526 d^{-1} at 12°C (equivalent to a half-life of around 132 days) and 0.00361 d^{-1} at 9°C (equivalent to a half-life of around 192 days).
The variation of the k_{obs} at pHs other than 7 is more difficult to estimate as it is not known if the same activation energy would apply to other pHs and this will vary with pH. However, as a first approximation the variation of the k_{obs} at other pHs can be assumed to be similar[4] to that seen at pH 7 (i.e. the value of k_{obs} at 12°C would be expected to be smaller than the value at 25°C by a factor of 0.0228/0.00526 = 4.3 and the value of k_{obs} at 9ºC would be smaller than the value at 25°C by a factor of 0.0228/0.00361 = 6.3).

Based on the above assumptions, plots of the variation of the expected hydrolysis half-life with pH can be constructed at temperatures of 9, 12 and 25°C. This is shown in Figure 1. As can be seen from the plot the hydrolysis half-life is predicted to reach a maximum just over 30 days at 25°C, around 130 days at 12°C and around 190 days at 9°C. It can also be seen from Figure 1 that the hydrolysis half-life is predicted to be above 40 days at pHs between approximately 6.3 and 7.9 at 12°C and pHs between approximately 6.1 and 8.1 at 9°C. The hydrolysis half-life is predicted to be above 60 days at pHs between approximately 6.5 and 7.7 at 12°C and pHs between approximately 6.3 and 7.9 at 9°C.

[3] The Arrhenius equation states that k_{obs}=Aexp(-Ea/RT), where A is the pre-exponential factor, Ea is the activation energy of the reaction, R is the universal gas constant and T is the absolute temperature. Thus a plot of ln k_{obs} versus 1/T allows the values of Ea (-slope) and A (intercept is ln A) to be estimated and the value of k_{obs} to be calculated at any given temperature.
[4] Arrhenius plots indicate that at pH 5 the activation energy would be around 56,100 J/mole and at pH 9 would be around 93,600 J/mole. The average of these two values is 74,900 which is similar to that estimated at pH 7. The registration dossier gives slightly lower activation energies for pH 5 and 9 (59.4 kJ/mol and 36.1 kJ/mol) – the reason for this discrepancy is not clear at present.

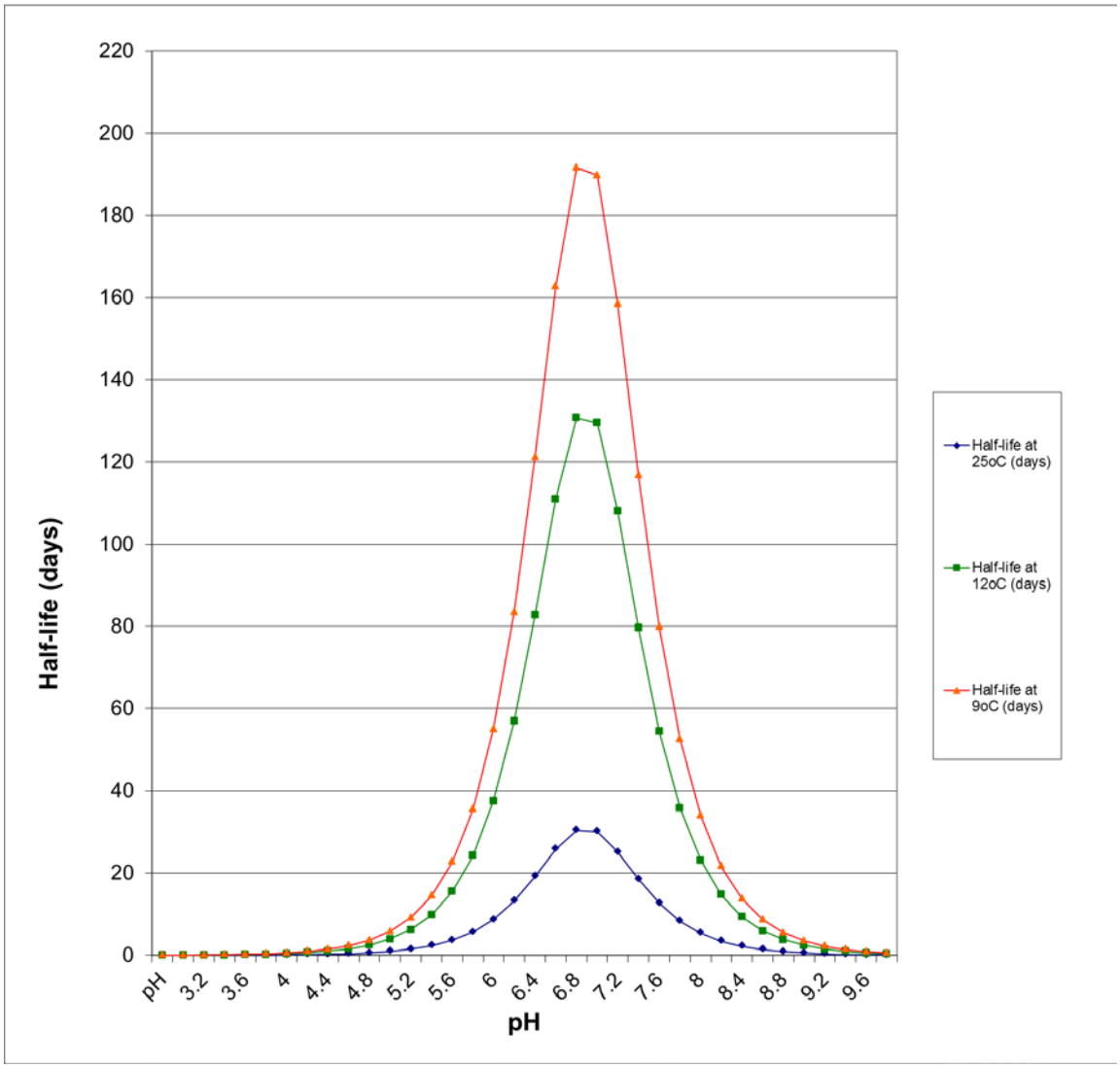


Figure 1: Variation of hydrolysis half-life with pH and temperature for L4

The Registrant(s) have performed a similar calculation (pers. comm, Jan 2016). They calculate that the pH range where the half-life exceeds 40 days is between 6.37 and 8.09 at 12°C, with a maximum half-life of 148 days occurring at pH 7.23. The 60 day threshold is exceeded between pH 6.56 and 7.91. At 9°C, the 40 day threshold is exceeded between pH 6.25 and 8.28, with the 60 day threshold exceeded between pH 6.43 and 8.10 (maximum half of 209 days at pH 7.27). At 25°C there are no values where the 40 (or 60) day thresholds are exceeded. The Registrant(s) highlight that the error in the calculations is greatest at the lower temperatures (9 and 12°C) because of the temperatures used in the experiment itself.

These calculations used the E_a values noted in the footnote on the previous page, which are slightly different to the values used by the eMSCA. The pH range where the respective thresholds are exceeded shift slightly (by around 0.3 pH units) but the width of the pH range for the exceedance remains the same (e.g. around 1.6 pH units for 12 degrees and 40 days).The eMSCA notes that for some other siloxanes, for example D4 and D5, the rate of hydrolysis is known to be significantly impacted by DOC.

The registration dossier considers that the data for L4 are also applicable to be read-across directly to L5 and a hydrolysis half-life of 30.3 days at pH 7 and 25°C has been used. The Registrant(s) considers the study to be reliability 1 (reliable without restrictions) and the read-across from the study to be reliability 2 (reliable with restrictions).

Supporting data on hydrolysis

Supporting data from the hydrolysis studies using L3 and D5 are available for the read-across of the L4 data. It is expected that hydrolysis rates will decrease with increasing chain length in the category. The half-lives (at 25 °C) of L3 are 5 h, 14 d and 10 h (pH5, 7 and 9) which are around half the respective values for L4. Therefore, the hydrolysis half-lives for L4 will likely be a “best-case” for L5. Direct read-across of the D5 (i.e. cyclic) is more difficult, as this requires selecting equivalence for a particular structure – i.e. whether L5 and D5 should be considered the same. There is further discussion of read-across of the biodegradation data between linear and cyclic siloxanes in section 7.7.1.2. However, the D5 data are useful as supporting information, particularly if the trends in cyclic hydrolysis rates are considered.

The QSAR study predicted that the hydrolysis half-life for L5 at a temperature of 20-25°C would be around 6.6 hours at pH 4, 2,000 hours at pH 7 (83 days) and 14 h at pH 9. The QSAR was developed using the available experimental data for twelve related linear and cyclic siloxanes. For comparison, in the registration dossier for L4, the QSAR predicts the half-life for L4 to be 3.9 h (20-25°C). Predictions are not provided for other pH values.

The eMSCA notes that for some other siloxanes, for example D4 and D5, the rate of hydrolysis is known to be significantly impacted by dissolved organic carbon (DOC), (ECHA, 2015). The impact on the hydrolysis rate for L4, and hence L5 is not known, but can reasonably be assumed to be similarly impeded.

In summary, experimental hydrolysis half-lives were read-across to L5 from L4 tested with OECD TG 111, showing a hydrolysis half-life for L4 of 30 days at pH 7 and 25 °C. Registrant(s) conclude that the L4 is not persistent in the aquatic environment. However, at pH 7 and 10°C a long half-life of around 165 days has been demonstrated. Since a temperature of 12°C is relevant for the freshwater environment, the hydrolysis half-life has been calculated at pH 7, equating to 130 days at 12°C. Since hydrolysis rates will decrease with increasing chain length in the category, a longer hydrolysis half-life can be expected for L5.

7.7.1.2. Phototransformation/photolysis

7.7.1.2.1. Phototransformation in air

No information on phototransformation in air is included in the registration dossier. However, on ECHAs dissemination page the results of calculations of the rate constant for the reaction of L5 with hydroxyl radicals in air using the AOPWIN (v1.92 - a model to calculate atmospheric oxidation half-life) program are available. The calculated rate constant is 1.8 $\times 10^{-12}$ cm^3 $molec^{-1}$ sec^{-1}. For a 24 hour average concentration of OH radicals of 5×10^5 molec cm^{-3}, this corresponds to a half-life of 9 days. It is noted that there is some uncertainty associated with the result, as the calculation method has not been validated for this type of substance (siloxane). Further, measured data and predictions for a number of other silanes and siloxanes are included and two of the three data sources are in the training set for AOPWIN. The Registrant(s) consider that these data correlate well with the AOPWIN-predictions and conclude that a half-life of 9 days will be used further in the exposure assessment.

7.7.1.2.2. Phototransformation in water and soil

There is no information available on phototransformation in water and soil.

7.7.1.3. Biotic degradation

7.7.1.3.1. Biodegradation in water

7.7.1.3.1.1. Estimated data

No estimations have been carried out in the registration dossier.

7.7.1.3.1.2. Screening tests

No screening tests on L5 are available. A read-across from experimental results for the structurally similar substance, octamethyltrisiloxane (L3; CAS RN 107-51-7) was used.

Read-across to ready biodegradation study on L3 (OECD TG 310)

The OECD TG 310 ready biodegradability test is reported in the registration dossier for L3 (registration dossier, 2009). The test was carried out in accordance with GLP. Activated sludge was collected from a wastewater treatment facility treating mainly residential wastes. Following preconditioning the activated sludge was diluted in test medium to give a total suspended solids concentration of 4 mg l^{-1}. The initial concentration of the test substance was 20 mg l^{-1} based on DOC.

The tests were carried out in glass serum bottles with a nominal volume of 160 ml. After addition of the test substance, the bottles were sealed with butyl rubber septa and crimp caps. Biodegradation was measured by carbon dioxide evolution. Positive control experiments were conducted using sodium benzoate.

No biodegradation was observed (as CO_2 evolution) for the test substance over the 28 day test. The reference substance was biodegraded by 96.5% over the 28 days. The test fulfils the validity criteria, and the study is given a reliability score of 1.

The result of no biodegradation is read across to L5. The Registrant(s) have included in the summary of ready biodegradation a table of results on substances that fall within the Reconsile Siloxane Category of substances. The linear siloxanes L2, L3, L4 and L5 fall within this category along with many other siloxanes. Within this group, there is in general no evidence of significant biodegradation for any of the members. However, the results reported in the table have not been further assessed by the eMSCA.

Based on the read- across, L5 is not readily biodegradable in a standard screening test.

7.7.1.3.1.3. Simulation tests

Water

No data on simulation tests in water are included in the registration dossier.

Sediment

Data on simulation tests in sediment are not available for L5 but for L2, L3, D4 and D5.

Read-across to sediment simulation study on L3 (OECD TG 308)

In the substance evaluation decision for L5, a sediment simulation test (OECD TG 308) at 12°C was requested. Aerobic and anaerobic transformation in aquatic sediment systems, including the identification of transformation products, was to be performed. Test results from an OECD TG 308 sediment simulation study with L3 have been made available to eMSCA in February 2021. The eMSCA notes that there are some issues with the test, which are discussed further below.

A comparison of the known properties of L5 with those of L3 reveals that L5 has a vapour pressure below that of L3, but L5 has a Henry's law constant higher than that for L3. Therefore, a higher volatility for L5 than L3 from water can be expected. Both substances have a similar predicted long residence time in air once volatilised. The potential for adsorption of L5 (as measured by the log Koc) is however higher than that of L3, which may counteract to some extent the higher volatility of L5 compared to L3 when the whole sediment is considered. There is no study on hydrolysis available for L5, but there is for a study on L3 and L4. The hydrolysis half-life is higher for L4 than for L3, and L5 is again expected to be even more hydrolytically stable than L4.

Table 11: Comparison of properties of L5 with L3

Property	Value	
	L5	L3
Molecular formula	$C_{12}H_{36}O_4Si_5$	$C_8H_{24}O_2Si_3$
Molecular weight (g/mole)	384.85	236.53
Water solubility at 23°C (mg/l)	0.00007	0.034
Vapour pressure at 25°C (Pa)	7.8	530
Henry's law constant at 12°C (Pa m3 mol-1)	2.0×10^7	1.62×10^6
log Kow at 25°C	9.41	6.6
log Koc	6.3	4.34
Half-life in air (days)	9	13
Hydrolysis half-life at pH ~7 (days)	*Read-across from L4* 165 at 10°C 130 at 12°C 30 at 25°C	 61 at 10°C 52 at 12°C 13.7 at 25°C
Ready biodegradability	No	No
Half-life in sediment (days)	Expected to be >>180 days by read-across	6.91 years

Study setup

The study on aerobic transformation in aquatic sediment systems was performed according to OECD TG 308 to GLP standard (DOW, 2020) at 12°C for 140 days. The Registrant(s) assess the study to be Klimisch score 1 (valid without restrictions). This used ^{14}C-radiolabelled L3 with a chemical purity of 99.9%, a radio-chemical purity of 99.4%, specific activity 64.5 mCi/mmol. Two sediments were used: Calwich Abbey Lake, UK (silt loam) and Emperor Lake, UK (sandy clay loam). When compared to the quality criteria of OECD TG 308, point 13, it is stated that 'recoveries should range from 90% to 110% for labelled chemicals and from 70% to 110% for non-labelled chemicals. Most samples in the study are within the mentioned range. The samples with recoveries outside the quality criteria were the day 7 samples from the Calwich Abbey Lake sediments, with a recovery of 81.6%, and the samples from Emperor Lake from day 57 and to the completion of the study (140 days), with a recovery from 85.5% - 89.1%. In our assessment, we conclude that the study does not completely fulfil the quality criteria for all samples used. Although some of these values fall outside the 90% to 110% range of recovery targeted for radiolabelled chemicals, the recoveries obtained seem reasonable when allowing for the challenging properties of L3, including low aqueous solubility and high air-water partition coefficient. Also, the deviation from the targeted range is small and the study is considered by the eMSCA as reliable despite these issues. The characteristics of the two sediments are detailed in Table 12.

Table 12: Characteristics of the two sediments used in the OECD TG 308 study

Property	Calwich Abbey Lake Sediment	Emperor Lake Sediment
% Organic Carbon	4.7% w/w	2.0% w/w
pH (water/0.01M $CaCl_2$)[5]	7.0 / 6.9	6.5 / 5.6
Textural Class	Silt Loam	Sandy Clay Loam
Particle Size Distribution: Sand	27.1% w/w	63.7% w/w
Particle Size Distribution: Silt	70.4% w/w	16.1% w/w

[5] pH at Day0, Pre-acclimation pH not available.

Property	Calwich Abbey Lake Sediment	Emperor Lake Sediment
Particle Size Distribution: Clay	2.5% w/w	20.2% w/w

Test system flasks were prepared as follows: to 250 mL Erlenmeyer-type flasks, approximately 50 g dry weight (*d.w.*) Calwich Abbey Lake sediment or 60 g d.w. Emperor Lake sediment[6] was added. The sediments were topped with the corresponding surface water to the 225 mL mark. This gave a sediment layer thickness of around 2 cm. The test systems were then equilibrated for 2 to 3 weeks at 12 °C.

Aeration of test system

The oxygen saturation in the control vessels for Calwich Abbey Lake and Emperor Lake was measured before and after aeration events. While the Calwich Abbey Lake sediments had an average oxygen saturation (%O_2) of 4.8% and 53%[7] in the controls at the start and end of each aeration event respectively, the Emperor lake sediment controls had an average % O_2 of 19 % and 55%. The aeration events were performed more frequently for the Calwich Abbey lake sediments than for the Emperor lake sediments due to the lower oxygen consumption in the Emperor lake system, and had an average interval 2,2 days vs 3,5 days. Both of the values after aeration are lower than desired for the formation of an aerobic layer in the surface of the sediment. The lower levels were suggested by the Registrant(s) to be a result of biodegradation of the diethylene glycol methyl ether (DEGME) solvent. By comparison, the typical oxygen content in the aerobic layer is described in the OECD guideline as ranging from 7 – 10 mg/L, approximately equivalent to 65 - 93% saturation at 12 °C. During the exposure period, the dissolved oxygen (DO) probe was moved further away from the water: headspace interface by switching to a longer needle, as it was realized that the initial DO-probe placement was not yielding representative measurements. At the start of the study, the pH of the overlying water was 7.0/6.9 (water/0.01M $CaCl_2$) for the Calwich Abbey Lake and 6.5/5.6 (water/0.01M $CaCl_2$) for Emperor Lake. At exposure termination, pH increased to average values of 7.5/7.38 and 7.35/6.95 (water/0.01M $CaCl_2$), respectively.

Application of test material

Following the acclimation period, natural water corresponding to the origin of the sediments was added at 12 °C to fill each test vessel. From each test vessel 20 mL of water was then removed in order to give a consistent headspace. Prior to dosing approximately 60 mL of water was removed and the associated sediments spiked with 10 µL of L3 in DEGME[8] (applied loading approximately 0.005% *v*/*v*). Spiking was performed in 1 µL aliquots using a microsyringe at multiple positions on the surface of the sediment (using an approximate grid pattern of 3-4-3). Spiking provided an initial nominal concentration of 150 ppb (ng ^{14}C L2 per g of sediment/ dw.). Following a query from the eMSCA, the Registrant(s) explained that the application rate was selected based on the available amount of test substance and the required analytical sensitivity resulting from the specific activity of the radio-labelled test substance.

There were 17 flasks dosed with L3 for each sediment (allowing for eight planned sampling intervals in duplicate and one spare vessel). Four control flasks were prepared with 10 µL of DEGME. Immediately following spiking, the reserved water was replaced in the vessels leaving a 20 mL head space void. Vessels were then closed tightly with a septum cap and

[6] Sediment wet weights are quoted as 143 – 151 g Calwich Abbey, and 118 – 122 g Emperor Lake
[7] The measurements up to day 25 showed an increase from 9.2 to 37% for the aeration events, but the 4.8% and 53% is considered more reliable due to a better placed probe.
[8] Diethylene glycol methyl ether (DEGME), is indicated in the report to be readily biodegradable and non-toxic to micro-organisms. The report indicates that as it is water miscible and has a specific gravity greater than one, this facilitated the distribution of L3 to sediment (and thereby mitigated loss through volatilization).

incubated in the dark at 12 °C for 140 days, except when removed from the incubator during regular aeration events.

The ^{14}C-radiolabelled L3 application solution was supplied to the test laboratory as a solution in DEGME, and was used directly without any dilution in the study. The solution was characterized (non-GLP) by the supplier prior to shipment. Concentration, specific activity, and radiochemical purity were reported on the provided certificate of analysis (CoA).

Sampling and collection of volatiles and evolved ^{14}CO2

Sampling was performed at day 1, 7, 28, 57, 77, 98, 119 and 140 for both Calwich Abbey Lake (CAL) and Emperor Lake (EL). Chemical analysis was performed using liquid scintillation counting (LSC) for ^{14}C, and HPLC-RAM for speciation. Oxygen and pH were only measured in the control vessels, with values assumed to be representative of the exposure vessels containing L3.

At each sampling interval, volatile compounds were captured in sequential traps that comprised 1) dry ice/acetone bath, 2) two vials containing *Perkin Elmer Ultima Flo M cocktail* and, finally, 3) a carbon dioxide trap containing the product *Oxosol C14* cocktail from National Diagnostics for trapping $^{14}CO_2$. Traps were rinsed with tetrahydrofuran (THF) solvent in order to recover any residual radioactivity.

Table 13,Table 14 and Table 15 summarize the results of the study. Abrupt initial losses from the systems were observed, with 14 % of ^{14}C activity lost from the Calwich Abbey Lake system from day 0-7 and 10% during the rest of the study (days 7-140), while 9,3% was lost from the Emperor Lake system from day 0-7 and a further 3.8% during the rest of the study (days 7-140). The early losses were considered to be a consequence of the volatile nature of the test substance. The radioactivity associated with the sediment, water and air compartment is presented in Table 13. All values were calculated relative to the total amount of applied radioactivity as ^{14}C-L3, which was based on LSC analysis of the dosing solution, determined as 1.42x10^7 dpm (equivalent to 6.4 µCi as ^{14}C-L3).

Results

Table 13: Distribution of ^{14}C in the two sediments at the end of the study

Media	Calwich Abbey Lake Sediment (day 140)	Emperor Lake Sediment (day 140)
% Air – CO_2 + aeration loss	2.2	2.5
% Water	4.0	5.2
% Sediment	95.5	81.4
% Recovery	101.7	89.1

Chromatographic profiling samples from overlying waters were mainly generated using a solid phase extraction (SPE) method. However, for the vessels sacrificed at Day 57 of incubation only direct HPLC analysis was conducted. Interpretation of the chromatograms was made difficult by the low levels of ^{14}C activity in the overlying waters (mostly under ~3,000 dpm/g for the (CAL) system and only slightly higher in the (EL) system) and significant variations in the retention times for some of the peaks. Further, in several cases the combined 14C activity for the chromatographic peaks was below 80% of the amount injected, especially for the CAL waters.

Therefore, from Day 77 and continuing through the remaining sampling intervals, 50 mL volumes of overlying water were extracted by SPE and eluted with THF in order to increase sensitivity for the water analysis. In these sample extracts (4 time points x 2 vessels from each sediment system) the injected 14C activity ranged from approximately 5,000 dpm to

10,000 dpm, and the average ratio of recovered to injected radioactivity was 91.5% for EL samples, and 95.4% for CAL samples.

Speciation analysis of SPE cartridge extract from the overlying water, solvent extraction of sediments and cryogenic trapping were performed by HPLC with flow scintillation detection. Observed peaks in combination with known radioactive content of each extract were used to calculate the percentage of applied radioactivity (normalised as above) that corresponded to parent L3, trimethyl silanol (TMS), Dimethylsilanediol (DMSD) and pentamethyldisiloxanol (PMDS).

Speciation data are presented in Table 14 as fractions of applied radioactivity. Both results from direct injection and SPE are available for overlying water and sediments in the study report, but only results from SPE extraction are included in Table 14 since the SPE was considered necessary for reliable sample preparation in overlying water.

TMS was the major transformation product (resulting from hydrolysis and identified[9] via mass spectrometric analysis). TMS, DMSD and PMDS increased in overlying water throughout the experiment and were present at up to 3.1, 1.3 and 0.5% in the overlying water at the end of the experiment. L3 was found at up to 0.42% at day 140 in overlying water and was the only one of the species found in sediments. In both sediment systems, the applied radioactivity was overwhelmingly present as L3 in sediment. All percentages in this paragraph are normalised to the applied radioactivity.

The $^{14}CO2$ levels are found mostly in overlying waters at early stages of the study but more is eventually found in the headspace of the vessels. The amount of applied radioactivity present as CO_2 was 0.12% and 0.14% in Calwich Abbey lake sediments and Emperor lake sediments respectively. The limited amounts of carbon dioxide observed in the study were considered to be consistent with the results from a screening test (OECD TG 310) where no biodegradation was observed.

Table 14: Chemical speciation in the two sediments at the end of the study (day 140 - averaged) as fractions of applied radioactivity

Media	Species	Calwich Abbey Lake Sediment	Emperor Lake Sediment
Overlying water	% L3	0.3	0.4
	% TMS	2.1	2.9
	% PMDS	0.5	0.5
	% DMSD	1.1	1.3
Sediment	% L3	89.7	75.5
	% TMS	0	0
	% PMDS	0	0
	% DMSD	0	0
Total	% L3	89.9	75.7
	% TMS	2.1	2.9
	% PMDS	0.5	0.5
	% DMSD	1.1	1.3

[9] No indication was given in the report that a certified analytical reference standards was using to verify this identification

Data generated were normalised using the total applied radioactivity residue to the test systems at day 0. It should be noted that the values at day 0 also show the losses occurring through vessel dosing and volatile loss as the system re-equilibrated. As Table 15 shows, some loss of test substance did occur, and the applied radioactivity is mostly found as L3 in sediment during the study period. The values for applied radioactivity in sediment ranged from 77.2% to 106.6% for Calwich Abbey Lake sediment, and from 78.2% to 90.6% (averages of duplicate vessels) for Emperor Lake sediment. The significantly wider range in the Calwich sediment was associated with a few values of 100% or greater for individual vessels, and exceptionally large deviations between duplicate vessels (15% to 26%) for samples from day 57, 77, and 98. Aside from the possibility that these few vessels received more spiking solution than the rest, which seemed unlikely since the phenomenon was not observed for any Emperor vessels, the authors considered that the most likely explanation was sampling error. However, it was also possible that the total 14C activity in the original sediment was not uniformly distributed in the test vessel prior to sub-sampling. As these deviations were not observed among the Emperor Lake vessel duplicates, the variation might be associated with the differing texture (more sandy) and lower OC content of this sediment. Unfortunately, the sampling design does not allow further testing of this hypothesis.

Table 15: Percentage of applied radioactivity associated with the sediment compartment of each test system over the exposure period of the OECD TG 308 study. Averages of duplicate vessels sacrificed on each sampling day

Sample day	Calwich Abbey Lake		Emperor Lake	
	Sediment	Recovery %	Sediment	Recovery %
1	85.7	90	90.6	98.2
7	77.2	81.6	86.8	92
28	97.8	100.5	86.5	91.6
57	98.3	102	81.1	87.8
77	106.6	111	78.2	85.5
98	97.3	91.9	78.3	86.5
119	87.8	93.2	78.6	87.3
140	95.5	101.7	81.4	89.1

% recovery calculated relative to total applied radioactivity

Non-extractable residue (NER)

NER in the CAL and EL sediments was determined by applying 0.1M HCl to a portion of the sediment, following extraction with tetrahydrofuran (THF). The HCl extract was analysed by LSC to determine the total 14C activity remaining after THF extraction. In the CAL sediment, the HCl extractable fraction ranged from 6.3% to 10.9% (maximum 9.8% excluding vessel CAL-19) for all vessels. Sediments from vessels sacrificed at incubation Day 57 showed values below 8.0% mostly, with values increasing for some vessels sacrificed on Day 77 or later. For the EL sediments, the HCl extractable fraction was slightly lower, ranging from 5.4% to 8.5% across all vessels and showing no distinct trend with time. Overall, these low values and general lack of temporal trends, along with a modest degree of transformation of parent L3, suggests that most of this residual activity was likely associated with the residual THF entrained in the sediment. Thus, the apparent formation of NER was low or non-existent on the time scale of this study.

Kinetics

The Registrant(s) provided degradation pseudo first order half-lives from the study. calculated according to the FOCUS guidance (2014) that states:
"Loss of mass balance due to not accounting for volatiles or bound residues would not affect the kinetic evaluation procedure as long as the sink data (sum of observed data for identified metabolites not specifically included in the fit as compartments, unidentified minor metabolites, organic volatiles, CO2 and bound residues) is not included in the fit. However, losses specific to a particular substance, whether partly or completely unaccounted for, may not only impact the kinetic evaluation of the substance itself, but also any degradation products further down the metabolic pathway, as the route scheme would be affected."

The kinetics calculations were performed using the Hockey-stick model (FOCUS, 2014) and demonstrate that the degradation of L3 followed a bi-phasic model. The hockey stick model with single first order kinetics in each phase was then used to calculate the half-lives. This calculation used all the samples and also took account of volatilisation that occurred at the start of the test, and the degradation follows first-order kinetics independently before and after a break point. The measured total radioactivity per sediment mass at each sampling time was normalized by the total applied radioactivity (i.e., 1.42×10^{7} DPM as 14C-L3) per mean sediment mass (116.4 and 140.1 g for Emperor Lake and Calwich Abbey Lake, respectively); thus, the radioactivity applied per sediment mass was 1.22×10^{5} and 1.01×10^{5} DPM/g-ww, respectively.

The first order kinetic model was not applied to normalized L3 concentrations in Emperor Lake sediment because the model was not able to reproduce the initial drop in normalized non-specific total radioactivity values (NTR), as shown in Figure 2. For Calwich Abbey, the profile of normalized L3 does not show a trend that is suited for mono-phasic or bi-phasic approach (Figure 3). The calculations for Emperor Lake were optimized with measured concentrations of L3 and normalized concentrations of degradation products. For Calwich Abbey lake, however, it was considered not reasonable to use either total radioactivity or L3 concentration, so only the normalized concentrations of degradation products were used.

Due to the variability of total radioactivity in the wet sediments from individual test vessels following the removal of the overlying water, kV and k1 could not be reliably calculated from measured L3 or total radioactivity. The main issue was the variability associated with the determination of total radioactivity in the wet sediments from individual test vessels following the removal of the overlying water. Instead, normalized concentrations of degradation products were used for the purpose of kinetic parameter estimation, as the method was shown to also yield consistent outcomes for the Emperor Lake system.

Figure 2: Log-linear regressions of normalized concentration of L3 in the Emperor Lake sediment system during the incubation period: (a) monophasic and (b) biphasic approaches.

Figure 3: Log-linear regressions of normalized concentration of L3 in the Calwich Abbey Lake sediment system during the incubation period: (a) monophasic and (b) biphasic approaches.

Table 16: Degradation half-lives for L3 in the two sediments used in the OECD TG 308 study calculated using the FOCUS guidance

	Calwich Abbey Lake Sediment	Emperor Lake Sediment
Degradation half-life (days) Optimized with measured concentrations of L3	-	1180 3.22 yrs

	Calwich Abbey Lake Sediment	Emperor Lake Sediment
Degradation half-life (days) Optimized with normalized concentrations of degradation products	2532 6.91yrs	1398 3.83 yrs
Average	**6.91 yrs**	**3.5 yrs**

A substantial proportion of the substance was present outside of the sediment-water system. L3 retained in the sediment degraded slowly and very little was present in water. TMS, PMDS and DMSD were detected in water and TMS was the dominant species in this compartment. On ECHA's dissemination page Registrant(s) state that 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.

Different half-lives are observed in the two sediments tested. A part of the explanation for this may be the difference in organic carbon content, since hydrolysis might be attenuated by adsorption to dissolved organic matter and particulates. The hydrolysis rates for the cyclic siloxanes D4 and D5 are also assumed to be impeded by DOC (MSC opinion for D4 and D5– (ECHA 2015). The Calwich Abbey lake sediments have a higher amount of carbon and also the slowest degradation.

Further, the two sediments also have some differences in their pH values. The Calwich Abbey Lake sediment had a pH of 7.04 and 6.89 (water and CaCl2, respectively) at the start of the test and ended at 7.38 and 7.08 at Day 141. The Emperor lake sediment had a pH of 6.51 and 5.56 (water and $CaCl_2$, respectively) at the start of the test and ended at 6.95 and 6.03. In the hydrolysis test on L3, pH was shown to have a dramatic effect on the hydrolytic half-life; so that a deviation above or below pH 7 will lead to increased hydrolysis. The Calwich Abbey lake sediment thus has an initial pH where L3 would likely be more hydrolytically stable.

Generally, the longer half-life is preferred for comparison to the persistence criteria in REACH Annex XIII. In this case both sediments are considered to be representative. Therefore, the eMSCA concludes that the half-life from the Calwich Abbey Lake sediment system of 6.9 years should be used to represent the half-life for L3 in sediment. This is also the same value as the Registrant(s) use in their exposure assessment.

Despite the problems encountered during the test and deviations from validity criteria, the study is considered reliable, and the degradation half-life demonstrate that L3 is very persistent.

Data from further simulation studies

Simulation tests in sediment are also available for L2, D4 and D5. Information on the degradation in sediment is available on ECHA's dissemination page for three related substances, the linear siloxane hexamethyldisiloxane or L2 and the two cyclic substances (octamethylcyclotetrasiloxane or D4 and decamethylcyclopentasiloxane or D5). PBT assessments have been performed previously for both D4 and D5 which included a detailed evaluation of the persistence of D4 and D5, and both substances have been identified as SVHC due to PBT and vPvB properties (MSC SVHC supporting document for D4 and D5 ECHA 2018a). The data available for D4 and D5 are summarised in Table 17, along with the data for L5.

Table 17: Comparison of properties of L2, D4 and D5 with L5

Property	Value			
	L5	L2	D4	D5
Molecular formula	$C_{12}H_{36}O_4Si_5$	$C_6H_{18}OSi_2$	$C_8H_{24}O_4Si_4$	$C_{10}H_{30}O_5Si_5$
Molecular weight (g/mole)	384.85	162.38	296.62	370.8
Water solubility at 23°C (mg/l)	0.00007	0.93 mg/L	0.056	0.017
Vapour pressure at 25°C (Pa)	7.8	5500	132	33.2
Henry's law constant at 25°C (Pa m3 mol-1)	4.17×10^{7}	$0.78x10^{6}$	1.21×10^{6}	3.34×10^{6}
Henry's law constant at 12°C	2.0×10^{7}	$0.37x10^{6}$	n.a.	n.a.
log Kow at 25°C	9.41	5.06	6.49	8.03
log Koc	6.30	3.00	4.22	5.17
Half-life in air (days)	9	11.5	12.7-15.8	10.4
Hydrolysis half-life at pH ~7 and 12°C (days)	130	17.4 at 10°C 4.8 at 25°C	16.7	315
Ready biodegradability	No	No	No	No
Half-life in sediment (days)	Expected to be >>180 days by read-across	192 days (first order kinetics) and 360 days (HS - FOCUS kinetics) at 12 °C (whole system).	~242 days at 24°C (aerobic conditions) ~356 days at 24°C (anaerobic conditions)	~1,200-2,700 days at 24°C (aerobic conditions) ~800-3,100 days at 24°C (anaerobic conditions)

Read-across to sediment simulation study on L2 (OECD TG 308)

Test results from an OECD TG 308 sediment simulation study with L2 are available and have been used as supporting study by the Registrant(s) in their dossier. The eMSCA notes that there are some issues with the L2 test, especially regarding recovery and mass balance.

L5 has a vapour pressure below that of L2 but a Henry's law constant higher than that for L2, indicating a higher volatility for L5 than L2. The potential for adsorption of L5 (as measured by the log Koc) is however higher than L2, which may to some extent counteract the higher volatility of L5 compared to L2 when the whole sediment is considered. Both substances have a predicted long residence time in air once volatilised. The hydrolysis half-life in water is longer for L5 than for L2, with 165 (based on read-across from L4) and 17.4 days at 10°C respectively. As L2 has been demonstrated to have a long half-life in sediment it can reasonably be assumed that the same will apply to L5 and that the half-life will be similarly >180 days.

For L2, an aerobic transformation in aquatic sediment systems study was performed according to OECD TG 308 to GLP standard (DOW, 2019). The Registrant(s) assesses the study to be Klimisch score 1 (valid without restrictions). This used ^{14}C-radiolabelled L2 with

a radio-chemical purity of 96.9%, specific activity 75.4 mCi/mmol and concentration of 0.5 mCi/mL. Two sediments were used: Calwich Abbey Lake, UK (silt loam) and Emperor Lake, UK (sandy clay loam). However, the eMSCA concludes that the study does not fulfil the validity criteria of OECD TG 308 where (point 13) it is stated that 'recoveries should range from 90% to 110% for labelled chemicals and from 70% to 110% for non-labelled chemicals.'

Sampling of duplicate test vessels, sacrificed at each sampling time point, was performed at day 1, 7, 18, 44, 74 and 99 (Calwich Abbey Lake) and day 1, 7, 20, 41, 70, 100 and 107/108 (Emperor Lake). At each sampling interval, volatile compounds were captured in sequential traps that comprised 1) dry ice/acetone bath, 2) vials containing non specified scintillation cocktails and finally a carbon dioxide trap. A further trap was added early in the study due to the suspected passage of air drawing volatiles (including L2) into the carbon dioxide trap (and consequently causing analytical problems). Traps were rinsed with tetrahydrofuran (THF) solvent in order to recover any residual radioactivity.

Table 18 through Table 22 summarise the results of the study. Significant initial losses from the systems were observed, with nearly 50% of ^{14}C activity lost from the Calwich Abbey Lake system on day 1 and 33% was lost from the Emperor Lake system. These were considered to be a consequence of the volatile nature of the test substance. During method development with L2 dosed into deionized water, the glass coil cold trap immersed in a dry ice/acetone bath was found to be highly effective at capturing and retaining L2 from a gas stream for a flow rate and time comparable to that used for the regular aeration of the test vessels. The breakthrough of the cold trap was significant for the real test systems, particularly early after dosing, before the L2 had reached equilibrium distribution between the sediment and water.

The Registrant(s) has speculated that the transport mechanism for L2 coming out of the natural waters was different, perhaps involving a particulate phase formed during bubbling that passed through the cold trap and on to the liquid traps. The normalised (to day 1 radioactive recovery) radioactivity associated with the sediment compartment is presented in Table 18.

Table 18: Distribution of ^{14}C in the two sediments used at the end of the study

Media	Calwich Abbey Lake Sediment (day 99)	Emperor Lake Sediment (day 107/108)
% Air	<0.1	<0.1
% Water	22.7	65.7
% Sediment	77.3	34.3
% Recovery (100% = normalisation against day 1 samples)	52.9	68.9

Chromatographic profiling samples from overlying waters and sediments were generated using a solid phase extraction (SPE) method. TMS was the major transformation product (resulting from hydrolysis and identified[10] via mass spectrometric analysis). Two minor peaks were considered to be (a) an impurity of L2 (as this was detected on day 1) and (b) either a degradation product of TMS or of the impurity. The presence of impurities cannot be verified as no purity assessments were performed on the application solution. The limited amounts of carbon dioxide observed in the study were considered to be consistent with the known slow mineralisation of the test substance. As the carbon dioxide levels are

[10] No indication was given in the report that a certified analytical reference standards was using to verify this identification

only depicted graphically (and as DPM[11]), it is unclear what proportion of total ^{14}C this represented.

Table 19: Chemical speciation in the two sediments at the end of the study

Media	Species	Calwich Abbey Lake Sediment (day 99)	Emperor Lake Sediment (day 107/108)
Overlying water	% L2	3.7	0.2
	% TMS	94.6	99.2
	% other	1.7	0.6
Sediment	% L2	73.6	37.6
	% TMS	25.5	61.3
	% other	0.9	1.1
Total	% L2	57.7	13.8
	% TMS	41.2	85.4
	% other	1.1	0.8

Data generated were normalised using the total radioactive residue of the test systems sacrificed on day 1, which were represented as 100% applied radioactivity. Following a query from the eMSCA, the Registrant(s) indicated that the 1 d values are considered to represent the effective dose for the study. Values at 0 d would include the losses occurring through vessel dosing and volatile loss as the system re-equilibrated. Table 20 shows, significant loss of test substance occurred. There was additional uncertainty in the accuracy of the chromatographic profiling because analyses of radioactive content and radioactive purities, pre- and post- dosing of the application solution, were not reported.

Table 20: Percentage of applied radioactivity associated with the sediment compartment of each test system

Sample day Calwich A. / Emperor		Calwich Abbey Lake Sediment	Emperor Lake Sediment	
	Total applied radioactivity in sediment	Relative contribution from L2	Total applied radioactivity in sediment	Relative contribution from L2
1	74.3	70.5	67.6	78.7
7	86.1	83.4	67.2	72.4
18 / 20	88.5	85.0	56.0	65.2
44 / 41	84.7	86	57.5	71.9
74 / 70	81.2	77.1	40.7	46.6
99 / 100	77.3	73.6	42.1	41.5
107-8	-	-	34.3	37.6

% recovery calculated relative to day 1 of total AR

[11] Disintegrations per minute

Kinetics

The original kinetics calculations in the test report were performed using a first order kinetic model [ln (fraction [L2]t)=-kt] applied to the natural log-transformed values of the average and normalised %L2 across all compartments (i.e., whole system data) for the duplicate test vessels at each sampling interval. Values of k were obtained from linear regression, the corresponding first order model is ln (1-fraction [TMS]t)=-kt. The calculated rate constants and half-lives documented in the finalised study report are presented in Table 21.

The Registrant(s) have also supplied supporting information and used the methodology presented in Appendix 11 of FOCUS 2006:2014, where a correction procedure can be applied to account for dissipation by volatilisation. The Registrant's calculations in Table 22 have led to an increase in the half-life of the substance exposed with the Calwich Abbey Lake sediment (from 192 to 360 days),but made little difference to the half-life of the substance tested in the Emperor Lake sediment (increased from 53 to 54 days).

Table 21: Original first-order kinetics calculation for the two sediments in the OECD TG 308 study

	Calwich Abbey Lake Sediment	Emperor Lake Sediment
Total System Rate Constant ($days^{-1}$)	3.61×10^{-3}	1.31×10^{-2}
Total System DT_{50} (days)	192 (90% confidence interval = ± 56 d)	53 (90% confidence interval = ± 17 d)

The revised kinetics demonstrate that the degradation of L2 followed a bi-phasic model. The hockey stick model with single first order kinetics in each phase was then used to calculate the half-lives. This calculation used all the samples and also took account of significant volatilisation that occurred at the start of the test. The Deg50 (whole system) (after adjusting for volatilisation) for the Calwich Abbey Lake sediment was calculated to be 360 days, and 54 days for the Emperor Lake sediment.

Table 22: Degradation half-lives for L2 in the two sediments used in the OECD TG 308 study calculated using the FOCUS guidance

	Calwich Abbey Lake Sediment	Emperor Lake Sediment
Degradation half-life (days)	360	54
Standard error	186	9.0

MSCA concludes that a significant loss of L2 occurred due to its volatility. This means that a significant proportion of the substance was present outside of the sediment-water system. L2 retained in the sediment degraded slowly. L2 remaining in the water was virtually all hydrolysed, and only TMS was detected to a significant extent in this compartment. The Registrant(s) state that the intermediate siloxane hydrolysis/degradation products, and silanol hydrolysis/degradation product, may also meet the screening criteria for persistence (P/vP) in sediment.

Despite considerable problems with the study data and the analytical problems encountered, the data indicate that the half -life is higher than > 180 days in sediment and the substance can be regarded as very persistent.

Comparison with D4 and D5

A comparison of the known properties of L5 with those of D4 and D5 reveals that L5 has a vapour below that of D4 and D5. However, the Henry's law constant is higher than that of D4 and D5, so a higher volatility from water can be expected. All three substances have a similar predicted long residence time in air once volatilised. The potential for adsorption of L5 (as measured by the log K_{oc}) is higher than that of both D4 and D5. Similarly, the hydrolysis half-life for L4 in water is between that of D4 and D5. As both D4 and D5 have been demonstrated to have long half-lives in sediment it can be assumed that the same may apply to L4 and that the half-life will be similarly >180 days.

This supports the results of the sediment simulation study performed on L3, demonstrating a long half-life. Still there is some uncertainty based in the structural differences between the substances. It is not known whether the length of linear structure versus the cyclic structure will have the same impact on the degradation in sediment. Substances with linear structures are generally considered more biodegradable than substances with branched and cyclic structure. It is however uncertain if this holds for the siloxanes.

Further support for the expected trend in the linear substances comes from the increasing hydrolysis half-lives for L2, L3 and L4 respectively. Together this indicates that the persistence of siloxanes with increasing chain length will be greater than or at least equal to the shorter chains.

7.7.1.3.2. Biodegradation in soil

No data on biodegradation of L5 in soil are included in the registration dossier.

A study on the effect of temperature and humidity on the degradation of L4 (decamethyltetrasiloxane) in soil has been carried out (registration dossier, 2014), and is reported in the registration dossier for L5. This study used a London soil from Michigan, USA (22% clay, 28% silt, 50% sand, 2.4% organic carbon, pH 7.6). The test substance used was radiolabelled ("mostly on the dimethylsiloxyl moiety") and had a radiochemical purity of 99.21%.

For the experiments, 5 g of air-dried soil was weighed into pre-weighed 25 ml Teflon tubes. The dry soil in the tubes was pre-conditioned for at least one week in containers with controlled humidity atmosphere. The air humidity levels used were 32, 42, 92 and 100% relative humidity (RH). Furthermore, humidity in the atmosphere was the only source of moisture in the study. Each pre-conditioned soil sample was spiked by dropping a solution of the test substance onto multiple positions on the soil surface to give a concentration of 10 µg/g (dry weight basis). The tubes were capped immediately following spiking and thereafter vortexed for five minutes. The tubes were then purged with the appropriate humidity-controlled air for one minute; tubes for the closed system experiments were capped, tubes for the open system experiment were placed into controlled humidity chambers. Experiments were conducted at 22°C, with two additional experiments in closed systems conducted at 4°C and 37°C (at 42% RH).

At the appropriate sampling times, soil was extracted sequentially with tetrahydrofuran and then with 0.1 M HCl/0.01 M $CaCl_2$ aqueous solution. Both extracts were analysed by high performance liquid chromatography coupled to Radiomatic detection for speciation, and by liquid scintillation counting (LSC) for total radioactivity. Radiolabel not extracted by this method was recovered by combustion of the soil residue using a biological oxidiser, capturing the evolved CO2 and measuring using LSC.

The average total recovery in the closed system experiments was in the range 89.7 to 114.2%. In the open system (100% RH) more than half of the spiked radioactivity was lost within 3 days, and more than 90% was lost within two weeks.

The half-lives determined for the dissipation of the parent substance at 22°C are shown in Table 23. It can be seen that the rate of degradation was greater as the soil became drier.

Table 23: Degradation half-lives of L4 in soil (closed system)

Relative humidity of air (%)	Half-life (days) at 22°C
100	106.6
92	10
42	4.5
32	3.7

For the two additional experiments, carried out at different temperatures and at a relatively humidity of 42%, the half-lives were determined as 29 days at 4°C, and 1.2 days 37°C. Given the half-life of 4.5 days at 22°, these results show a clear temperature dependence in the degradation. In the open system, volatilisation was the predominant process for removal of L4 from soil.

Two degradation products were identified: dimethylsilanediol and trimethylsilanol. The amount of non-extractable residue increased with time, and was similar for both soils. The amount increased with increasing temperature, and with decreasing humidity. The Registrant(s) states that the nature of the non-extractable fraction was not completely understood.

The study was not carried out according to GLP and seems to not be compliant with the recommended study design(s) of OECD 307 or comply with the stipulations in this guideline for sampling, handling and treatment of soils. Nevertheless, the Registrant(s)s give it a reliability score of 2.

The results of this test show that L4 is degradable in soil but that the rate of degradation is dependent on the moisture content. The test was carried out with dry soil in atmospheres of differing relative humidity. Using a 100% relative humidity atmosphere the half-life approached 107 days at 22°C. Given the structural similarity between L4 and L5 it would be expected that L5 would behave similarly to L4, therefore the actual rates of degradation in soil of L5 are also unclear.

The eMSCA notes that the use pattern of L5 does not suggest that direct emission to soil is likely to occur. Instead, the majority of exposure is likely to be due to the spreading of sewage sludge. This type of exposure, and measurement of any degradation, would be different to the method of soil exposure measured in the soil study for L4, or indeed for the OECD 307 test guideline. The eMSCA also notes that the moisture content of the sludge is unknown, and also what moisture content in soil subsequently results when the sludge is spread.

Overall, the available information suggests that the half-life for L4 in soil will vary with the actual conditions present in the soil and may, under some circumstances be relatively short (half-life of a few days) but under others may be expected to be relatively long (half-life up to the order of 200 days or more). Given the structural similarity between L4 and L5 it would be expected that L5 would behave similarly to L4, but the actual rates of degradation of L5 are not clear.

In terms of standardised test conditions (i.e. OECD TG 307) recognised in the REACH guidance for persistence determination, it is not possible to benchmark the results of the non-standard soil studies. Therefore, despite being useful supporting information, the standard half-life of L5 in soil remains unknown.

7.7.1.4. Summary on degradation

L5 is predicted to degrade in the atmosphere as a result of reaction with hydroxyl radicals. The half-life for L5 in the atmosphere is around 9 days.

There are no hydrolysis tests for L5. The hydrolysis half-life of the related read -across substance L4 is dependent on pH and temperature. At pH 7 half-lifes reached a maximum

of 30 days at 25°C, 130 days at 12°C and 165 days at 10°C. It would be expected that the hydrolysis of L5 would follow a similar pattern to that of L4. Experience from other siloxanes (D4 and D5) suggest that DOC may impede the hydrolysis and that the hydrolytic half-life for L4 may therefore be longer than suggested by the results in pure water.

There are no biodegradation screening tests available for L5 but read-across from a structurally similar substance (L3) suggests that L5 will not be readily biodegradable in standard test systems.

No information is available on the potential for degradation of L5 in sediments. It would be expected that adsorption onto sediment will reduce the potential for hydrolysis in sediments compared with water. A read-across to the structurally related substances L2 and L3 suggests that L5 will have a half-life in sediments higher than 180 days. The simulation study on biodegradation of L3 in sediments (OECD 308) demonstrates a very long half-life for L3 in sediments of 3.5-6.91 years at 12°C. The simulation study on L2 (OECD 308) further indicates a half-life in sediment of 360 days for L2, supporting a long half-life for L5 since it is expected to be more persistent than L2. However, the L2 study has several deficiencies and results may therefore be considered not entirely reliable.

Based on the reduced hydrolysis and higher organic carbon partitioning, L5 is expected to be more persistent than both L2 and L3, suggesting that L5 will have a half-life in sediments higher than 180 days.

Degradation is soil has been demonstrated in laboratory studies for the substance L4, which can be read across to L5. The half-life in soil seems to increase with increasing water content/humidity. Overall, the available information suggests that the half-life for L4 in soil may, under some circumstances be relatively short (half-life of a few days) but may under others may be expected to be relatively long (107 days). The study is however not easily interpreted and has several issues. L4 is a volatile substance and loss by volatilisation may also occur alongside degradation in water and soil systems. Given the structural similarity between L4 and L5 it would be expected that L5 would behave broadly similarly to L4.

7.7.2. **Environmental distribution**

7.7.2.1. Absorption / desorption

The log Koc for L5 has been estimated as 6.3 using a validated QSAR method. The study was given a reliability score of 2 in the registration dossier. A QSAR Model Reporting Format (QMRF) and a QSAR Prediction Reporting Format (QPRF) are included. The QMRF shows the model relies on six chemicals, four of these are siloxanes (L3, L4, D4 and D5).

The Registrant(s) comment that using expert judgement the substance was within the applicability domain of the model. This was based on the structural category being represented in the model, and no non-standard effects on log Koc are expected. The prediction is considered sufficient to indicate that the Koc is high, although it was noted that the prediction is “slightly outside the applicability domain”.

The eMSCA notes that the upper domain of the model is defined by L4 (log Kow = 8.21). The log Kow of L5 is 9.4, so the prediction for L5 relies on extrapolation rather than interpolation. The graphical representation of the model suggests a linear fit for the available data.

7.7.2.2. Volatilisation

The substance has a vapour pressure of 7.8 Pa at 25ºC and a water solubility (7.0×10^{-5} mg l^{-1} at 23ºC). Using these data the Henry’s law constant can be estimated (using the EUSES program for temperature correction) as 2.0×10^{7} Pa m^3 mol^{-1} at 12ºC (or 4.17×10^{7} Pa m^3 $mole^{-1}$ at 25ºC) and the dimensionless Henry’s law constant (Kaw) can be estimated as 8.43×10^{3} at 12°C (or 1.68×10^{4} at 25°C). The relatively high Henry’s law constant

indicates that the substance will be volatile in the environment, transferring readily from the water phase to the atmosphere unless already adsorbed to organic carbon.

7.7.2.3. Distribution modelling

On ECHA's dissemination page, the following predicted distribution of L5 in a sewage treatment plant (estimated using the SimpleTreat model) is available: 3.75% to air, 88.9% to sludge, 0% degraded and 7.38% to water.

This indicates that sludge is the main compartment for partitioning, but partitioning to air and water is also significant.

7.7.2.4. Potential for long range transport

The potential for long range transport has been investigated by the eMSCA using the OECD Pov and LRTP screening tool version 2.2[12].

In order to assess the effects of the uncertainties, notably the rate of degradation in soil, the modelling was carried out several times using different assumptions for this parameter. The inputs used and the resulting modelled outputs are summarised in Table 24.

For all estimates, the molecular weight was set at 384.85 g/mole, the degradation half-life in air was set at 216 hours (9 days), the half-life in water was set at 3,120 hours (130 days, corresponding to the approximate estimated half-life for hydrolysis in water at pH 7 and 12°C for the read-across substance L4), the log Kow was set at 9.41 and the log Kaw was set at 3.93 (Kaw = 8.43×10^{3}). The key outputs for the simulations are displayed graphically in Figure 4 .

As can be seen from all of the simulations result in the substance appearing on the border between the lower and upper left hand quadrant for the characteristic travel distance. Although the plots show the points just in the upper left hand quadrant, the program output indicates that the points lie in the lower left hand quadrant. This signifies borderline potential for long range transport. However, the simulations also result in the substance appearing in the lower left hand quadrant in terms of the transfer efficiency. Taken overall, the results suggest a relatively low potential for long-range transport. However, it should be noted that the log Kaw for L5 is outside of the recommended range for the model, which adds further uncertainty to the predictions.

It is also relevant to note that the assumptions made over the half-life in soil do not significantly affect the predicted overall persistence, characteristic travel distance or transfer efficiency.

Table 24: Summary of long range transport potential estimated using the OECD Pov and LRTP screening tool

Input assumptions	Modelled outputs		
	Pov (days)[1]	CTD (km)[2]	TE (%)[3]
Half-life in soil = 4,800 hours (200 days)	185 (water)	4,471	0.012
Half-life in soil = 2,880 hours (120 days)	185 (water)	4,471	0.012
Half-life in soil = 1,128 hours (47 days)	185 (water)	4,470	0.012
Half-life in soil = 240 hours (10 days)	185 (water)	4,470	0.012

Note: 1) Pov is an estimate of the overall persistence of the substance in the environment. The emission compartment to which the persistence relates is given in brackets.

[12] http://www.oecd.org/env/ehs/risk-assessment/oecdpovandlrtpscreeningtool.htm

2) Characteristic travel distance (CTD) which is an estimate of the distance from a point source at which the chemical's concentration has dropped to 38% of its initial concentration. For all the simulations here the CTD relates to transport by air and so will be dependent on the assumptions made over the half-life in air.
3) Transfer efficiency (TE). This is an estimate of the percentage of emitted chemical that is deposited to surface media after transport away from the region of release

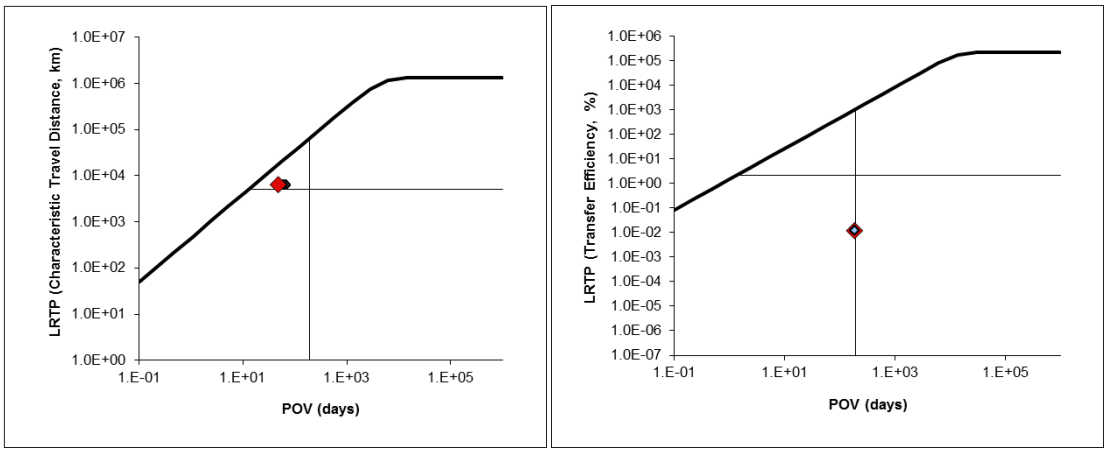


Figure 4: Long-range transport potential of L5

As sorption to particles in air is not likely to be significant for chemicals with a low log K_{OA}[13], this means that associated deposition processes involving particles (wet particle deposition by snow or rain or dry particle deposition) can be ignored in LRTP assessments of L5.

Therefore, it is considered that L5 has a potential for long-range transport via the atmosphere but a low potential for subsequent (re-)deposition in remote areas.

7.7.3. **Bioaccumulation**

7.7.3.1. Aquatic

7.7.3.1.1. Aqueous study

The registration dossier contains details of a test on the bioaccumulation of L5 in fish, according to OECD test guideline 305 and in compliance with GLP (registration dossier, 2006). Fathead minnow (*Pimephales promelas*) were used, with an average wet weight of 1.16 g and an average length of 53 mm at the start of the test. The test was conducted under flow through conditions, in 57 l polyethylene aquaria containing approximately 42 l of test medium using a replacement rate of 10 volume additions per day. The mixing chambers were sealed to limit volatilisation of the substance.

Stock solutions of the ^{14}C labelled substance were made up in dimethylformamide. Two test concentrations were used, nominal levels[14] 7 and 70 ng l^{-1}, mean measured concentrations 4 and 39 ng l^{-1}.

The duration of the uptake phase of the test was 35 days, with sampling on days 0, 3, 7, 14, 21, 28 and 35. The depuration phase was 35 days, with sampling on days 1, 3, 7, 10, 14, 21, 28 and 35. The concentration of the substance was measured on a whole fish basis, and in water samples taken on the same days using a pipette. Determination of the concentrations was by liquid scintillation counting.
Mortalities were within the guideline requirements, with 8.3, 6.7 and 6.7% mortality observed in the solvent control, 4.0 and 39 ng/l treatments respectively.

[13] Log Koa (KOAWIN v1.10 estimate): 5.368
[14] The water solubility of the substance is 7.0×10^{-5} mg l^{-1} which is equivalent to 70 ng/l. The higher nominal concentration therefore corresponds to a saturated solution.

The concentration in fish reached a plateau after 21 days of uptake.

The BCF values based on the steady state concentrations in fish and in water were 1,430 l kg^{-1} (4 ng l^{-1}) exposure) and 1,240 l kg^{-1} (39 ng l^{-1} exposure). In the 4 ng l^{-1} exposure, the uptake rate (k_1) was 138 l kg^{-1} d^{-1}, and the depuration rate (k_2) was 0.0949 d^{-1}, giving a kinetic BCF of 1,450 l kg^{-1}. In the 39 ng l^{-1} exposure, k_1 was 151 l kg^{-1} d^{-1}, k_2 was 0.121 d^{-1}, and the kinetic BCF was 1,240lkg^{-1}. The Registrant(s) states that growth correction was not applied. They cite the fish weight data as indicating growth during the test to be minimal.

Mean lipid content was measured at the test initiation as 2.9%, the end of uptake as 1.7% and test termination as 2.3%, (The Registrant(s) calculate the lipid normalised BCF values as 4210 and 3650 (steady state), and 4260 and 3650 (kinetic) using the value at the end of the uptake period.

Consideration of error in steady state BCF values

It is possible to investigate the uncertainty in the steady state BCF. In the registration dossier the steady-state concentration in fish was determined as the mean concentration measured in the fish on days 21, 28 and 35 for both treatment groups. The mean concentrations (along with standard deviation) over these time periods are summarised below.

4 ng l^{-1} treatment group

Mean fish concentration (± standard deviation): 5,730 ± 1,665 ng/kg.

The standard deviation around the mean measured water concentration of 4 ng l^{-1} was ±0.6 ng l^{-1}. Thus, the BCF (± standard deviation) that can be estimated from the steady state concentration is as follows.

Mean steady state BCF based (as assumed in registration dossier): 1,430 ± 470 l kg^{-1} (not lipid normalised).

The lipid contents of the fish were determined at the start of the test (day 0), the end of the uptake phase (day 35) and the end of the depuration phase (day 70). The mean (± standard deviation) of the lipid contents at these time points were respectively 2.9%, 1.%7 and 2.3%, with the overall mean of the three sampling points being 2.3%.

Taking these values into account the mean steady state lipid normalised BCF_L are estimated by the eMSCA in Table 25. The 95% confidence intervals have been estimated assuming a normal distribution[15].

Table 25: Summary of steady-state BCF for the low exposure group

	BCF_L (l kg-1)		
Lipid content assumed	**Mean**	**Standard deviation**	**95% C.I.**
Day 0 – 2.93%	2,445	±1,162	168 to 4,721
Day 35 – 1.69%	4,238	±1,521	1,257 to 7,220
Day 70 – 2.32%	3,087	±1,735	~0 to 6,487
Overall mean – 2.31%	3,101	±1,640	~0 to 6,314

[15] For a normal distribution, 95% of the area is with 1.96 standard deviations of the mean.

39 ng l^{-1} treatment group

Mean fish concentration (± standard deviation): 48,200 ± 12,900 ng kg^{-1}.

The standard deviation around the mean measured water concentration of 39 ng l^{-1} was ± 4.7 ng l^{-1}. Thus, the BCF (± standard deviation) that can be estimated from the above two steady state concentration is as follows.

Mean steady state BCF (as assumed in registration dossier): 1,240 ± 360 l kg^{-1} (not lipid normalised). Using the same lipid contents as above the mean steady state lipid normalised BCF_L are estimated in Table 26. The 95% confidence intervals have been estimated assuming a normal distribution[16].

Table 26: Summary of steady-state BCF for the high exposure group

	BCF_L (l kg^{-1})		
Lipid content assumed	**Mean**	**Standard deviation**	**95% C.I.**
Day 0 – 2.93%	2,109	±955	238 to 3,981
Day 35 – 1.69%	3,657	±1,202	1,301 to 6,012
Day 70 – 2.32%	2,664	±1,446	~0 to 5,449
Overall mean – 2.31%	2,675	±1,361	~0 to 5,343

Consideration of error in simultaneous and sequential fits for kinetic BCF

It is also possible to investigate the uncertainty in the kinetic BCF. For this analysis, the raw data in the full test report have been used and the data were fitted to the equations in the OECD 305 Test Guideline using the Levenberg – Marquardt nonlinear least square algorithm. Both the simultaneous and sequential methods were used. Where there was a mixture of detectable and non-detectable concentrations at the same time point, a concentration of LoD/2 was assumed for the not detectable data points.

4 ng l^{-1} treatment group

The values of k_1, k_2 and BCF, along with the respective estimated 95% confidence intervals, are summarised in Table 27 below. As there was no significant growth of the fish during the test growth-correction of the data is not necessary. The lipid normalised kinetic BCF_{kL} has been estimated using a similar approach as outlined above for the steady-state BCF, taking into account the different lipid contents measured during the study.

Table 27: Summary of kinetic BCF for the low exposure group

Parameter	**Value**	**Estimated 95% Confidence Interval**	**Estimated standard deviation**
Sequential method			
k_1	111.9 l kg^{-1} d^{-1}	97.8-125.9 l kg^{-1} d^{-1}	±7.2 l kg^{-1} d^{-1}
k_2	0.0632 d^{-1}	0.0370-0.0895 d^{-1}	±0.013 d^{-1}
BCF_k	1,770 l kg^{-1}	1,004-2,536 l kg^{-1}	±391 l kg^{-1}
BCF_{kL} (using the Day 0 lipid content – 2.93%)	3,020 l kg^{-1}	596-5,445 l kg^{-1}	±1,237 l kg^{-1}
BCF_{kL} (using the Day 35 lipid content – 1.69%)	5,236 l kg^{-1}	2,507-7,966 l kg^{-1}	±1,393 l kg^{-1}
BCF_{kL} (using the Day 70 lipid content – 2.32%)	3,815 l kg^{-1}	20-7,609 l kg^{-1}	±1,936 l kg^{-1}

Parameter	Value	Estimated 95% Confidence Interval	Estimated standard deviation
BCF_{kL} (using the overall mean lipid content – 2.31%)	3,831 l kg^{-1}	297-7,365 l kg^{-1}	±1,803 l kg^{-1}
Simultaneous method			
k_1	156.0 l kg^{-1} d^{-1}	112.7-199.3 l kg^{-1} d^{-1}	±22.1 l kg^{-1} d^{-1}
k_2	0.109 d^{-1}	0.079-0.139 d^{-1}	±0.015 d^{-1}
BCF_k	1,431 l kg^{-1}	868-1,994 l kg^{-1}	±287 l kg^{-1}
BCF_{kL} (using the Day 0 lipid content – 2.93%)	2,443 l kg^{-1}	533-4,352 l kg^{-1}	±974 l kg^{-1}
BCF_{kL} (using the Day 35 lipid content – 1.69%)	4,235 l kg^{-1}	2,165-6,305 l kg^{-1}	±1,056 l kg^{-1}
BCF_{kL} (using the Day 70 lipid content – 2.32%)	3,085 l kg^{-1}	67-6,102 l kg^{-1}	±1,540 l kg^{-1}
BCF_{kL} (using the overall mean lipid content – 2.31%)	3,098 l kg^{-1}	295-5,901 l kg^{-1}	±1,430 l kg^{-1}

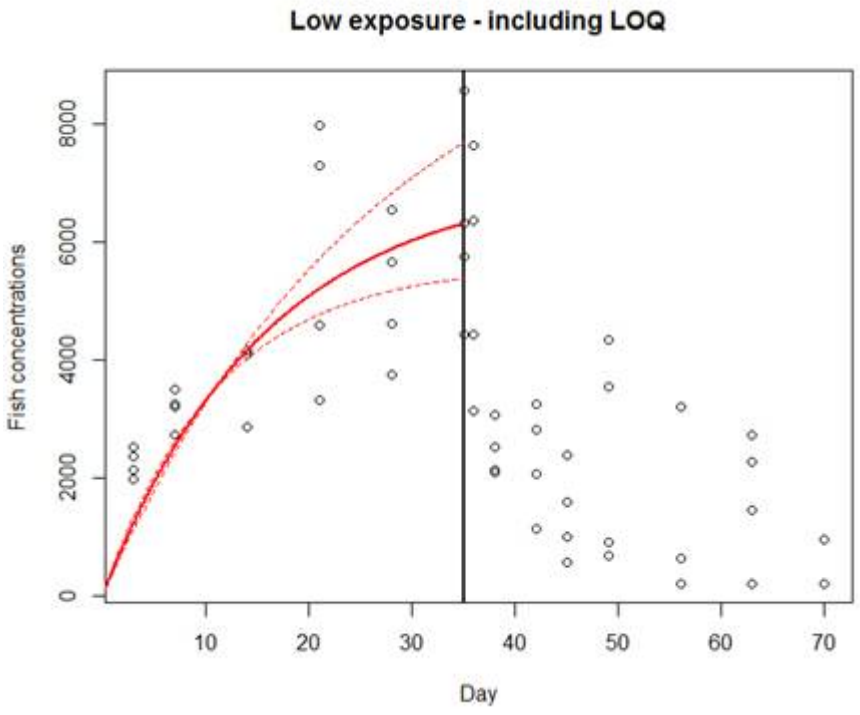


Figure 5: Sequential fit for 4 ng l-1 treatment group

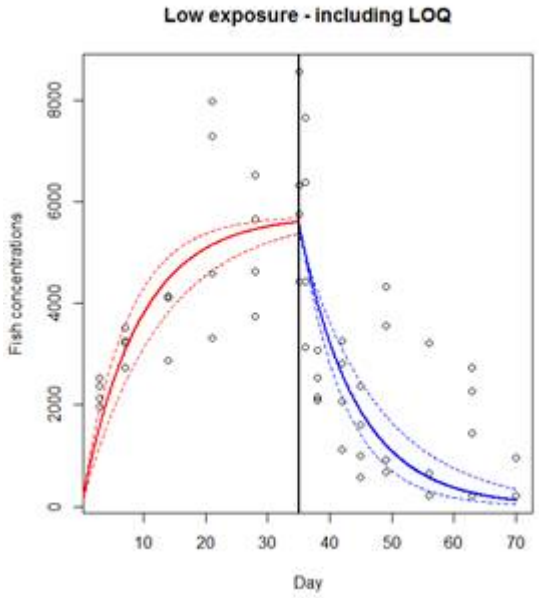


Figure 6: Simultaneous fit for 4 ng l-1 treatment group

39 ng l^{-1} treatment group

The values of k_1, k_2 and BCF, along with the respective estimated 95% confidence intervals, are summarised in Table 28 below. As there was no significant growth of the fish during the test growth-correction of the data is not necessary. The lipid normalised kinetic BCF_{kL} has been estimated using a similar approach as outlined above for the steady-state BCF, taking into account the different lipid contents measured during the study.

Table 28: Summary of kinetic BCF for the high exposure group

Parameter	Value	Estimated 95% Confidence Interval	Estimated standard deviation
Sequential method			
k_1	93.9 l kg^{-1} d^{-1}	83.6-104.3 l kg^{-1} d^{-1}	±5.3 l kg^{-1} d^{-1}
k_2	0.059 d^{-1}	0.033-0.085 d^{-1}	±0.013 d^{-1}
BCF_k	1,598 l kg^{-1}	863-2,333 l kg^{-1}	±375 l kg^{-1}
BCF_{kL} (using the Day 0 lipid content – 2.93%)	2,726 l kg^{-1}	497-4,956 l kg^{-1}	±1,137 l kg^{-1}
BCF_{kL} (using the Day 35 lipid content – 1.69%)	4,727 l kg^{-1}	2,154-7,299 l kg^{-1}	±1,313 l kg^{-1}
BCF_{kL} (using the Day 70 lipid content – 2.32%)	3,443 l kg^{-1}	~0-6,911 l kg^{-1}	±1,769 l kg^{-1}
BCF_{kL} (using the overall mean lipid content – 2.31%)	3,458 l kg^{-1}	222-6,694 l kg^{-1}	±1,651 l kg^{-1}
Simultaneous method			
k_1	114.4 l kg^{-1} d^{-1}	77.2-151.6 l kg^{-1} d^{-1}	±19.0 l kg^{-1} d^{-1}
k_2	0.090 d^{-1}	0.060-0.120 d^{-1}	±0.015 d^{-1}
BCF_k	1,273 l kg^{-1}	677-1,869 l kg^{-1}	±304 l kg^{-1}
BCF_{kL} (using the Day 0 lipid content – 2.93%)	2,172 l kg^{-1}	387-3,958 l kg^{-1}	±911 l kg^{-1}
BCF_{kL} (using the Day 35 lipid content – 1.69%)	3,766 l kg^{-1}	1,692-5,840 l kg^{-1}	±1,058 l kg^{-1}

Parameter	Value	Estimated 95% Confidence Interval	Estimated standard deviation
BCF_{kL} (using the Day 70 lipid content – 2.32%)	2,743 l kg^{-1}	~0-5,515 l kg^{-1}	±1,414 l kg^{-1}
BCF_{kL} (using the overall mean lipid content – 2.31%)	2,755 l kg^{-1}	167-5,344 l kg^{-1}	±1,321 l kg^{-1}

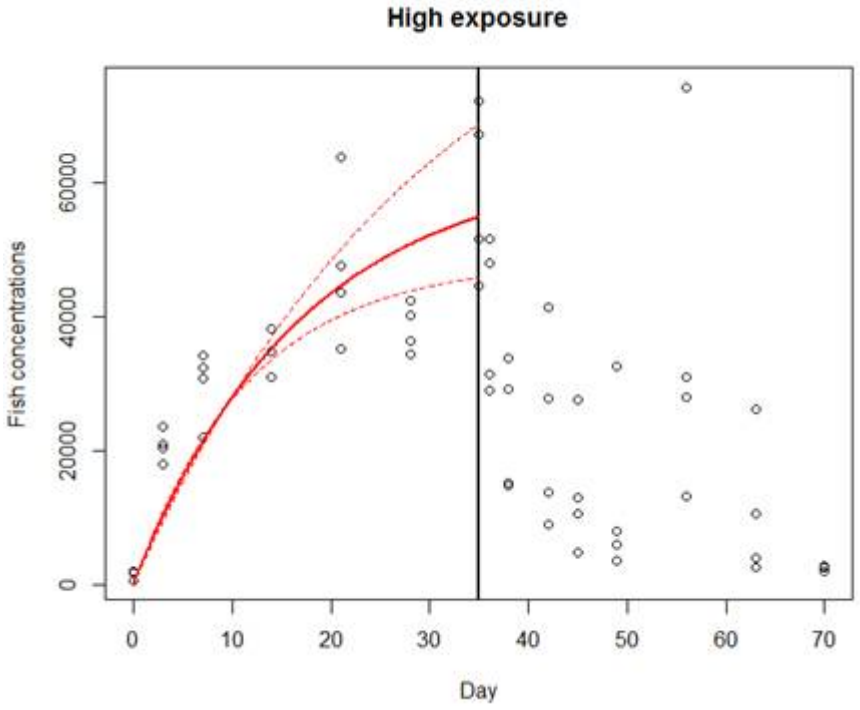


Figure 7: Sequential fit for 39 ng l-1 treatment group

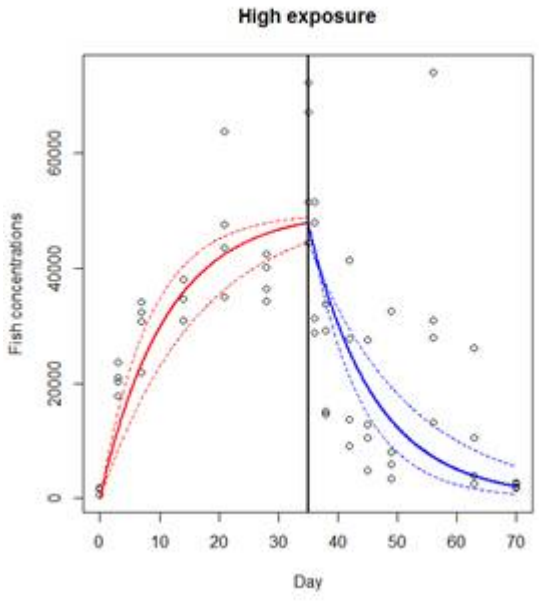


Figure 8: Simultaneous fit 39 ng l-1 treatment group

Analysis of the BCF study

The validity criteria for the test were mostly met, but one validity criterion mentioned in the protocol was that the concentration of the test substance should be maintained within ±20% of the mean measured concentrations during the uptake phase of the test. There were four measurements (out of 28) that fell above or below this criterion. With a very strict interpretation of validity, the study could be seen as not valid, but based on the low concentrations tested (4.0 – 39 ng/L), this type of variability is expected.
The study is given a reliability score of 1 by the Registrant(s). The study has been reviewed by the eMSCA and on its own, the study seems to be reasonably well performed for such a difficult to test substance. There are some uncertainties with the uptake phase, as not all concentrations fall within the range prescribed by the validity criteria of the OECD TG 305. However, the aqueous concentrations are rather consistent during the test for such extremely low concentrations and this likely cannot be improved upon.

The eMSCA has further considered a number of aspects of the fish bioconcentration test in more detail. These issues are discussed below:

Growth and growth correction

There was no significant growth of the fish during the test, in either the control group or the exposed groups. The lack of fish growth in the L5 test is similar and consistent with growth data from L3 and L4 across all three BCF tests.

Therefore, the lack of growth seen in the study is not an indication of toxicity from L5 but rather results from the fact that the fathead minnows used in the BCF tests are effectively adults and so do not grow significantly over the duration of a typical BCF test.

The Registrant(s) have subsequently also provided an analysis of the length and weight data to show that growth in the test was insignificant (pers. comm, Nov 2015).

Possibility of toxic effects occurring in the study

The eMSCA also notes that lipid content decreased during the uptake period for L5 but then increased during depuration. The same was observed for L3, but for L4 data are only available at the start and end of the test, although the pattern looks similar. This may be a result of fish variability. An alternative option is that this suggests an adverse effect on fish due to the uptake of the chemical or solvent – i.e. the fish lipid content reduces during exposure, but the animals then recover in clean water during the depuration phase.

The eMSCA notes that there was no statistical effect on growth in the FELS tests for L3 and L4. Dimethylformamide was used as solvent in both the bioaccumulation studies and the FELS tests. The L3 dietary test RSS notes that the fish were observed to be normal and healthy. In the L4 test, a similar observation was made on fish health (up to the power outage on day 25 of depuration), although the eMSCA is cautious about interpreting the effects due to the low oxygen levels starting much earlier in the test.

Reviewing the mortality in the aqueous bioaccumulation tests, the RSSs state the following:

- For L3, mortality at the end of the test (52 days) was 7.5, 8.3 and 6.7% in the solvent control, 1.7 and 21 µg/l treatment groups respectively.
- For L4, mortality at the end of the test (62 days) was 8.3, 11 and 11% in the solvent control, 0.43 and 5.3 µg/l treatment groups respectively.
- For L5 mortality at the end of the test (70 days) was 8.3, 6.7 and 6.7% in the solvent control, 4.0 and 39 ng/l treatment groups respectively.

For all three, the RSS states that the mortality did not appear to be treatment-related, and all surviving fish in the test appeared *normal and healthy throughout the test with no overt signs of toxicity.* Therefore, the mortality in the L5 study is similar to the other two linear siloxanes (and within the guideline requirement of <20% mortality in the controls).

Overall, the eMSCA considers that there were no adverse toxic effects in the L5 bioconcentration study.

Lipid content and normalisation

As indicated above, the fish lipids declined slightly during the test. The mean (±standard deviation) lipid contents were 2.9% at the start of the test, 1.7% at day 35 and 2.3% at day 70. There was a statistically significant difference between the mean lipid contents at the start of the test and those at day 35 ($p=0.049$), but not between those at day 0 and day 70 ($p>0.05$) nor those at day 35 and day 70 ($p>0.05$). The mean lipids represent those in the controls and exposed groups combined (two fish from each group were sampled at each time point).

The data are presented in terms of the fish code numbers and it is not entirely clear which values represent the control groups and those that represent the exposed groups so it is not possible to compare directly the lipid contents in the control groups and those in the exposed groups. The overall average fish lipid content (average of days 0, 35 and 70) is 2.31±0.96%.The OECD 305 test guideline specified no minimum lipid content for fish to be used in the test, and includes the following advice on lipid normalisation to 5% (appendix 5, section 8):
If lipid analysis was not conducted on all sampled fish, a mean lipid value is used to normalise the BCF. For the steady-state BCF, the mean value recorded at the end of the uptake phase in the treatment group should be used. For the normalisation of a kinetic BCF there may be some cases where a different approach is warranted, for example if the lipid content changed markedly during the uptake or depuration phase. However, a feeding rate that minimises dramatic changes in lipid content should be used routinely.

The eMSCA's current understanding of the bioaccumulation process is that the lipid content should have more effect on the k2 value than the k1 value (when normalising this effectively normalises the k2 rather than the k1). Uptake (k1) is generally assumed to be independent of lipid content, however, this is complicated by depuration also occurring during the uptake period. There is a potential issue with this as the lipid content during the depuration may be different than during the uptake.

Concentration dependence

From the results in it can be seen that there is no obvious concentration dependence for the steady state and sequential BCF values. The highest values for BCF are obtained using the sequential method for kinetic BCF deviation where growth is not considered.
While for L4 the higher treatment was 79% of the measured water solubility value, for L5, the higher treatment is only 56% of solubility. For L4, the higher treatment BCF values were consistently significantly below (i.e. steady state, simultaneous and sequential) the lower treatment values. For L5 this is not the case, providing confidence that the higher treatment was not affected by solubility concerns.

Uptake and clearance rate

It is known that controlled exposure of highly hydrophobic substances in laboratory studies is difficult (Gobas & Lo, 2016, Schlechtriem et al. 2017). According to Goss et al. (2018) it is, however, possible to estimate the BCF from measured clearance rate constant in fish. K1 contains mostly information that can be estimated rather reliable and which is not chemical specific (Brooks et al., 2012). For the same reason only clearance is measured in fish feeding studies (OECD 305, 2012).

It is possible to recalculate k1 and BCF according to the given methods in OECD 305 guideline. For a first rough calculation using the method from Sijm et al. (1995): $k1=520*\text{Weight [g]}^{-0.32}$; with a fish weight of 1.3 g, and lipid content of 2.3 %. For the low concentration this gives a k1 of 478, resulting in a BCF of 5038 L/kg and a 5% lipid normalized BCF of 10952 L/kg. For the high concentration with the same k1, this results in a BCF of 3950 L/kg, and a lipid normalized BCF of 8588 L/kg.

Second, there are some issues with the lipid content and possibly the condition of the fish. The lipid content seems to be very low for fathead minnow. Because of the large difference between the default lipid content and the lipid content of the fish in the test, even more uncertainty is introduced.

Missing analysis of dissolved organic carbon (DOC) and total organic carbon (TOC)

The levels of DOC and TOC are not reported in the study. Considering the high Log K_{OW} of L5, this is a possible issue, since it could interfere with uptake. The importance of DOC is also commented in the OECD TG 305 document.

> "*Organic matter content, quantified as total organic carbon (TOC) and dissolved organic carbon (DOC) can have a significant effect on the amount of freely dissolved test substance during flow-through fish tests, especially for highly lipophilic substances. Sorption of the test substance to organic matter may reduce its bioavailability and therewith result in an underestimation of the BCF*"[16]

The eMSCA has asked the Registrant(s) for the information but it seems not to be available. From the evidence that is available, the average DOC in the water used was 2 mg/L and considering the lack of growth there would be limited extra food to add to the DOC. Further, the fish were adult and lipid concentration decreased during exposure and the exposure was done under flowthrough conditions and faecal matter was removed throughout the study to limit build-up.

Nevertheless, the eMSCA would like to emphasize the uncertainty related to the BCF calculation and the possibility of its underestimation due to the presence of DOC in the testing medium. The absence of DOC measurements is thus a major shortcoming in the test. The water sampling was performed using a pipette and analysed via liquid scintillation, which does not allow to discriminate between freely dissolved L5 and L5 absorbed to DOC. Besides that, it could be reasoned that for such hydrophobic substances total water concentrations are not very informative at all for the bioaccumulation potential, even if the formal requirement of DOC < 2mg/L is met.

Other estimates of uncertainty

The Registrant(s) have used a probabilistic distribution method to investigate the uncertainty in the BCF for L5 (personal communication. Nov 2015). The analysis again used the LoD/2 for the non-detectable concentrations. The method involved constructing a probability distribution for the BCF_k using the variance in k_1 and k_2 over the two concentrations. The Crystal Ball Monte-Carlo simulation software was used to construct the probability distribution (N=10,000 runs) and the median (±standard deviation) for the BCF_k was 1,337± 705 l kg^{-1}. This estimate of the BCF_k is similar to the values obtained by the eMSCA above and to the steady state BCF value. Unfortunately, the report does not consider the effects of lipid normalisation on the data.

Discussion

Overall, the bioconcentration study is considered to be partly reliable. The scatter in the data points means that the 95% confidence interval around the BCF is rather large. Some of this uncertainty results from the variability in the fish concentrations measured at various time points, but the variability in the lipid measurements at each time point is also an important contributor to the overall uncertainty in the BCF_L and BCF_{kL} obtained.

As no significant growth occurred in the study, growth correction of the results is not appropriate. The study clearly shows that the BCF of L5 is likely to be >2,000 l kg^{-1}. There is also one estimate of the BCF_{kL} >5,000 l kg^{-1} but this only occurs at one exposure concentration when the lipid content of the fish on day 35 of the study are used for the lipid normalisation. Importantly all of the steady-state BCF_L values are <5,000 l kg^{-1}. However, the estimated 95% confidence intervals of many of the estimates of the BCF are

[16] OECD TG 305 https://www.oecd.org/env/ehs/testing/1-GD-OECD-TG305-2016-04-12.pdf

>5,000 l kg^{-1} and so the possibility that the actual BCF for L5 could be above 5,000 l kg^{-1} cannot be totally ruled out.

Overall, it is considered that the results of this study provide strong evidence that the BCF for L5 is >2,000 l kg^{-1}, and the possibility that the BCF is >5,000 l kg^{-1} cannot be excluded. Using the overall mean lipid content (2.31%), the lipid-normalised BCF ranges between 2675 – 3831 l/kg. Normalized to 5% the BCF-values are BCF_{ss} = 4210 l/kg (4 ng/l) and 3650 l/kg (39 ng/l) and BCF_k =4260 l/kg (4 ng/l) and 3650 l/kg (39 ng/l). The BCF_k = 4260 from the low exposure group is used for further assessment of L5.

Further remarks on the registrant(s) interpretation of the aquatic BCF-study

The Registrant(s) cite the ECHA PBT guidance (ECHA, 2017) suggesting that valid BCF values may not be possible for low solubility chemical from aqueous fish bioconcentration studies due the difficulty in maintaining test substance concentration. In response the eMSCA notes that there is no indication there was a problem in maintaining the exposure of L5. R11 also states that the aqueous test *may still be applied to strongly hydrophobic substances (having log Kow >6.0) if a stable and fully dissolved concentration of the test substance can be maintained in the water*.

The Registrant(s) state that steady state may be difficult to achieve for highly lipophilic and adsorbing substances. However, the robust study summary (RSS) in the registration dossier states that steady state was reached during the exposure period, as a plateau was reached at day 21 for both test concentrations. It is explained that this is because the subsequent fish concentrations measured after that time were not statistically different. Therefore, reaching steady state does not appear to be an issue for the L5 study. In any case as a kinetic BCF is derived, achievement of steady state is not essential to reach a conclusion in this case.

In their PBT assessment, the Registrants consider that the depuration rate constant from the fish bioconcentration test carries the most weight for the bioaccumulation assessment. They argue that these are more reliable metrics as they are *independent of the exposure concentration and route of exposure*. The eMSCA is unclear why these issues are a concern in this instance, and highlights that the REACH Annex XIII criteria specify a BCF value exceeding 2000 or 5000.

Therefore, a depuration half-life might be useful when a valid BCF value is not available, and the half-life information comes from that test. However, in the view of the eMSCA, the BCF value is a result that should be taken from the test for comparison with the Annex XIII criteria. The eMSCA would agree that interpreting a fish dietary study with respect to the Annex XIII criteria is more challenging, and note the draft OECD guidance for this test does tentatively suggest the use of the k2 value for used in PBT assessment (described in more detail below).

The Registrant(s) argue that the half-life in the fish in the test is <70 days, which according to Goss et al (2013) is indicative of a chemical that is not bioaccumulative. The eMSCA disagrees with this, principally as the value derived by Goss et al (2013) is not animal specific. Different taxa have markedly different rates of metabolic capacity, and so it is not appropriate to derive a single half-life applicable across all species.

In the MSC opinion (ECHA, 2018) for the P and B assessment of D4 and D5, the value cited by Goss et al (2013) was considered not to account for a number of sources of variation in elimination half-lives. Such sources include sizes of different organisms, species, lipid content and metabolism. Other complications were cited as growth and reproductive activity. When the assumptions used to derive the 70-d value were analysed, it was shown that the BMF could exceed 1 when the elimination half-life was as short as 7.7 days and when the conditions more closely mirrored the fish dietary bioaccumulation test guideline (for example uptake is greater due to a higher feeding rate than assumed by Goss et al (2013), and food lipid content is greater than the standard lipid content of the fish).

The MSC opinion also highlights that the kinetic process of bioconcentration is dependent on the fish size as the uptake rate constant can vary with size, the corresponding depuration rate constant will be higher or lower to achieve the same BCF value.

A comparison of the depuration rate constant in fish bioconcentration tests to the measured fish BCF value is described in report published by the UK Environment Agency[17], and cited in the draft OECD guidance for the OECD 305 Bioaccumulation test method. The analysis indicates a (lipid normalised) k2 value below 0.085 d^{-1} (8.2 days) is comparable to a BCF exceeding 5000. This is considerably shorter than the 70 days ascribed to Goss et al (2013). The eMSCA appreciates that there is some uncertainty in the analysis, for instance it does not account for different fish species, and reflects only the ~150 chemicals in the dataset. Therefore, it would be used as part of weight of evidence.

For comparison, the half-lives determined for L5 were between 0.059 and 0.109 d^{-1}, which straddle the 0.085 day-1 value representing a BCF of 5000 (k2 from the simultaneous fit were above the threshold, and those derived from the sequential fit were below). One interpretation could be that L5 half-life data are close to 5000. As suggested above, given measured BCF values are available for L5, in the opinion of the eMSCA, these should take preference over the prediction of the BCF based on the k2 value.

7.7.3.1.2. Fugacity ratios

The Registrant(s) also determines fugacity ratios for L5 based on the measured log K_{ow} (9.4) and BCF values (steady state and kinetic for each concentration). These are in the region of 5E-05 to 6E-05, which the Registrant(s) states as indicating the chemical in the organism is at a lower fugacity (or chemical activity) than in the water. The Registrant(s) states the value of the ratios suggests that either uptake may be less than expected or alternatively elimination is faster than might be expected based on lipophilicity. Finally it notes that the *calculated fugacity ratios presented should be used with caution at this stage*.

The eMSCA notes that there is not yet acceptance of fugacity ratios by regulators for REACH. The F/R value is also sensitive to the log Kow value (inversely affected). For L5, the high log Kow value (9.41, OECD 123) is a further reason that the F/R value is very small. It is arguable that a QSAR would also suggest relatively low BCF based on the log Kow value. However, this is at odds with the measured fish data which indicates high levels of accumulation.

The eMSCA notes that substances with a high BCF may well have F/R <1 for biota water. This is because the theoretical maximum fugacity ratio for biota/water for water exposure alone is one. Therefore, using a BCF test in the F/R calculation alone will not provide a full indication of biomagnification potential.

The eMSCA notes that in the case of another siloxane (D5), the fish BCF values exceeded 5000, BMF and TMF values exceeded one, and yet the F/R <1. This suggests that F/R may not be a robust guide for the fish BCF value or REACH “B” assessment.

Overall, while the eMSCA appreciates the theoretical outcome of the F/R calculation, the available measured data in whole animals should be preferred. In this case the (lipid normalised) BCF values of 2675 - 3831 are in contrast to the low levels of accumulation that are suggested by the fugacity ratios.

7.7.3.2. Bioaccumulation in terrestrial organisms (soil dwelling organisms, vertebrates)

No data are available in the registration dossier.

[17] Environment Agency, 2012: "Depuration rate constant: growth correction and use as an indicator of bioaccumulation potential"

7.7.3.3. Summary of bioaccumulation

A aquatic fish bioconcentration study using fathead minnow (*Pimephales promelas)* is available. Using the overall mean lipid content (2.31%), the lipid-normalised BCF ranges between 2675 – 3831 l kg-1 . The scatter in the data points means that the 95% confidence interval around the BCF is rather large, but the study clearly shows that the BCF of L5 is likely to be >2,000 l kg-1. There is also one estimate of the BCFkL >5,000 l kg-1 but this only occurs at one exposure concentration when the lipid content of the fish on day 35 of the study are used for the lipid normalisation. Importantly, all of the steady-state BCFL values are <5,000 l kg-1. However, the estimated 95% confidence intervals of many of the estimates of the BCF are >5,000 l kg-1 and so the possibility that the actual BCF for L5 could be above 5,000 l kg-1 cannot be ruled out.

This is further underlined when k1 and BCF are recalculated according to the given methods in OECD 305 guideline. They give a BCF of 5038 l kg-1 and a 5% lipid normalized BCF of 10952 l kg-1 for the low concentration. For the high concentration with the same k1, this results in a BCF of 3950 l kg-1 , and a lipid normalized BCF of 8588 l kg-1 for the high concentration.

7.7.4. **Environmental monitoring data**

In a compilation of Norwegian monitoring from 2002 – 2012[18] (Arp, 2012), L5 was detected more frequently than L2 and L3 but less than the cyclic siloxanes D4-D6. L5 was not detected above the LOD in fresh/marine water, nor freshwater sediment (7 and 3 samples respectively), but was in marine sediment, WWTP sludge and water, (11 samples, 4 detections - max 55 ng/g dw; 3 samples, 2 detections, max 400 ng/g dw, 5 samples, 1 detection 35 ng/l) from monitoring performed in 2005 and 2007. A number of biota were also sampled: Cod liver (21 samples, 3 samples above the LOD max 1.46 ng/g ww), Polar Cod fillet (4 samples, no detections), Blue Mussels (2 samples, no detections), bird liver (14 samples, no detections). These were different studies conducted in 2007 and 2009.

The frequency of detection of L5 in the remaining environmental matrices was similar to L4, although the detections in marine sediment (max 55 ng/g dw), STP sludge (400 ng/g dw) and STP water (35 ng/l) were at higher concentrations. For L3, again it was detected in fish liver (4 samples, max 33 ng/g), but not the remaining biota. A similar detection pattern in the environmental matrices was also seen, with detection in 3 STP sludge samples (max 31 ng/g dw), and 1 STP water sample (32 ng/l), although not in marine sediment.

The Norwegian Environment Agency has since performed more environmental monitoring projects that included L5. In samples collected in 2016 (Schlabach et al. 2017) the linear siloxanes were detected in all samples of indoor air, house dust and sewage sludge. L5 was detected in all samples of surface water (5-9,5 ng/L) leachate water (3.7-4.4 ng/L), sewage sludge 350-405 ng/g), house dust (< 10 to 464 ng/g) and indoor air (5,57 to 1460 ng/m^3), L5 was not detected in rat but 70% of samples from brown trout are within < 0,03 to 0,11 ng/g f.w. The measured concentrations were higher than for L4 but below the predicted no-effect levels and the authors expressed that they expected the exposure via environmental pathways to be much lower compared to the exposure via use of personal care products. In another campaign performed in 2017 L5 was found in inlet wastewater and landfill runoff in higher concentrations than for L4 (COWI 2018).

In samples collected in 2018 (Schlabach et al 2019), the linear siloxanes were detected in all selected sample types, including indoor environments. L5 was detected in all samples of indoor air, sewage water, sediment and common mussel. In addition L5 was detected in

[18] This includes data from a further citation: Green, N., Schlabach, M., Strand, A., Schøyen, M., Kaj, L. 2007. Siloxanes in the environment of the Inner Oslofjord. Report 986/2007. TA2269. Norwegian Pollution Control Authority (SFT).

67% of surface water samples and 40% of gull eggs. The authors in this study also expected that the exposure via environmental pathways would be much lower compared to the exposure via use of personal care products The results from the studies demonstrate higher detection frequencies and levels of L5 compared to L3 and L4. This seems to reflect the higher reported tonnage of L5 compared to L3 and L4 at that time.

Evenset et al (2009) sampled sediment and biota in a number of locations in the Norwegian Arctic in 2004 and 2008. L4 and L5 were not detected at the three locations sampled for sediment. This was similar to other linear and cyclic siloxanes. Fish liver from Atlantic cod and Polar cod were sampled at three locations and whole Polar cod at one further location. L4 and L5 were not detected in any fish (LOD appears to be between 0.15 – 0.75 ng/g ww). L3 was detected in two liver samples, and the cyclic siloxanes were detected in nearly all samples. The samples taken in 2004 were not analysed until 2008.

The Swedish Environmental Research Institute performed a national screening programme of different media for siloxanes in 2004 (Kaj et al, 2005b). This contained two parts, firsrly a national programme with sites designated as “background”, “potential point” and “diffuse” sources. Matrices sampled were air, sediment, water, sludge and biota. Secondly a regional screening programme covering sites in thirteen regions with STP “water”, sludge, sediment and fish sampled. Both programmes analysed for D4, D5, D6, L2, L3, L4 and L5. L3, L4 and L5 were not detected in any of the background samples (3 air, 3 sediment and 3 biota). L3 was not detected in any point or diffuse sources. L4 and L5 were both detected in sediment samples (L4: ¼: 0.9 ng/g dw; L5 2/4: 0.7 and 1.7 ng/g dw) from potin sources. Both L4 and L5 were also detected in the three sludge samples from diffuse sources (8 – 16 and 24 – 46 ng/g dw respectively). In the regional screening, L4 and L5 were not detected in STP water or fish (muscle) samples. L4 was detected in 43 out of 51 municipal sewage treatment plants, in one sediment samples, and detected in 2 out of 39 breast milk samples (0.008 and 0.013 µg/l). L5 was detected in 42 out of 51 regional sludge samples and 3 sediment samples. It was not detected in any of the 39 breast milk samples (LOD. 0.04 µg/l). Overall, concentrations of the linear siloxanes were much lower than for the cyclic siloxanes, in some cases for D5 by up to three orders of magnitude. L3 was not detected in any sediment or STP water samples but was detected in 12 sludge samples, and 6 breast milk samples (0.003 – 0.008 µg/l).

Kaj et al 2005a also conducted a wider analysis of siloxanes in the Nordic countries. This included monitoring of air (24, LOD 0.006ug/m3), soil (2, 0.1 ng/g dw), water (13), sediment (24, variable LOD generally <1 ng/g dw), WWTP/landfill effluent (23, variable LOD generally <0.001 ug/l), WWTP sludge (14, ng/g dw), and biota. Biota consisted of composite samples of livers of different fish species (21), seabird eggs (17), and blubber of cetaceans (7). L5 was not detected in any air sample, nor natural waters or the two soil samples. It was detected in all sewage sludge samples 3 – 550 ng/g, and some landfill and STP influents and one STP effluent (<LOD – 0.041 µg/l). It was not detected in any of the biota.

L4 was not detected in air, soil or water samples. However, it was detected in the remaining media. L4 was detected in all WWTP sludge samples (range 1-450 ng/g dw), a small number of sediment samples (<LOD – 29 ng/g dw), and some industrial effluent. It was detected in one biota sample (fish liver, 1.1 ng/g ww), which was notable for also containing high levels of D5 (around 100 times those of D5 in other samples). L3 was not detected in any of the biota, air, sediment or natural waters. It was detected in two of the STP influents (0.0034 – 0.014 µg/l).

As part of routine monitoring (McGoldrick et al, 2014) predatory fish (Lake Trout, *Salvelinus namacycush*, or Walleye, *Sander vitreus* where Lake Trout were not present) were collected by Environment Canada across 16 Canadian water bodies in 2009 and 2010L5was only found in one out of the 87 fish caught (detection limit, DL, 0.50 ng/g w/w), and neither were L2 (HMDS, DL 0.30 ng/g w/w) or L3 (DL 0.42 ng/g w/w). L5 was detected in one sample (DL 0.27 ng/g w/w). In contrast the cyclic siloxanes D4, D5 and D6 were detected in all samples (0.60, 0.50, 0.37 ng/g w/w respectively).

Sanchis et al (2015) have reported detecting both cyclic and linear VMS in different media at the Antarctic. L4 was detected in soil (range below LOD – 602 pg/g dw, 11 samples) and phytoplankton (range below LOD – 17 pg/g dw, 11 samples), but was not detected in vegetation or Krill samples (17 and 11 samples respectively). The findings for L4 were generally consistent with the detection of L5 and L6, but L3 was also detected in Krill.

In contrast, the cyclic siloxanes were detected in all of the media sampled, and often at concentrations up to 100 times greater. The concentrations of cyclic VMS in phytoplankton were found to be negatively correlated with sea surface salinity, and Sanchís considered this to indicate a possible source from ice and snow melting. The cyclic siloxanes are the main focus of the discussion in the paper, principally as they are detected at higher concentrations than the linear homologues.

The findings of this paper have been questioned (MacKay et al. 2015; Warner et al., 2015). One of the main concerns raised with the study was the possibility of contamination of the samples during collection and analysis, owing to inadequate sampling and storage procedures. Although Sanchís et al. (2015b) replied to these comments, some of the concerns raised by MacKay et al. (2015) and Warner et al. (2015) do appear to be legitimate and so the data are not considered further here.

Zhang et al (2011) conducted monitoring of siloxanes, including L4 and L5, in the sediment of the Songhua River, and sewage sludge from eight WWTPs in the north east of China. The area sampled includes locations downstream of large and small cities, and a major silicone production site. 25 sediment samples and one sample from each WWTP were collected. Limits of detection for L4 and L5 were 0.86 and 0.35 ng/g dw, respectively, and this appears to be both sediment and sludge. The paper does not provide specific concentrations of L4 and L5..

Lee et al (2014) sampled sludge from 40 domestic, mixed and industrial wastewater treatment plants in Korea in 2011 for linear and cyclic siloxanes. They found much higher concentrations of the cyclic siloxanes compared to linear siloxanes. Concentrations of specific linear siloxanes are not provided in the paper (or in the supplementary information), only a summed total. Based on relative load graphs in the article, the longer chain lengths were detected (L10 was the most prominent), but the shorter chains, including L5, appear to have been at or around the detection limit. The researchers also noted that higher siloxane concentrations occurred in domestic WWTPs compared to the industrial plants.

Wang et al (2015) conducted 7 day consecutive monitoring of influent, effluent and sludge of a WWTP receiving domestic and food processing waste in China in 2014. L3, L4 and L5 were all below their detection limit (0.082, 0.09 and 0.091 µg/l) in the influent and effluent. In the sludge, L3 was below the detection limit (0.113 µg/kg), but both L4 and L5 were detected in all samples (1.27 – 92.9 and 33 – 164 µg/kg respectively). Similar to other studies, concentrations of the cyclic siloxanes were significantly higher.

Olofsson et al (2012) reviewed trends of L3, L4 and L5 in Swedish sewage sludge between 2004 and 2010. Ten WWTPs receiving a mixture of effluent (large cities, medium cities, mixed domestic and industrial, and domestic) were sampled in the autumn of each year. L3, L4 and L5 were sampled in 6 or 7 of the years, with between 49 and 54 samples being taken in total for each of the three substances. The paper provides median concentrations of 17, 57 and 240 µg/kg dw for L3, L4 and L5 respectively, with stated increases in concentrations of 28, 34, 26% over the period of sampling. More detailed data, such as the range of concentrations, is not provided in the paper, although the supplementary data does provide a graphical illustration. The total median concentration for all the siloxanes, including D4, D5 and D6, was 13500 µg/kg dw.

Bletsou et al (2013) conducted monitoring of a single WWTP in Athens, Greece. The plant is indicated to serve 3,700,000 people. Samples of influent, effluent and sludge were collected over seven consecutive days in April, 2012. L4 was detected in 6 out of 7 influent samples (<LOD – 0.148 µg/l), 6 out of 7 effluent samples (<LOD – 0.099 µg/l), and all

seven sludge samples (0.050 - 0.063 mg/kg). L3 was not detected in the 7 influent and effluent samples, but was detected in the sludge (0.16 – 0.26 mg/kg). L5 was detected in all influent (0.010 – 0.067 ug/l) and effluent samples (0.0007 -0.012 ug/l), and sludge (0.21 -0.25 mg/kg). The eMSCA has been unable to obtain the supplementary information detailing the LOD.

Liu et al (2014) investigated the occurrence of seven musk and seventeen siloxanes at 42 wastewater treatment plants across 23 cities in China from samples of anaerobic digested sludge after the dewatering process. Site predominantly received a mixture of domestic and industrial effluent, although a few received either exclusively domestic or industrial effluent. The l.o.q. for L3, L4 and L5 were 0.5, 0.6 and 0.7 ng/g of sludge. The concentrations of L3, L4 and L5 are not reported. By eye, the log Box & Whisker plots suggest L4 was not detected above the l.o.q. while L3 and L5 ranged from the l.o.q. to ~800 and 90 ng/g respectively, with medians of 20 and l.o.q. Cyclic siloxanes (D4, 5 and 6) were reported to account for 68% of the siloxanes detected, while L11-16 accounted for 84% of the linear siloxanes.

Sanchis et al (2013) tested a new analytical method by sampling WWTP influent and effluent, river and sediment in north east Spain. 15 influent and 16 effluent samples were taken from 17 WWTP as integrated samples over 24 hours in February 2011. One of these was also additionally sampled over one week in June 2011. Three aqueous and six sediment samples from two rivers were also collected in the February. All WWTPs appear to receive effluent from at least 135,000 people, and the level of treatment varied with some suites also having tertiary treatment or nitrogen and/or phosphate removal. The influent samples showed that the main compounds were cyclic siloxanes and L5. L5 was the most frequently found compound and was detected in all 15 WWTP influents in higher concentrations than for L4. L3 was only above the method limit of quantification (MLoQ) in four, and detectable but not quantifiable in a further three. L4 was above the MloQ in seven and detectable but not quantifiable in a further three. Neither L3 or L4 were above the method MLoQ in the effluent, but detectable but not quantifiable in a further three and eleven samples respectively. L5 was above the limit in five and detectable but not quantifiable in the remainder apart from one sample. By contrast, for example, D5 was detected in all effluent samples. For the river sampling, L3 was detected in one site in both sediment and water, while L4 and L5 were detected at the same point but only in sediment. MLoQ was 1.2, 1.4 and 0.5 ng/l in wastewater, and 0.9, 0.6 and 1.8 ng/g in river sediment. MLoD was half the MLoQ for sediment, and approximately 20-33% for wastewater. The river water MloQ is not discussed in the paper or supplementary information.

Ratola and co-workers have reported initial findings of cyclic and linear siloxanes at several locations in Portugal (Ratola et al., 2016). They sampled pine needles, soils and air (using SIP[19] disks) across eight sites in Portugal covering urban, industrial, rural/remote, industrial, beach locations and a WWTP for four cyclic siloxanes (D3, D4, D5 and D6), four linear siloxanes (L2, L3, L4 and L5) and a silane in winter and summer. The use of pine needles built on a previous project to use them as biomonitors of airborne persistent organic pollutants. Analytical recoveries across the three matrices were similar, but varied for the different chemical with recoveries of the more volatile siloxanes (for example L2 and D3) being lower than the less volatile ones (for example L5 and D6). At the time of the presentation only limited data were available for pine needles and soils for the wintertime in Porto (actual sample type not specified). The linear siloxanes were detected at low concentration (<1 ng/g wet weight) or were not detected. Cyclic siloxanes were detected at higher concentrations in almost all samples.

Pelletiera et al (2021) studied the bioaccumulation of the cyclic siloxanes (D3 to D6) and linear siloxanes (L3 to L5) in a food web in the St. Lawrence River downstream of the effluent of the municipal wastewater treatment plant in Montreal, Canada (Pelletier et al . 2021). In all biotic samples from individuals feeding in the effluent plume cyclic siloxanes were detected and the linear siloxane L5 was also abundant in walleye and gull

[19] Sorbent-impregnated polyurethane foam [disks]

eggs. Sediment-biota accumulation factor (BSAF) have been calculated for total siloxanes (∑D3 to D6 and L3 to L5) showing values of 65.4, 27.8, 9.9 and 6.4 g dw/kg ww for walleye, northern pike, yellow perch and round goby respectively.

Summary

In summary there is limited environmental monitoring of L5 available. Where sewage sludge has been monitored, L5 can generally be detected and in higher concentrations than for L3 and L4. Given the use in cosmetics and lack of biodegradability, detection at influent/ effluent and sludge of STPs is expected. There is insufficient data on wider environmental contamination to draw any firm conclusions.

Generally, the levels detected for the linear siloxanes are significantly lower than for the cyclic siloxanes. It should be noted that there is a large difference in supply volume for linear siloxanes compared to the cyclic siloxanes. More recent studies from Norway (Schlabach et al 2017, 2019) demonstrate higher detection frequencies and levels of L5 compared to L3 and L4.

Although D4 and D5 are registered at much higher volumes than L5, several uses of D4 and D5 have been restricted. During the evaluation period the tonnage band of L5 has already increased since the substance is an alternative for the restricted uses of D4 and D5. Therefore, higher concentrations of L5 in the environment can be expected in future.

7.8. Environmental hazard assessment

7.8.1. Aquatic compartment (including sediment)

The available aquatic toxicity tests have generally been carried out using the highest test concentration possible (derived from a nominal exposure concentration of 70 ng l^{-1}, which represents the water solubility of L5 in water; the data were reported in terms of the mean measured concentration at this nominal exposure level).

7.8.1.1. Fish

7.8.1.1.1. Short-term toxicity to fish

The short-term toxicity data to fish given in the registration dossier are summarised in Table 29. The substance is not acutely toxic to fish at concentrations up to the limit of solubility in the test medium.

Table 29: Summary short-term toxicity of L5 to fish

Species	Value	Remarks	Reference
Rainbow trout (*Oncorhynchus mykiss)*	96h-LC_{50} > 75 ng l^{-1}	Test to OECD 203, reliability score 1. Flow through. Measured concentration (nominal 70 ng l^{-1})	Registration dossier, 2010

7.8.1.1.2. Long-term toxicity to fish

The long-term toxicity data for fish given in the registration dossier are summarized in Table 30.

Table 30: Summary long-term toxicity of L5 to fish

Species	Value	Remarks	Reference
Rainbow Trout (*Oncorhynchus mykiss*)	60-d (post-hatch) NOEC ≥ 7.9 µg/l	Read-across from L4 FELS, OECD 210. Flow through test, with results expressed as TWA concentrations. No effects for the following endpoints: hatching, larval survival abnormal appearance and behaviour. Tested up to the limit of solubility of L4.	Registration dossier, 2013
Fathead minnow *(Pimephales promelas)*	35d-NOEC ≥ 39 ng l^{-1}	Results from OECD 305 bioconcentration test, dossier reliability score 1. Endpoint mortality. Measured concentration (nominal 70 ng l^{-1}). As this was from a bioconcentration study not all relevant long-term endpoints (for example growth) were studied.	Registration dossier, 2006

No standard long-term fish toxicity test is available using L5. In the registration dossier, the Registrant(s) has included a Fish Early Life Stage (FELS) study using L4, and a NOEC based on the fish bioconcentration test summarised in section 7.7.6.1.

The FELS test for L4 is reviewed in detail in the substance evaluation of that substance. For the purposes of this evaluation, the study is considered to be valid.

In the fish bioconcentration test using L5, the substance was not toxic to fish over longer-term exposure at concentrations up to the limit of solubility in the test medium. Sub-lethal endpoints such as adverse impacts on growth or potentially sensitive early life stages are not considered in a bioconcentration study. This means this test alone cannot fulfil the chronic fish toxicity endpoint.

Taken together, the eMSCA considers that there is sufficient data to fill the endpoint, and demonstrate that L5 is not likely to be chronically toxic to fish up to the limit of water solubility.

7.8.1.2. Aquatic invertebrates

7.8.1.2.1. Short-term toxicity to aquatic invertebrates

No short-term toxicity data for invertebrates are included in the registration dossier. Testing for the endpoint is waived, as a long-term test result is available.

7.8.1.2.2. Long-term toxicity to aquatic invertebrates

The long-term toxicity data for aquatic invertebrates given in the registration dossier are summarized in Table 31. The substance is not toxic to aquatic invertebrates over longer-term exposure at concentrations up to the limit of solubility in the test medium.

Table 31: Summary long-term toxicity of L5 to aquatic invertebrates

Species	Value	Remarks	Reference
Daphnia magna	21d-NOEC ≥ 47 ng l^{-1}	Test to OECD 211, reliability score 1. Flow-through conditions, results expressed as arithmetic mean concentrations. Endpoint reproduction, mortality and growth. Measured concentration (nominal 70 ng/l)	Registration dossier, 2010

The eMSCA considers that there is sufficient data to fill the endpoint, and demonstrate that L5 is not likely to be chronically toxic to Daphnia up to the limit of water solubility.

7.8.1.3. Algae and aquatic plants

The algal toxicity data given in the registration dossier are summarised in Table 32. The data relate to the read-across substance L4 (decamethyltetrasiloxane, CAS No. 141-62-8, EC No. 205-491-7). There are no data for L5 itself. L4 is not toxic to algae at concentrations up to the limit of solubility in the test medium and the Registrant(s) concluded that L5 would behave similarly to L4.

Table 32: Summary long-term toxicity of L4 to algae

Species	Value	Remarks	Reference
Pseudokirchneriella subcapitata	72h-NOEC ≥ 2.2 µg l^{-1} 72h-EC_{50} >2.2 µg l^{-1}	Test to OECD 201, reliability score 1. Endpoint growth rate. Measured concentration (nominal 6.7 µg/l). The data relate to the read-across substance L4 and the read-across of the data to L5 was given a reliability score of 2.	Registration dossier, 2008

The eMSCA considers that there is sufficient data to fill the endpoint, and demonstrate that L5 is not likely to be chronically toxic to algae up to the limit of water solubility.

7.8.1.4. Sediment organisms

The registration dossier notes that there is no requirement for sediment toxicity testing at Annex IX (NB: ECHA public dissemination site states the supply tonnage as 10-100 tonne/year), but that due to *the high absorption potential and potential for persistence in sediment, the compartment has been assessed*.

Measured long-term sediment toxicity data are available with L5 for three sediment dwelling species *Lumbriculus variegatus*, *Chironomus riparius* and *Hyalella azteca*. The Registrant(s) states that the studies were all conducted in natural sediment and show no effects at the highest concentrations tested.

The maximum test concentrations were selected for each sediment test based on the limit of test substance solubility in organic carbon. In each test, the sediment was dosed just above the limit of organic carbon solubility to allow for potential volatilisation losses of the test substance. The results are summarised in Table 33.

Table 33: Summary of long-term toxicity data to sediment organisms provided in the registration dossier for L5

Species	Value (not normalised for OC)	Remarks	Reference
Lumbriculus variegatus	NOEC (28d) ≥19 mg/kg dw Endpoints: Number of oligochaetes recovered and biomass	OECD Guideline 225 (Sediment-Water Lumbriculus Toxicity Test Using Spiked Sediment). GLP compliant. Mean (arithmetic) measured sediment dry weight concentrations. Natural sediment (2.5 % organic carbon). Static conditions.	Registration dossier, 2016
Chironomus riparius	NOEC (28d) = 17 mg/kg dw Endpoints: Emergence and combined developmental rate	OECD Guideline 218 (Sediment-Water Chironomid Toxicity Test Using Spiked Sediment). GLP compliant. Mean (arithmetic) measured sediment dry weight concentrations. Natural sediment (3.1% organic carbon). Static conditions.	Registration dossier, 2020
Hyallela azteca	NOEC (28d) ≥33 mg/kg dw Endpoints: Survival and growth	ASTM E1706-19 (Standard Test Method for Measuring the Toxicity of Sediment-Associated Contaminants with Freshwater Invertebrate). GLP compliant. Mean (arithmetic) measured sediment dry weight concentrations. Natural sediment (3.2% organic carbon) Renewal of overlying water but not renewal of test substance.	Registration dossier, 2020

In the *Lumbriculus variegatus* test performed according to OECD 225 and GLP using L5 no effects were observed up to a maximum (mean measured) concentration of 19 mg/kg dw. Normalised to 5% organic carbon, NOEC is 38 mg/kg dw.

Furthermore, in the 28 day sediment toxicity study with *Chironomus riparius* conducted according to OECD TG 218 no effects were observed on the emergence and combined developmental rate up to the maximum mean measured concentration, 17 mg/kg sediment dry weight (nominal test substance concentration 35 mg/kg sediment dry weight). A NOEC value of ≥27 mg/kg was determined based on mean measured concentrations and normalised for a standard sediment of 5% organic carbon.

In the 28 day sediment toxicity study conducted according to ASTM Standard E1706-19 with the sediment organisms *Hyalella azteca*. No effects were observed on the survival and growth at mean measured concentrations up to 34 mg/kg dry weight (the highest concentration tested). Normalised to 5% organic carbon, NOEC is 52 mg/kg sediment dry weight for mean measured concentrations.

Overall, the lack of effects in both the *Lumbriculus, Chironomus* and *Hyallela* test using L5 is consistent with the test performed using L4.

7.8.1.5. Other aquatic organisms

None.

7.8.2. **Terrestrial compartment**

Table 34: Summary of toxicity to soil microorganisms

Species	Value	Remarks	Remarks
Soil microorganisms	NOEC (28d) ≥ 100 mg/kg soil dw (nominal)/850 mg/kg soil (measured)	OECD TG 216. Soil Microorganisms: Nitrogen Transformation Test.	Registration dossier, 2019

A 28-day toxicity to soil microorganisms to test for effects of L5 on nitrate formation rate of soil microflora has been included in the registration dossier. No effects on nitrate formation rate were observed up to the highest concentration tested (100 mg/kg dw).

Table 35: Summary of toxicity to soil macroorganisms

Species	Value	Remarks	Remarks
Eisenia fetida	NOEC (56d) ≥ 1000 mg/kg soil dw (nominal) on mortality, growth and reproduction	OECD TG 222. Earthworm Reproduction Test (*Eisenia fetida/Eisenia andrei*)	Registration dossier, 2019

A 56 day earthworm reproduction test at concentrations up to 1000 mg/kg soil dw has been included in the registration dossier. No effects on survival or reproduction were observed. A 56 day NOEC value of ≥1000 mg/kg dry weight has been determined for the effects of the test substance on growth and survival of adult earthworms, based on nominal concentrations.

PNEC soil has not been derived due to lack of effects in the available tests.

7.8.3. **Microbiological activity in sewage treatment systems**

Table 36: Summary of microbiological activity in sewage treatment systems

Species	Value	Remarks	Remarks
Activated sewage sludge	EC50 (3 h) > 100 mg/l	OECD TG 209. Read-across from L4	Registration dossier.

The microbiological toxicity data given in the registration dossier are summarised in Table 36. The data relate to the read-across substance L4 (decamethyltetrasiloxane, CAS No. 141-62-8, EC No. 205-491-7). There are no data for L5 itself. L4 is not toxic to activated sewage sludge at concentrations up to 100 mg/l and the Registrant(s) concluded that L5 would behave similarly to L4.

A read-across table summarising the results of thirteen microorganism tests is also provided as supporting information. None of these are reported to exhibit toxicity[20].

The eMSCA notes that no chemical analysis was performed, and the test substance was volatile. The Registrant(s) note that the study for L4 was performed in excess of the water solubility of the substance (100 mg/l vs. 0.0067 mg/l)

Overall, the weight of evidence is considered by the eMSCA to be adequate to indicate that there is not a significant concern for micro-organism toxicity up to the limit of solubility for L5.

PNEC STP: 1 mg/L , derived from the EC50 value with an assessment of 100.

7.8.4. Summary and discussion of the environmental hazard assessment

The available ecotoxicity data show that L5 does not cause adverse effects in fish, aquatic invertebrates, algae, sediment organisms or soil micro- and macroorganisms, when exposed at concentrations up to the water solubility limit in the test media.

Thus, based on the available ecotoxicity data L5 does not fulfil the T-criterion of REACH Annex XIII based on ecotoxicity. However, effects in other taxa cannot be excluded.

7.8.5. PNEC derivation and other hazard conclusion

Table 37: PNEC derivation

PNEC DERIVATION AND OTHER HAZARD CONCLUSIONS		
Hazard assessment conclusion for the environment compartment	**Hazard conclusion**	**Remarks / Justification**
Freshwater	n/a	The Registrant(s) have not derived any aquatic PNEC because of the lack of effects in the available tests.
Marine water		
Intermittent releases to water		
Sediments (freshwater)	n/a	
Sediments (marine water)	n/a	
Sewage treatment plant	PNEC (STP)>: >1 mg/L	Assessment factor 100
Soil	n/a	The Registrant(s) have not derived any aquatic PNEC because of the lack of effects in the available tests,
Air	No value	The Registrant(s) have not derived a PNEC air. This is justified by the lack of indication of abiotic effects in the atmosphere.
Secondary poisoning	PNEC oral= 0.83 mg/kg food	Assessment factor: 300 Based on a NOAEL (adverse liver weight increase) of 25 mg/kg

[20] One test performed with D4 using *Escherichia coli*and*Staphylococcus aureus* over 24 h is described as exhibiting “little or no toxicity”

PNEC DERIVATION AND OTHER HAZARD CONCLUSIONS		
Hazard assessment conclusion for the environment compartment	**Hazard conclusion**	**Remarks / Justification**
		bw/d in the 28-d oral repeat dose study[21].

7.8.6. Conclusions for classification and labelling

There are no effects in the acute or chronic aquatic toxicity tests. Therefore, the eMSCA considers that the substance needs not to be classified for the environment.

7.9. Human Health hazard assessment

No specific concerns for human health were listed on the CoRAP. The human health hazard assessment was focussed on the end-points of relevance to the 'T' criterion, as given in the criteria for the identification of PBT substances in Reach Annex XIII; as such, only the end-points carcinogenicity, germ cell mutagenicity, reproductive toxicity and repeated-dose toxicity were evaluated.

. Unless otherwise stated, the UK eMSCA has consulted the original study reports and where this has been done the assigned reliability scores assigned are those of the UK eMSCA and not the Registrant(s). A literature review conducted by the eMSCA did not identify any further information (see Section 7.14). Where the registration dossier includes data from other members of the analogue group (L3 and L4) to inform on L5 a summary of the data and the conclusions from the relevant evaluation document are presented.

7.9.1. Toxicokinetics

Not relevant to the targeted evaluation.

7.9.2. Acute toxicity and Corrosion / Irritation

This information is not relevant to the evaluation.

7.9.3. Sensitisation

This information is not relevant to the evaluation.

7.9.4. Repeated dose toxicity

7.9.4.1. Repeated-dose toxicity: oral

The repeated dose oral toxicity of dodecamethylpentasiloxane (L5) has been investigated in two oral studies, one non-guideline range-finding study and a guideline 28-day oral study in rats (OECD 407).

Table 38: Summary of repeated-dose studies via the oral route

Method	Results	Remarks
7 day repeat dose. (oral, gavage)	No mortality or treatment related effects observed at any dose.	Test material: Dodeca-

[21] Conversion factor NOAEL to NOEC = 10; assessment factor = 300.

Method	Results	Remarks
Rat (Sprague Dawley) 0, 100, 300 or 1000 mg/kg bw/d Vehicle: corn oil 5 per sex/dose Range-finding study Registration dossier (2009)	NOAEL: none set as this was a range-finding study.	methylpenta-siloxane (L5) Reliability: 4 Reliability proposal from Registrant(s). Original study report not consulted by the UKCA.
28 day repeat dose. (oral, gavage) Rat (Sprague Dawley) 0, 25, 250 or 1000 mg/kg bw/d Vehicle: corn oil 5 per sex/dose + 5 per sex recovery groups (control and 1000 mg/kg bw/d) OECD 407 Guideline value for classification for STOT-RE Cat 1 ≤30 mg/kg bw/d and Cat 2 ≤300 mg/kg bw/d Registration dossier (2010)	**Control** Perilobular fatty change (severity 1*; 2/5 females) **25 mg/kg bw/d** Clinical signs and mortality: No mortality. Hair loss around the eyes (2/5 females). Clinical chemistry: ↓total bilirubin (both sexes). No other treatment related differences. Organ weights: ↑mean absolute and relative liver weights (+19.8% and +16.3% respectively in females). ↑absolute thymus weight (13.7% and 3.5% males and females respectively). Histopathology: Perilobular fatty change (severity 1.6; 5/5 females). Other findings: no indication of any abnormal distributions of dioestrus, metoestrus, proestrus or oestrus. **250 mg/kg/bw/d** Clinical chemistry:↓total bilirubin (both sexes). Organ weights: ↑mean absolute and relative liver weights (+20% and +19% respectively males; 25.9% and 25.2% in females). ↑absolute thymus weight (15.3% and 17.9% males and females respectively). Histopathology: Perilobular fatty change in the liver (mean severity 2; 5/5 females). ↑ α-2u-globulin in kidney (males). Other findings: no abnormal distributions of dioestrus, metoestrus, proestrus or oestrus day 22. **1000 mg/kg bw/d (above the level for classification)** Body weight: no treatment-related effects at end of treatment; ↑ day 8 of recovery (both sexes). Haematology: a number of statistically significant differences which were gender-specific, owing to slightly high control values, or occurred in the absence of concomitant changes in related parameters Clinical chemistry: ↓total bilirubin and ASAT (both sexes); ↓cholesterol, ↓phospholipids and ↓ALP (males; not dose responsive) Neurobehaviour: no treatment-related findings in the FOB. ↑locomotor activity (0-10 minutes in males) Organ weights: ↑mean absolute and relative liver weights (not evident after the recovery period). ↑absolute thymus weight (16.9% and 7.5% males and females respectively). Gross pathology: accentuated lobular pattern on livers of males. Histopathology: ↑α-2u-globulin in the kidneys in the absence of morphological changes and no dose response (males). Hepatocellular hypertrophy (not present at end of recovery). Perilobular fatty change (minimal) (still present after recovery). Bile duct proliferation (1 female)	Test material: Dodeca-methylpenta-siloxane (L5) Reliability: 1

Method	Results	Remarks
	Other findings: no abnormal distributions of dioestrus, metoestrus, proestrus or oestrus. NOAEL: 25 mg/kg bw/d based on adverse liver weight increases (≥20%) accompanied by changes in histopathology at 250 mg/kg/d. **Severity grades for clinical symptoms assigned as follows: 0=not present, 1 = present/slight, 2= moderate, 3=marked.*	

In a non-guideline range-finding study rats were dosed with L5 over a period of 7 days. No mortality or treatment related effects were observed at any of the doses tested.

In an 28-day oral study according to OECD, 407 rats were dosed with L5 for 28 days. No mortality was observed at any of the doses tested. At doses of 25 and 250 mg/kg/d, which are below the guidance cut-off value for classification for STOT-RE Category 2 (adjusted to ≤300 mg/kg bw/d for a 28-day oral study), the main effect was on the liver. Liver weight increased by ≥20% in both males and females at doses of 250 mg/kg bw/d and at this level is considered adverse.

Other findings associated with the liver included decreased levels of total bilirubin (both sexes) and perilobular fatty change (females). The latter finding is also seen in control animals but an increase in incidence and severity with dose was observed so is considered treatment related. In animals dosed at 1000 mg/kg bw/d, this finding was not apparent at the end of recovery.

The eMSCA proposes a NOAEL for this study of 25 mg/kg bw/d based on adverse liver weight increases (≥20%) accompanied by changes in histopathology at 250 mg/kg/d.

7.9.4.2. Repeated dose toxicity: inhalation

There are no data on inhalation toxicity that has been generated using L5. Instead, the dossier includes information generated with the closely related substance L4. Two repeated-dose studies were performed with L4 via the inhalation route, a 90 day repeated-dose study according to OECD 413 and a repeated-dose study combined with reproduction/developmental screening (OECD 422). Neither of the studies raised concerns for human health following repeated exposure to L4. The Registrant(s) have proposed to read-across from these studies to inform on L5.

The results from the combined study that are relevant to reproductive toxicity are described in Section 7.9.7

Table 39: Summary of repeated-dose studies via the inhalation route

Method	Results	Remarks
90 day Repeat dose study + 28 day recovery (inhalation 6 hours daily whole body) Rat (Sprague-Dawley) 0, 70 or 400 ppm (nominal) (vapour) equivalent to 0, 0.9 and 5.1 mg/l/6h/d or a calculated internal dose* of 0, 243 and 1377 mg/kg bw/d *10/sex/dose + 10/sex/dose recovery*	**0 ppm (Control)** Two animals died (cause unknown). Two neoplasms (not specified) were reported in males. Alveolar macrophages (1/10 males; minimal severity). **At 70 ppm (equivalent to approx. 0.9 mg/l or an internal dose of 240 mg/kg bw/d)** No biologically significant and/or treatment related findings. **At 400 ppm (equivalent to approx. 5.1 mg/l or an internal dose of 1377 mg/kg bw/d) (above the concentration for classification)** Transient changes in food consumption and body weight gain (both sexes, recovery group).	Test material: decamethyl-tetrasiloxane (L4) Reliability: 1

Method	Results	Remarks
groups (control and high dose only) OECD TG 413 Guideline value for classification for STOT-RE Cat 1 ≤0.2 mg/l/6h/d and Cat 2 ≤1 mg/l/6h/d Registration dossier 7.5.464 (2010)	Organ weight: ↑ liver weight to body weight ratio (8% main females group). Urinalysis: ↓ urine volume, and ↑ urobilinogen (males main group; not seen in recovery group). Statistically significant difference also reported in urobilinogen (recovery group females). Microscopic : ↑ incidence of alveolar macrophages (2/10 males and 5/10 females; minimal severity) (statistical significant in females) Neoplasms: benign subcutaneous fibroma (common skin lesion) (1 male) NOAEC: >400 ppm (equivalent to 5.1 mg/l/6h/d or an inernal dose of 1377 mg/kg bw/d).	
Combined repeated dose and reproduction/ developmental screening (inhalation, vapour, whole body) Rat (Sprague-Dawley) male/female 0 and 400 ppm (equivalent to ~5.1 mg/l/day) for 6 hours/day or a calculated internal dose* of 0 and 1377 mg/kg bw/d 10 per sex/group for -28/29 days (males/females) (toxicity group) -15 days pre-mating, during the mating period up to and including day 19 of gestation (reproductive group females) OECD TG 422 Guideline value for classification for STOT-RE Cat 1 ≤0.6 mg/l/6h/d and Cat 2 ≤3 mg/l/6h/d Registration dossier 7.5.346 (2007)	The tested concentration was above the cut-off value for classification No deaths and no significant treatment-related clincal signs of toxicity. Effects seen in the toxicity phase animals: Significant ↑ body weight gains in 3rd week of gestation. ↓ Food consumption (Weeks 1 and 2) (within historical control data) and ↓ total food consumption (males). No differences in absolute organ weights. Spleen to body weight ratio slightly ↓ (toxicity group females). No histopathological correlate, nor any effect of exposure in other lymphoid tissues. This was considered to be random variation and not of toxicological significance. No gross lesions attributed to the test substance. No functional or neurological effects. NOAEC: 400 ppm (equivalent to 5.1 mg/l/6h/d or an internal dose of 1377 mg/kg bw/d) for the systemic toxicity. Fertility and offspring effects reported at Section 7.9.7.	Test material: decamethyltetrasiloxane (L4) Reliability: 1

* Calculated as follows: $NOAEL_{internal}$ (mg/kg bw/d) = $NOAEC_{inhalation}$ (mg/l) x 45 l/kg bw/h (rat respiration rate) x 6 (daily inhalation exposure) x 1 (default respiratory absorption of 100%).

In a 90-day inhalation study conducted in accordance with OECD TG 413, decamethyl-tetrasiloxane (L4) was well tolerated at concentrations of 70 and 400 ppm. There were no clinical signs or treatment-related effects associated with exposure on body weights, food consumption, ophthalmology or neurobehaviour. Significant changes in clinical chemistry, haematology and urinalysis may be treatment-related, however they are not considered to be biologically significant as they show no dose response and fall within the reported range of historical control data. Similarly, changes in organ weight are not considered toxicologically significant as there were no effects observed in the underlying histopathology. The only treatment-related microscopic finding was an increase in the

incidence of alveolar macrophages in the highest concentration group which reached statistical significance in females. This was also observed but to a lesser extent in the control group. This is a common finding in inhalation studies and, in the absence of other findings in the lung, is not considered toxicologically significant. Based on the results of this study a NOAEC for L4 for systemic toxicity in male and female rats is considered to be >400 ppm (5.1 mg/l/6h/d).

In a combined repeat dose inhalation study, with reproductive/developmental screening carried out with L4, largely according to OECD TG 422, no clinical signs or effects on body weight and food consumption were reported at the only tested concentration of 400 ppm (5.1 mg/l/6h/d). The study deviated from the OECD test guideline in that only a single dose was tested. However, as this exceeded the guidance values for classification for STOT-RE, it is considered reliable for concluding on STOT classification. There were no treatment related changes on neurobehaviour, haematology, clinical chemistry, organ weights or histopathology. Based on these results, a NOAEC of 400 ppm (5.1 mg/l) is proposed for the systemic toxicity of L4. Effects on reproductive endpoints are considered under section 7.9.7.

7.9.4.3. Summary of Repeat Dose Toxicity

The short-term toxicity of L5 was investigated via the oral route. The main findings were on the liver. Toxicity by the inhalation route is informed on by studies with the closely related substance L4.

Effects on the liver were observed following treatment via the oral route. Increased liver weight was reported in males and females at doses below the guideline value for classification, reaching 20% or more at doses of 250 mg/kg bw/d. Other findings associated with the liver included decreased levels of total bilirubin (both sexes) and perilobular fatty change.

A classification for STOT-RE is indicated when toxic effects that may include the following descriptions occur at or below 300 mg/kg bw/d in a 28-day oral rat study.

a) Morbidity or death resulting from repeated or long-term exposure
There were no treatment-related deaths or cases of moribund animals at any concentration.

b) Significant functional changes in the central or peripheral nervous systems or other organ systems
There were no such changes in any organ systems.

c) Any consistent and significant adverse change in clinical biochemistry, haematology or urinalysis parameters
There were no such changes at doses below the guidance values.

d) Significant organ damage noted at necropsy and/or subsequently seen or confirmed at microscopic examination
There were no such effects at doses below the guidance values.

e) Multi-focal or diffuse necrosis, fibrosis or granuloma formation in vital organs with regenerative capacity
There were no such effects.

f) Morphological changes that are potentially reversible but provide clear evidence of marked organ dysfunction (e.g. severe fatty change in the liver)
No toxicologically significant morphological findings were reported in the liver at doses below the guideline for classification in animals dosed via the oral route.

g) Evidence of appreciable cell death (including cell degeneration and reduced cell number) in vital organs incapable of regeneration

There were no such effects.

Additionally, there were no generalised changes that involved several organ systems or significant/severe changes in the general health status of the animals.

In the studies via the inhalation route with L4, effects on the liver were confined to doses above the guidance value for classification. Effects on the liver were considered to be adaptive. Changes in clinical biochemistry were consistent with an effect on the liver, although these are not considered toxicologically significant. These are compared against the criteria for classification for STOT-RE in the evaluation report for L4. Classification for STOT-RE is not proposed for L4.

Overall, based on the information available the eMSCA considers that L5 does not meet the criteria for classification for STOT-RE.

7.9.5. **Mutagenicity**

7.9.5.1. 7.9.5.1 *In vitro* genotoxicity data

The results of the genotoxicity testing are summarised below. In the absence of gene mutation studies carried out with L5, the Registrant(s) have proposed read-across from L4, which is a member of the same analogue group, and has been used to inform on the mutagenic potential of L5.

Table 40: Summary of *in vitro* genotoxicity studies

Method	Results	Remarks
In vitro mammalian chromosome aberration test Chinese Hamster lung fibroblasts (V79) OECD 473 Test concentrations: ***Without metabolic activation:*** Experiment 1: 2.5, 5, 10 mM (4 hour treatment, 20 hour fixation); Experiment 2: 0.125, 7.5, 10 mM (20 hour treatment, 20 hour fixation); ***With metabolic activation:*** Experiment 1: 2.5, 5, 10 mM (4 hours treatment, 20 hours fixation). Experiment 2: 4, 7, 10 mM (4 hours treatment, 20 hours fixation) Experiment 3: 2.5, 5, 10 mM (4 hours treatment, 20 hours fixation) Appropriate positive controls and solvent controls. Registration dossier (2010)	Experiment I: negative with and without metabolic activation. Experiment II: negative without metabolic activation; positive with metabolic activation: the mean % aberrant cells (excluding gaps) exceeded the upper limit of negative control range, however there was no clear dose response. Experiment III: negative with metabolic activation. However analyses of test item concentration showed limited availability of test item in aqueous minimum essential medium (MEM) phase. Overall this result is considered as negative. No cytotoxicity at concentrations up to the limit concentration	Test material: dodecamethyl pentasiloxane (L5) Reliability: 2 Updated report provided during evaluation process.

L5 has been tested in a mammalian cell chromosome aberration study *in vitro*. This study was carried out following the OECD guideline 473 and according to GLP. The results for Experiment I with and without activation were negative. In the confirmatory assay a negative result was obtained in the absence of metabolic activation, but in the presence of metabolic activation the study gave a positive result, although there was no clear dose response or reproducibility with this finding.

A third experiment in the presence of metabolic activation gave a negative result, however, there may have been limited availability of the test substance during the minimum essential medium (MEM) phase of the study. This result should therefore be treated with caution, but overall is considered negative.

No further information is available on the registered substance; however, an Ames test and an *in vitro* mouse lymphoma cell assay carried out on a closely related substance (decamethyltetrasiloxane (L4)) are included in the registration dossier. Both these studies were negative.

Based on the data available, the eMSCA considers that L5 is considered negative for *in vitro* genotoxicity.

7.9.5.2. *In vivo* genotoxicity data

No *in vivo* genotoxicity data was submitted in the registration dossier.

7.9.5.3. Human information

No information available.

7.9.5.4. Summary and discussion of mutagenicity

A single *in vitro* study carried out with L5 was submitted as part of the registration dossier: a cytogenicity study in Chinese Hamster Ovary Cells. The results from the first two experiments gave ambiguous results, and while a third experiment appeared to support the negative findings from experiment I, uncertainties regarding the exposure duration and concentration mean that the result should be treated with caution.

Read-across from L4 to inform on this endpoint is proposed by the Registrant(s) on the basis of structural similarity, similar physicochemical properties and hydrolysis patterns. No *in vivo* test results were reported in the registration dossier.

Overall, the eMSCA considers that it is unlikely that L5 is mutagenic based on the information available.

7.9.6. **Carcinogenicity**

No chronic repeated-dose study was submitted in the registration dossier to enable the assessment of the carcinogenic potential of the registered substance.

7.9.7. **Toxicity to reproduction (effects on fertility and developmental toxicity)**

No studies have been carried out directly on dodecamethylpentasiloxane (L5). Instead, information on reproduction and development is available from a combined repeat dose toxicity with reproduction/developmental screening test (OECD 422) and a developmental toxicity test (OECD 414) carried out with the closely related substance decamethyltetrasiloxane (L4). The Registrant(s) has proposed that information from L4 can be used to inform on L5.

Table 41: Summary of reproductive effects from the combined repeated-dose study with reproductive/developmental screening and prenatal developmental toxicity study

Method	Results	Remarks
Combined repeated dose and reproduction/ developmental screening (inhalation, whole body)	**Parental** See Section 7.9.4.2 **Fertility** No effect on testes or epididymides weights or histopathology. No other parameters examined. Three dams in the treated group failed to deliver a litter. One of these showed signs of parturition (blood discharge) on day 25 but	Test material: decamethyl-tetrasiloxane (L4) Reliability 1

<table>
<tr><th>Method</th><th>Results</th><th>Remarks</th></tr>
<tr><td>Rat (Sprague-Dawley) male/female

10 per sex/group

0 and 400 ppm (equivalent to approximately 5.1 mg/l) for 6 hours/day or a calculated internal dose* of 0 and 1377 mg/kg bw/d

Equivalent or similar to OECD TG 422

Registration dossier 7.8.2.042 (2007)</td><td>no pups were found although 7 implantation sites were present. There were no implantation sites present in the other two animals. All control animals produced litters.

In dams that successfully produced litters, there were no changes in litter size, male-to-female ratio, pup body weights or the pup survival. There were no effects on duration of gestation, number of implantation sites, number of corporea lutea, mating and fertility indices, litter size and weight or ratio live births/litter.

Developmental (Offspring)
No adverse effects on pups up to day 4 post partum. Effects on histopathology and organ weight in pups not investigated.

NOAEC: 400 ppm (equivalent to approximately 5.1 mg/l/ 6 hours/day or a calculated internal dose of 1377 mg/kg bw/d for both fertility and offspring.</td><td></td></tr>
<tr><td>Developmental toxicity study

According to OECD TG 414 (Prenatal Developmental Toxicity Study) and EPA OPPTS 870.3700

Rat (Crj: CD(SD)) time-mated females, 24 per dose

oral: gavage: 0, 100, 300 and 1000 mg/kg bw/day

Vehicle: corn oil – (dried and deacidified corn oil)

Exposure: GD 6-20 (Daily)

[2020]</td><td>Maternal toxicity

There were no clinical signs considered related to treatment and there was no adverse effect of treatment on body weight gain or food intake during gestation at 100, 300 or 1000 mg/kg bw/day.

There were, however, effects seen on the thyroid glands. Particularly an increase in the incidence of diffuse follicular cell hypertrophy, when compared to controls, was seen in females given 300 or 1000 mg/kg bw/day.

Serum TSH concentrations on Day 20 of gestation were higher in all treated groups. As we did not have access to the full study report we do not know how much higher the levels were, but according to the information on the dissemination site the levels were only slightly higher and there was no dose-response.

There was a slight decrease in the mean serum thyroxine (T4) and triiodothyronine (T3) concentration in all treated groups, although there was no dose-response, according to the information on the dissemination site.

There was also an increase in liver weights seen in all treated females. A connection between liver toxicity and an increase in thyroid stimulating hormone (TSH) levels is known to happen. A subsequent reduction in levels of T4 and T3 was seen, as would be expected in a normal physiologically functioning system.
There was however a higher incidence of follicular cell hypertrophy in the two highest dose levels which was dose related.

Hypertrophy, follicular cells in the thyroid gland for females on Day 20 after mating:

<table>
<tr><th>Dose (mg/kg bw/day)</th><td>0</td><td>100</td><td>300</td><td>1000</td></tr>
<tr><td>Minimal</td><td>2</td><td>3</td><td>8</td><td>13</td></tr>
<tr><td>Total</td><td>2</td><td>3</td><td>8</td><td>13</td></tr>
<tr><td>Number of tissues examined</td><td>20</td><td>20</td><td>19</td><td>20</td></tr>
</table>

Maternal reproductive toxicity: no effects observed</td><td>Test material: decamethyl-tetrasiloxane (L4)

Reliability 1

(the eMSCA did not have access to the full study report)</td></tr>
</table>

Method	Results	Remarks
	NOAEL: 100 mg/kg bw/day based on a higher incidence of follicular cell hypertrophy in the two highest dose levels. **Fetuses:** Litter and foetal weights were unaffected by maternal treatment with decamethyltetrasiloxane at 100, 300 and 1000 mg/kg bw/day. There was no effect on embryo-foetal survival, live litter size or sex ratio at 100, 300 or 1000 mg/kg bw/day. No major abnormalities that were considered treatment-related were seen at foetal examination. There were however some minor abnormalities, variations, including an increase in incidence of delayed ossification across all treated groups and lens shape variation at 1000 mg/kg bw/day. The incidences of these variations were not given. Probably these effects are too mild to warrant a classification, however it is not quite clear whether this can be considered non-adverse. There was no indication of embryo/fetal toxicity or teratogenicity at any dose level tested. NOAEL: 300 mg/kg bw/day, based on increased incidence of variations in the highest dose group. Overall developmental toxicity: no	

* Calculated as follows: $NOAEL_{internal}$ (mg/kg bw/d) = $NOAEC_{inhalation}$ (mg/l) x 45 l/kg bw/h (rat respiration rate) x 6 (daily inhalation exposure) x 1 (default respiratory absorption of 100%).

7.9.7.1. Effects on fertility

In the combined repeated dose and reproduction/ developmental screening study three female rats, where there was evidence of copulation, failed to deliver a litter. One of these animals showed signs of parturition on day 25 and although no pups were found seven implant sites were present. There were no implantation sites recorded in the other two animals.

There were no treatment-related effects on weight or histopathology of the male reproductive organs.

There were no effects on the mean number of corporea lutea or mean mating and fertility indices. In dams that successfully produced litters, the duration of gestation, mean number of implantation sites, mean litter size and weight and mean ratio of live births/litter were unaffected by treatment.

A NOAEC of 400 ppm for fertility has been derived; however, as a specific reproductive effect cannot be ruled out, the eMSCA considers that it is not possible to set a NOAEC for fertility based on the results of this study when it is considered in isolation. These results also raise a concern over the potential of L4 to affect reproduction (fertility)/parturition. However, two reproductive toxicity studies have been carried out using the closely related substance hexamethyldisiloxane (L2) and data from these can be used to inform on L4 and support a NOAEC of 400 ppm. In the L2 studies, animals were exposed to L2 at concentrations approximately six times that used in the L4 screening study included in the current dossier.

In the developmental toxicity study there were no effects seen on reproductive parameters. One female in the middle dose group did not become pregnant, but apart from that the only effects seen in the dams were increased liver weights, increased TSH and lower T3

and T4 and a dose-response increase in minimal hypertrophy in the follicular cells of the thyroid glands. The NOAEL was set at 100 mg/kg bw/day based on the hypertrophy of the thyroid glands. The NOAEL for reproductive parameters was the highest dose levels.

In a two generation study Sprague Dawley rats were exposed to L2 at doses of up to 5000 ppm. No treatment-related effects were observed on sexual function or fertility at any of the concentrations tested. The mean number of pups born, live litter size and the percentage of males per litter at birth were unaffected by exposure at all concentration levels tested. A NOAEC for L2 of 5000 ppm (33 mg/l) for sexual function and fertility effects was identified.

A one generation study is also available in which Sprague Dawley rats were treated with L2 up to doses of 5000 ppm. No histopathological findings were observed in the tissues examined (cervix, coagulating gland, epididymis, ovaries, mammary gland, pituitary gland, prostate, seminal vesicles, testes, thyroid, uterus, vagina, vas deferens) nor were there any treatment-related effects noted on reproductive parameters (days between pairing , mating indices, fertility indices and duration of gestation), parturition or litter size. A NOAEC for L2 of 5000 ppm for fertility was identified from this study.

The eMSCA considers that data from full generational studies with L2 can be used to support the conclusion that the findings on fertility/parturition reported in the reproductive screening study with L4 are not adverse. This is justified based on the physicochemical, toxicokinetic and toxicological properties of each of the substances. Both L2 and L4 are members of an analogue group of linear and cyclic siloxanes containing no reactive functional groups. A characteristic of the group is that all the substances have high log Kow (increasing with increasing chain length) and low water solubility (decreasing with increasing chain length). L2 is the smallest of the linear siloxanes with the lowest molecular weight, shortest chain length and highest solubility in water. It can therefore be concluded that it will have a higher bioavailability than L4. As such, L2 can be considered to represent a worst case scenario. No data is available on the metabolism of L4, however the Registrant(s) have stated that L4 hydrolyses to dimethylsilanediol and trimethylsilanol, both of which are reported as metabolites in the toxicokinetic study with L2. L2 also shows similar effects to L4 following repeat dosing via the oral and inhalation routes, with the liver and kidney in rats being the target organs.

Consequently, while there were some effects observed following treatment with L4, there were no effects on reproductive parameters in the developmental toxicity study and data from L2 does not support the view that these are the result of an effect on fertility and therefore a NOAEC for L4 of 400 ppm (5.1 mg/l/6h/d) is identified for fertility based on the combined screening study.

7.9.7.2. Effects on offspring

In the combined repeated dose and reproduction/ developmental screening study no adverse effects were reported for pups up to day 4 post-partum. Investigation of effects on histopathology and organ weights in pups was not conducted. Based on the results of this study a NOAEC for L4 for developmental (offspring) toxicity in male and female rats is 400 ppm (approximately 5.1 mg/l/6h/d).

In the developmental toxicity study, there were no effects on litter and foetal weights, nor on embryo-foetal survival. There was a certain increase in some variations; delayed ossification across all treated groups and lens shape variation at 1000 mg/kg bw/day. The incidences of these variations were not given and as we did not have access to the full study report it is difficult to determine whether this is non-adverse. Probably these effects are too mild to warrant a classification.

There was no indication of embryo/fetal toxicity or teratogenicity at any dose level tested.

NOAEL (L4): 300 mg/kg bw/day, based on increased incidence of variations in the highest dose group

7.9.7.3. Summary of reproductive toxicity

Effects on Sexual Function and Fertility

No studies have been carried out directly on dodecamethylpentasiloxane (L5). There was one repeated-dose study with combined reproductive/developmental screening and one developmental toxicity study on L4. The Registrant(s) has proposed that information from L4 can be used to inform on L5. In the combined study, in males, no histopathological effects were observed on testes or epididymis. In dams that successfully produced litters, there were no significant changes in any relevant parameters. Three dams failed to produce litters, and based on the information in the study it is not possible to determine whether this was a specific reproductive effect. However, studies carried out with L2 found no effects on fertility or sexual function. Therefore, on a weight of evidence basis it is concluded that L4 does not have an effect on sexual function, fertility or parturition and no classification is proposed for this endpoint. The NOAEC for fertility is 400 ppm (5.1 mg/l).

In the developmental toxicity study, all but one female in the middle dose became pregnant and no reproductive parameters were affected. A NOAEL of 1000 mg/kg bw/day was set for reproductive parameters, however a NOAEL of 100 mg/kg bw/day for maternal toxicity was set based on increased hypertrophy of follicular cells in the thyroid glands.

Overall, the eMSCA considers that it is unlikely that L5 is toxic to sexual function and fertility based on the information available.

Developmental

No studies have been carried out directly on dodecamethylpentasiloxane (L5). The Registrant(s) has proposed that information from L4 can be used to inform on L5. In the combined study with L4 no adverse effects on pups up to day 4 post-partum were observed. Based on the results of this study a NOAEC of 400 ppm (equivalent to 5.1 mg/l) was derived. In the developmental toxicity study no effects were seen apart an increase in some variations in the highest dose group. A NOAEL of 300 mg/kg bw/day was set based on the increase in variations at 1000 mg/kg bw/day.

Overall, the eMSCA considers that it is unlikely that L5 is a developmental toxicant based on the information available. No classification is proposed for this endpoint.

7.9.8. **Hazard assessment of physico-chemical properties**

Not assessed

7.9.9. **Selection of the critical DNEL(s) / DMEL(s) and / or qualitative / semi-quantitative descriptors for critical health effects**

Not assessed

7.9.10. **Conclusions of the human health hazard assessment and related classification and labelling**

The human health hazard assessment was focused on the endpoints of relevance to the ‘T’ criterion, as given in the criteria for the identification of PBT substances in Reach Annex XIII; as such, only the end-points carcinogenicity, mutagenicity, reproductive toxicity and repeated-dose toxicity were the aim for the evaluation.

There is no information available on the effects of repeated exposure to L5 in humans. Information is available from a 28-day repeated-dose oral study (OECD 407) in rats. Results from a 7 day range-finding study were consistent with those from the longer-term study. The consistent findings show an effect on the liver and kidneys. The latter is not relevant to human risk assessment and the liver findings do not meet the criteria for classification. The Registrant(s) have proposed read-across from L4 to inform on exposure via the inhalation route. The substance evaluation for L4 concluded that L4 did not meet the criteria for classification as STOT RE.

The mutagenic potential of L5 has been investigated in a mammalian cell gene mutation assay. Based on this L5 is considered unlikely to be mutagenic. No further information is available for L5. Read-across from L4 has been proposed to inform on L5. L4 was considered to be negative for mutagenicity.

There is no information on the carcinogenic potential of L5.

No studies have been conducted with L5 to investigate reproductive toxicity and data from a reproductive developmental screening study and a developmental toxicity study with L4 has been included in the dossier to inform on this endpoint. The substance evaluation concluded there were no concerns for reproductive toxicity (fertility/parturition and development) following exposure to L4.

Overall, based on the information available there are no concerns for carcinogenicity, mutagenicity, reproductive toxicity or toxicity following repeated exposure (STOT RE) to L5. Therefore, the eMSCA considers that the substance needs not to be classified for these human health hazards.

Table 42: NOAELs from repeat dose toxicity studies

Study	NOAEL / NOAEC	LOAEL / LOAEC	Effects at the LOAEL
Rat, 7 day oral (range finding study)	1000 mg/kg bw/d	-	No effects seen at highest dose tested
Rat, 28 day oral	25 mg/kg bw/d (males)	250 mg/kg bw/d (males)	Increased liver weight in males and females together with changes in liver markers and histopathology in females.

7.10. Assessment of endocrine disrupting (ED) properties

7.10.1. Endocrine disruption – Environment

Not assessed

7.10.2. Endocrine disruption - Human health

Not assessed.

7.11. PBT and vPvB assessment

Persistence

There is no hydrolysis study available on L5 but, based on read-across to L4, L5 is expected to be to some extent susceptible to hydrolysis. Experimental data for L4 show a hydrolysis half-life of 30.3 days at pH 7 and 25 °C. The half-life for hydrolysis is however dependent on temperature and pH. By recalculating hydrolysis half-life to an environmentally relevant temperature of 12 °C and pH 7, a hydrolysis half-life of 130 days can be obtained. It is expected that L5 will generally behave similarly to L4 but may have a longer hydrolysis half-life.

There are no biodegradation screening tests available for L5 , but read-across to a screening test on ready biodegradability for L3 (0 % in 28 days, OECD 310) suggests that L5 will not be readily biodegradable in standard test systems. Therefore, the screening criteria for P and vP of REACH Annex XIII is met.

No simulation study on L5 is available, but a read-across to the structurally related substances L2 and L3 suggests that L5 will have a half-life in sediments >>180 days. Based on the reduced hydrolysis and higher organic carbon partitioning, L5 is expected to be more persistent than both L2 and L3. The simulation study on the potential for degradation

of L3 in sediment (OECD 308) demonstrates a long half-life (3.5 - 6.91 years) for L3 in sediment at 12 °C. The simulation study on L2 (OECD 308) indicates a half-life in sediment of 360 days for L2. Both studies underpin a long half-life for L5 since the substance is expected to be more persistent than L2 and L3.

Overall, read across data from sediment simulation studies with L2 and L3 demonstrates a long half-life of 3.5 – 6.91 years in sediment and L5 is expected to be even more persistent. L5 thereby fulfils the P and vP criteria of REACH Annex XIII.

Bioaccumulation

L5 has a log Kow of 9.41 and therefore meets the screening criteria for B and vB of REACH Annex XIII.

A reliable fish bioconcentration study using fathead minnow (*Pimephales promelas)* is available. Using the overall mean lipid content (2.31%), the lipid-normalised BCF ranges between 2675 – 3831 l/kg. The scatter in the data points means that the 95% confidence interval around the BCF is rather large. Some of this uncertainty results from the variability in the fish concentrations measured at various time points, but the variability in the lipid measurements at each time point is also an important contributor to the overall uncertainty in the BCF_L and BCF_{kL} obtained. Further, the DOC/TOC is not measured and this information is particularly important for hydrophobic substances such as L5.

As no significant growth occurred in the study, growth correction of the results is not appropriate. The study clearly shows that the BCF of L5 is likely to be >2,000 l kg^{-1}. There is also one estimate of the BCF_{kL} >5,000 l kg^{-1} but this only occurs at one exposure concentration when the lipid content of the fish on day 35 of the study are used for the lipid normalisation.

Importantly all of the steady-state BCF_L values are <5,000 l kg^{-1}. However, the estimated 95% confidence intervals of many of the BCFs are >5,000 l kg^{-1} and so the possibility that the actual BCF for L5 could be above 5,000 l kg^{-1} cannot be totally ruled out.

This is further underlined when k1 and BCF are recalculated according to the given methods in OECD 305 guideline. They give a BCF of 5038 L/kg and a 5% lipid normalized BCF of 10952 L/kg for the low concentration and for the high concentration with the same k1, this results in a BCF of 3950 L/kg, and a 5 % lipid normalized BCF of 8588 L/kg for the high concentration.

Overall, it is considered that the results of this study provide strong evidence that the BCF for L5 is >2,000 l kg^{-1} and it is likely that the BCF is >5,000 l kg^{-1}. On this basis, it is concluded that L5 meets the criteria for bioaccumulative (B), and very bioaccumulative (vB) of REACH Annex XIII.

Toxicity

T-criterion based on human health data:

L5 does not fulfil the T-criterion of REACH Annex XIII based on human health end points.

T-criterion based on ecotoxicity data:

The available ecotoxicity data show that L5 does not cause adverse effects in fish or aquatic invertebrates when exposed at concentrations up to the water solubility limit in the test media. Furthermore, information provided in the registration dossier on toxic effects on sediment organisms, soil microorganisms and soil macroorganisms show no effects. A read-across from L4 suggests that the substance would also not be toxic to algae at concentrations up to its water solubility. Thus, based on the available ecotoxicity data, L5 does not fulfil the T-criterion of REACH Annex XIII based on ecotoxicity.

Summary and overall conclusions on the PBT, vPvB properties

Based on the available data for L5 and including read-across test results from the linear siloxanes L2, L3 and L4 , the substance can be identified as a very persistent and very bioaccumulative (vPvB) substances according to Article 57(e) of REACH. The REACH Annex XIII criterion for T is not currently met.

7.12. Exposure assessment

Dodecamethylpentasiloxane (L5) was originally selected for substance evaluation in order to clarify concerns about:

- PBT/vPvB properties
- Wide dispersive exposure and
- Exposure of the environment

7.12.1. **Human health**

7.12.1.1. Worker

Human health effects by personal care/cosmetic products have not been assessed, since they are outside the scope of REACH. No hazards have been identified for human health, therefore no exposure assessment and risk characterisation regarding workers are needed.

7.12.1.2. Consumer

Human health effects by personal care/cosmetic products have not been assessed, since they are outside the scope of REACH. No hazards have been identified for human health, therefore no exposure assessment and risk characterisation regarding consumers are needed.

7.12.2. **Environment**

During the initial substance evaluation the environmental exposure section was reviewed and a general information request was identified and addressed in the decision. The Registrant(s) have provided an updated environmental exposure assessment which has been reviewed. No attempt has been made to replicate calculations provided in updates or new registrations submitted after the initial evaluation.

7.12.2.1. Aquatic compartment (incl. sediment)

ES3 – Professional and consumer use of personal care products

As specified in the decision, there were requested to update the exposure information by providing further information and justification on the input parameters used for the exposure assessment for ES3: Professional & consumer use of personal care products or alternatively, provide separate scenarios for professional consumer use and household consumer use of personal care products, including clear justification of the environmental emission factors chosen for each.

This request was based on the fact that Registrant(s) had used the approach from the UK Risk Assessment of D5 (Environment Agency, 2009) to determine the releases to air and water for the environmental modelling. Registrant(s) assumed that the use resulted in 90% of the chemical being released to air and 10% released to water. However, there was no supporting justification why the uses of L5 are the same as for D5. Basically, the environmental emissions from all three personal care product scenarios are described by ERC 8a, where default release factors of 100% to water, 100% to air, 0% to soil are assumed.

"Consumer use releases" of D5 have been assessed for the REACH Restriction dossier for D4 and D5 (ECHA, 2016). This suggests that releases are different depending on whether the personal care product is a “wash-off use” or “leave-on” product. The balance of wash-off and leave-on was not provided in the registration dossier of L5, but is needed for an accurate assessment of the consumer/professional use personal care emission scenario.

Further, it was unclear whether the exposure scenario “use of personal care products” adequately addresses environmental emissions from both professional salons and from household uses. The eMSCA considered that the emissions are probably not the same, for example due to the number of emission days and volumes used at salons compared to individual households.

Registrant(s) have included separate exposure scenarios for professional and consumer uses in the updated CSR. In addition, the consumer scenario has been split into leave-on and wash-off scenarios, with an estimate of the tonnage split between wash-off and leave-on products provided.

Registrant(s) did refine these exposure estimates to air and water providing additional justification based on a study by Montemayor et al. (2013). The Montemayor et al. (2013) study is discussed in the restriction report of D4/D5 (ECHA, 2016). It is noted that there is an apparent dosing error, which when corrected gives the average release to water of around 73% (range: 54 – 93%, based on the 95% confidence intervals). Therefore, the D4/D5 restriction dossier uses release estimates of 100% to water "for wash-off use" as a reasonable worst case. The eMSCA considers that a reasonable worst case assumption of 100% to water should also be used in the L5 dossier, as the data from Montemayor et al. (2013) are insufficient to justify a lower emission factor.

7.12.2.2. Terrestrial compartment

Not assessed

7.12.2.3. Atmospheric compartment

Not assessed

7.12.3. **Combined exposure assessment**

An assessment of cumulative risk from all registrations has not been conducted. The eMSCA concludes that L5 meets the REACH Annex XIII P/vP criterion and the B/vB criterion.

Therefore, Registrant(s) should review their exposure scenarios and risk reduction measures in order to minimize emissions and subsequent exposures of humans and the environment throughout the lifecycle of the substance.

7.13. Risk characterisation

7.13.1. **Human health**

Not evaluated by the eMSCA.

7.13.2. **Environment**

The eMSCA concludes that L5 meets the REACH Annex XIII vPvB criteria. Therefore the Registrant(s) should review their exposure scenarios and risk reduction measures to ensure the minimisation of emissions and subsequent exposure of humans and the environment, throughout the lifecycle of the substance.

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9. Abbreviations

%	Percentage
AOP	adverse outcome pathway
B	Bioaccumulative
BCF	Bioconcentration factor
BMF	Biomagnification factor
CLP	Classification, labelling and packaging (of substances and mixtures)
cm	Centimetre
CoRAP	Community Rolling Action Plan
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
CTD	Characteristic travel distance
d	Day
D4	Octamethylcyclotetrasiloxane
D5	Decamethylcyclopentasiloxane
D6	Dodecamethylcyclohexasiloxane
DMEL	Derived Minimal Effect Level
DNEL	Derived No Effect Level
DOC	Dissolved Organic Carbon
DSD	Dangerous Substances Directive
eMSCA	evaluating MSCA
ECETOC TRA	European Centre for Ecotoxicology and Toxicology of Chemicals Targeted Risk Assessment
ECHA	European Chemicals Agency
EPA	Environmental Protection Agency
ES	Exposure Scenario
ERC	Environmental release category (ERC)
EU	European Union
EUSES	European Union System for the Evaluation of Substances
F/R	Fugacity Ratio
g	Gramme
GC	Gas chromatography
GC/FID	Gas chromatography – Flame Ionisation Detection
GC/MS	Gas chromatography – mass spectrometry
GLP	Good laboratory practice
hPa	Hectopascal
ISO	International Organisation for Standardisation
IUCLID	International Uniform Chemical Information Database
IUPAC	International Union of Pure and Applied Chemistry
kg	Kilogram
kJ	Kilojoule
km	Kilometre
kPa	Kilopascal
kaw	Air-water partition coefficient
K_{oa}	Octanol-air partition coefficient
K_{oc}	Organic carbon-water partition coefficient
K_{ow}	Octanol-water partition coefficient

L	Litre
L2	Hexamethyldisiloxane
L3	Octamethyltrisiloxane
L4	Decamethyltetrasiloxane
L5	Dodecamethylpentasiloxane
LEV	Local Exhaust Ventillation
LSC	Liquid scintillation counting
Log	Logarithmic value
LOD	Limit of detection
LOQ	Limit of quantitation
M	Molar
m	Metre(s)
µg	Microgram
mg	Milligram
min	Minute
mL	Millilitre
mol	Mole
MS	Mass spectrometry
MSCA	Member State Competent Authority
m/z	Mass to charge ratio
ng	Nanogram
nm	Nanometre
NOAEL	No observed adverse effect level
NOEC	No-observed effect concentration
NOEL	No observed effect level
OC	Operational condition
OC	Organic Carbon
OECD	Organisation for Economic Co-operation and Development
p	Statistical probability
P	Persistent
Pa	Pascal
PBT	Persistent, Bioaccumulative and Toxic
PC	Product category
pg	Picogramme
pKa	Acid dissociation constant
PNEC	Predicted no effect concentration
PDMS	Polydimethylsiloxanes
ppb	Parts per billion
PPE	Personal Protective Equipment
ppm	Parts per million
PROC	Process Category
QMRF	QSAR Model Reporting Format
QPRF	QSAR Prediction Reporting Format
QSAR	Quantitative structure-activity relationship
RCR	Risk Charactorisation Ratio
r^2	Correlation coefficient
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals (EU Regulation No. 1907/2006)

RH	Relative humidity
RCR	Risk characterisation ratio
RMM	Risk Management Measures
RPE	Respiratory protective equipment
RSS	Robust Study Summary
t	Tonne
T	Toxic (hazard classification)
TE	Transfer efficiency
TG	Test Guideline
TMF	Trophic Magnification Factor
ug/l	microgram per litre
UK	United Kingdom
UV	Ultraviolet
vB	Very bioaccumulative
vP	Very persistent
vPvB	Very persistent and very bioaccumulative
wt.	Weight
WWTP	Waste water treatment plant

10. Appendix I: Trends in PBT properties across linear siloxanes

The table below summarises the expected trends in the linear siloxane category for different PBT endpoints based on the available information for these chemicals and the cyclic siloxanes D4, D5 and D6 (octamethylcyclotetrasiloxane, EC No. 209-136-7, CAS No. 556-67-2; decamethylcyclopentasiloxane, EC no. 208-764-9, CAS No. 541-02-6 and dodecamethylcyclohexasiloxane, EC No. 208-762-8, CAS No. 540-97-6).

Table 43: Trends for PBT endpoints

	L2 EC 203-492-7	L3 EC 203-497-4	L4 EC 205-491-7	L5 EC 205-492-2
Persistence	increasing half-life →			
Bioaccumulation	←	peaks at L3		→
Toxicity (aq)	Significant toxicity	No effects at L3 and higher (decreasing trend)		
Toxicity (sed)	decreasing trend L2 to L5 →			

Persistence (environmental half-life) is expected to increase with increasing chain length. This is the trend observed for the cyclic siloxanes for sediment half-life. The same trend is expected for the linear siloxanes because of a similar increase in hydrophobicity with increasing chain length based on water solubility and organic carbon partitioning data. Further support for the expected trend in the linear substances comes from the increasing hydrolysis half-lives for L2, L3 and L4 respectively, and the observed trend from the non-standard soil degradation studies.

Fish bioaccumulation, based on BCF, for the category appears to peak at L3. L3 has a larger log Kow value than L2, which explains why the BCF value is larger. Above L3, bioaccumulation decreases with increasing log Kow. This is likely to be due to decreasing bioavailability of the category members. Despite the decreasing trend beyond L3, the BCF value for L4 is still sufficiently large for the substance to meet the vB criteria. L5 is B but not vB. A similar trend is seen for the cyclic siloxanes where the bioconcentration factors decrease from D4 to D6.

The trend in ecotoxicity is inverse to the trend in water solubility in the category. L2 is very toxic to aquatic organism (both Daphnia and algae), but is not “T”. Chronic fish toxicity for L2 remains to be characterised. A complete chronic aquatic dataset is available for L3 and L4 and both show no effects. On this basis, beyond L2 the substances become too insoluble to exhibit effects, and so it is anticipated that L5 would similarly show no aquatic effects,

For the benthic compartment, decreasing bioavailability is also expected to result in a decreasing trend in toxicity along the category.