Annex 15 Report

Proposal for identification of a substance of very high concern (SVHC)

Decamethyltetrasiloxane (L4)

EC Number: 205-491-7

CAS Number: 141-62-8

November 2026

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List of abbreviations

AR	Applied radioactivity
BAF	Bioaccumulation factor
BASF	Biota-sediment accumulation factor
BCF	Bioconcentration factor
BMF	Biomagnification factor
BFR	Brominated flame retardant
CAS	Chemical Abstracts Service
CREED	Criteria for reporting and evaluating exposure datasets
DEGME	Diethylene glycol methyl ether
DFOP	Double first-order parallel
DMF	Dimethylformamide
DMSD	Dimethylsilanediol
DSC	Differential Scanning Calorimetry
DT_{50}	Time taken for 50% decline in mass or concentration. If the decline is described by first order kinetics then this is also called the half-life
$DegT_{50}$	Time taken for 50% of substance to decline in mass or concentration from a compartment due to degradation processes alone
ECHA	European Chemicals Agency
EC	European Community
EU	European Union
FOMC	First-order multicompartment
GB	Great Britain
GC-MS	Gas chromatography-mass spectrometry
HS	Hockey-stick
HPLC	High performance liquid chromatography
IUPAC	International Union of Pure and Applied Chemistry
K_{OW}	n-Octanol–water partition coefficient
L2	Hexamethyldisiloxane
L3	Octamethyltrisiloxane
L4	Decamethyltetrasiloxane
LOD	Limit of detection
LOQ	Limit of quantification

LRTP	Long range transport potential
LSC	Liquid scintillation counting
MCL	Mandatory classification and labelling
MSC	Member State Committee
M3T	1,1,1,3,5,5,5-heptamethyl-3-[(trimethylsilyl)oxy]trisiloxane
NER	Non-extractable residue
OC	Organic carbon
OECD	Organisation for Economic Cooperation and Development
P	Persistent
PMDS	Pentamethylsiloxanol
POP	Persistent organic pollutant
REACH	Registration, Evaluation, Authorisation and restriction of Chemicals
SFO	Single first order
SMILES	Simplified Molecular Input Line Entry System
SVHC	Substance of very high concern
TG	Test guideline
THF	Tetrahydrofuran
ThIC	Theroretical inorganic carbon
TIC	Total inorganic carbon
TMF	Trophic magnification factor
TMS	Trimethylsilanol
UK	United Kingdom
vB	Very bioaccumulative
vP	Very persistent
vPvB	Very persistent and very bioaccumulative

1 Proposal

Substance name: Decamethyltetrasiloxane

EC number: 205-491-7

CAS number: 141-62-8

Decamethyltetrasiloxane, which is also known as L4, has been identified as a substance of very high concern (SVHC) in accordance with the requirements set out in Annex 15 of EU REACH (ECHA, 2025a). This is based on the substance fulfilling the very persistent and very bioaccumulative (vPvB) criteria under Annex 13 of EU REACH (Regulation (EC) No 1907/2006).

This technical report documents an independent scientific assessment by the Agency[1] on whether L4 should be identified as a SVHC under UK REACH. It considers only studies presented in the equivalent document produced by the European Chemicals Agency (ECHA), the EU Member State Committee (MSC) support document (ECHA, 2025b). Relevant observations on studies made in the EU MSC support documenthave been summarised and Agency comments have been added. Prior to exiting the EU, the UK Competent Authority conducted a Substance Evaluation of L4 under EU REACH. Some unpublished study reports presented in ECHA (2025b) were evaluated by the UK as part of this work. As a result of the initial evaluation, a decision letter was issued requesting EU REACH registrants provide data on the persistence of the substance (ECHA, 2017). After EU exit, the evaluation was finalised by the Norwegian Competent Authority (ECHA, 2021)). The data that resulted from the Substance Evaluation decision were not available to the Agency and have not been examined. A literature search was considered unnecessary as the existing information is considered to be sufficient for decision making.

It is proposed to identify L4 as vPvB according to Article 57(e) of UK REACH.

Summary of how the substance meets the criteria set out in Article 57 of the REACH Regulation

A weight-of-evidence determination according to the provisions of Annex 13 of UK REACH was used to identify L4 as vPvB. This involved a read-across approach using Hexamethyldisiloxane (L2), Octamethyltrisiloxane (L3) and 1,1,1,3,5,5,5-heptamethyl-3-[(trimethylsilyl)oxy]trisiloxane (M3T) for some endpoints. They are all structurally similar substances with clear patterns in physicochemical properties (including volatility, water solubility, and hydrophobicity) based on chain length and molecular weight.

[1] The Health and Safety Executive (HSE) acting in its capacity as the Agency for UK REACH, and with support from the Environment Agency in accordance with Article 2B of UK REACH.

Persistence

No biodegradation screening or simulation studies are available for L4. A read-across approach using L2, L3 and M3T was therefore used to assess the biodegradation potential of L4.

These three substances are not readily biodegradable. Due to the similarity in structure, it is highly unlikely that L4 would be readily biodegradable in these test systems, as it will be less bioavailable than L2 and L3 (it is less water soluble and more hydrophobic). It therefore screens as potentially persistent (P) and very persistent (vP).

Three water-sediment aerobic degradation studies performed according to OECD TG 308 were presented in ECHA (2025b) and rated as 'reliable with restrictions':

- For L2, whole system $DegT_{50}$ values of 360 days and 54 days at 12°C were derived in the two test sediments. Despite some uncertainties, the parent substance that had partitioned to sediment degraded slowly. The half-life in one of the test sediments is highly likely to be > 180 days.

- For L3, very little degradation was observed over 100 days. $DegT_{50}$ values of 416 days or longer were derived at 12°C. The degradation half-life was >180 days in both sediments tested.

- M3T showed no significant degradation over 100 days. The half-life in one of the test sediments is highly likely to be > 180 days. Due to the anaerobic test conditions, it is not possible to conclude that this half-life is representative of aerobic conditions, and so it might not be definitive, and is therefore given a low weighting in the persistence assessment by the Agency.

L4 is more adsorptive than L2 and L3, so is expected to partition more to sediment, reducing potential losses via hydrolysis and volatilisation. It is also expected to be less degradable due to its lower water solubility and higher hydrophobicity. The half-lives for L2 and L3 therefore represent the "best case" for L4. It can therefore be concluded that the half-life of L4 in freshwater sediment is >180 days.

The Agency concludes from the evidence available that L4 fulfils the P and vP criteria of Annex 13 of UK REACH (freshwater sediment half-life > 120 or > 180 days, respectively).

Bioaccumulation

L4 screens as potentially bioaccumulative (B) and very bioaccumulative (vB) in aquatic organisms based on a measured log K_{OW} of 8.21 at 25.1°C (log K_{OW} > 4.5).

An aquatic exposure study performed to OECD TG 305 using *Pimephales promelas* (Fathead Minnow) yielded a lipid-normalised bioconcentration factor (BCF) of 6,201 L/kg calculated at the end of uptake at the lower exposure concentration. This is considered to

be a “best case” value (i.e. the BCF may be higher) and the most reliable result from the study (the reliability of the kinetic BCF values preferred by ECHA (2025b) is uncertain). However, given the overall uncertainties with this study, the information only has a medium weighting in the assessment.

Further evidence is provided in two dietary exposure studies performed to OECD TG 305 on *Oncorhynchus mykiss* (Rainbow Trout). Valid growth-corrected, lipid-normalised kinetic biomagnification factor (BMF_{KgL}) values ranged from 0.355 to 0.81. Although the laboratory dietary BMF values were < 1, they cannot be directly compared to the B/vB criteria. Modelled BCF values ranged from 5,592 to 61,580 L/kg. Despite some limitations of the studies (including excessively high fish growth in one study), the modelled BCF values are considered to be sufficiently reliable for regulatory purposes, and are given a high weighting in this assessment.

Based on modelled BCF values of 5,592 to 61,580 L/kg derived from dietary BMF data for *O. mykiss*, with a lipid-normalised BCF of 6,201 L/kg from an aquatic exposure study with *P. promelas* as supporting evidence, the Agency concludes that L4 meets the B and vB criteria (BCF > 2,000 or > 5,000 L/kg, respectively) set out in Annex 13 of UK REACH.

Conclusion

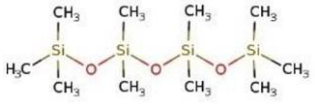
Based on the information available, the Agency concludes that L4 fulfils the vPvB criteria of Annex 13 of UK REACH and can therefore be identified as an SVHC in accordance with Article 57(e).

2 Justification

2.1 Identity of the substance and physical and chemical properties

2.1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	205-491-7
EC name:	Decamethyltetrasiloxane
SMILES[a]	C[Si](C)(C)O[Si](C)(C)O[Si](C)(C)O[Si](C)(C)C
CAS number:	141-62-8
IUPAC[b] name:	2,2,4,4,6,6,8,8-octamethyl-3,5,7-trioxa-2,4,6,8-tetrasilanonane
Index number in GB mandatory classification and labelling (MCL) List[c]:	No mandatory classification
Molecular formula:	$C_{10}H_{30}O_3Si_4$
Molecular weight range:	310.68 g/mol
Synonyms:	1,1,1,3,3,5,5,7,7,7-decamethyltetrasiloxane; tetrasiloxane; 1,1,3,3-tetramethyl-1,3-bis(trimethylsiloxy)disiloxane Acronyms: L4, MD2M
Structural formula:	

[a] SMILES: Simplified Molecular Input Line Entry System

[b] IUPAC: International Union of Pure and Applied Chemistry

[c] GB MCL list in accordance with the retained Regulation (EC) No 1272/2008 as amended for Great Britian

2.1.2 Composition of the substance

Substance type: mono-constituent

Table 2: Constituents other than impurities/additives

Constituents	Typical concentration
L4	≥ 80% w/w

2.1.3 Identity and composition of transformation products relevant for the SVHC assessment

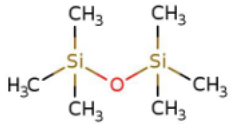
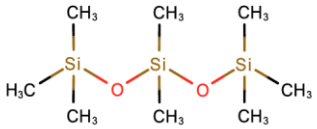
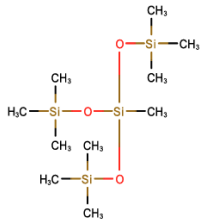
No transformation products were considered in ECHA (2025b).

The Agency does not consider it necessary to consider transformation products as part of this assessment.

2.1.4 Identity and composition of structurally related substances (used in grouping or read-across approach)

According to the ECHA Read-Across Assessment Framework (RAAF; ECHA, 2017) a category and read-across approach can be applied for substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity.
ECHA (2025b) described a category approach to read-across degradation data for L2, L3 and M3T to L4 where data for L4 are not available (see Section 2.3.1). Substance identities are provided in Table 3.

Table 3: Structurally related substance(s) identity, L2, L3 and M3T

EC name:	Hexamethyldisiloxane L2	Octamethyltrisiloxane L3	1,1,1,3,5,5,5-heptamethyl-3-[(trimethylsilyl)oxy]trisiloxane M3T
EC number	203-492-7	203-497-4	241-867-7
CAS number	107-46-0	107-51-7	17928-28-8
IUPAC name:	trimethyl[(trimethylsilyl)oxy]silane	2,2,4,4,6,6-hexamethyl-3,5-dioxa-2,4,6-trisilaheptane	2,2,4,6,6-pentamethyl-4-[(trimethylsilyl)oxy]-3,5 dioxa-2,4,6-trisilaheptane
Index number in GB MCL List	No mandatory classification	No mandatory classification	No mandatory classification
Molecular formula	$C_6H_{18}OSi_2$	$C_8H_{24}O_2Si_3$	$C_{10}H_{30}O_3Si_4$
Structural formula			
Molecular weight (g/mol)	162.8	237	311

Structural similarity

L4 belongs to a group of hydrocarbyl siloxanes. These contain a chain of alternating silicon and oxygen atoms (Si-O or siloxy) as a back-bone. The siloxy moieties are substituted with methyl groups.

L2, L3 and L4 are linear siloxanes with two, three and four siloxy moieties, respectively. M3T is a branched structural isomer of L4 where the longest chain contains three Si atoms and two O atoms, with a Si-O branch on the central silicon atom in the chain. All substances are mono-constituents.

Similarity in physicochemical properties

ECHA (2025b) provided a data matrix to support the read-across approach (replicated in Appendix A). In addition to property data reported in the EU REACH registration dossiers, predicted physicochemical data using the COSMOTherm model are presented for vapour pressure, water solubility, and n-octanol–water partition coefficient (log K_{OW}) for all four substances. This model calculates fluid-phase and liquid mixture thermodynamics using quantum chemistry and statistical mechanics. No further detail on the COSMOTherm predictions (including a reliability assessment and model version) were provided in ECHA (2025b).

The table provided in ECHA (2025b) also compared various environmental fate parameters. The Agency discusses this information in Section 2.3.

In summary, ECHA (2025b) concluded that there is a predictable trend in volatility, water solubility and hydrophobicity for L2, L3 and L4; L4 is the least volatile, least water soluble and most hydrophobic member of this homologous series. There are some differences between L4 and its isomer M3T due to the branched structure of M3T; L4 is slightly less volatile but slightly more water soluble. This group of substances is suitable for the purpose of reading-across information on environmental fate and behaviour.

2.1.5 Physicochemical properties

Physicochemical property information for L4 reported in ECHA (2025b) are summarised in Table 4. The data have been collated from publicly available sources. The Agency has not independently verified the reliability of this information unless otherwise stated.

Table 4: Overview of physicochemical properties

Property	Description/value	Reference/source
Physical state (at 20°C and 101.3 kPa)	Colourless liquid	Visual observations sourced from ECHA Chemicals Database
Melting/freezing point (°C at 101 325 Pa)	-70	Stecher *et al*. (1968)
Boiling point (°C at 101 325 Pa)	194	Mazzoni *et al*. (1991)
Boiling point (°C)	190.5	COSMOTherm (Glüge and Scheringer, 2023)
Vapour pressure (Pa at 25 °C)	73	OECD TG 104 (Abbas *et al*., 2011)
Vapour pressure (Pa at 25 °C)	19.05	COSMOTherm (Glüge and Scheringer, 2023)
Vapour pressure (Pa at 20 °C)	12.26	COSMOTherm (Glüge and Scheringer, 2023)
Water solubility (mg/L at 23 °C)	0.0067	Varaprath *et al.* (1996)
Water solubility (mg/L at 20 °C)	0.0107	COSMOTherm (Glüge and Scheringer, 2023)
Water solubility (mg/L at 25 °C)	0.0106	COSMOTherm (Glüge and Scheringer, 2023)
Partition coefficient n-octanol–water (log K_{OW}) (at 20 °C)	8.21	OECD TG 123 (Unpublished study report, 2008a)
Partition coefficient n-octanol–water (log K_{OW}) (at 25 °C)	7.42	COSMOTherm (Glüge and Scheringer, 2023)

Partition coefficient n-octanol–water (log K_{OW}) (at 20 °C)	7.40	COSMOTherm (Glüge and Scheringer, 2023)
Partition coefficient air–water (log K_{AW}) (at 19.7±0.4 °C)	3.22 ± 0.14	OECD TG 117 (Unpublished study report, 2010c)
Partition coefficient air–water (log K_{AW}) (at 25 °C)	2.36	COSMOTherm (Glüge and Scheringer, 2023)
Partition coefficient air–water (log K_{AW}) (at 20 °C)	2.16	COSMOTherm (Glüge and Scheringer, 2023)
Partition coefficient n-octanol–air (log K_{OA}) (at 19.7±0.4 °C)	4.87 ± 0.04	OECD TG 117 (Unpublished study report, 2010c)
Partition coefficient n-octanol–air (log K_{OA}) (at 20 °C)	5.43	COSMOTherm (Glüge and Scheringer, 2023)

The water solubility of L4 is 0.0067 mg/L based on a study performed at 23°C (Varaprath *et al*., 1996). This was measured in a non-GLP, non-guideline study which prepared a non-colloidal, saturated solution using a slow-stirring method which was then analysed by gas chromatography-mass spectrometry (GC-MS) (Varaprath *et al*. 1996). The EU REACH registrant rates the study as ‘reliable with restrictions’ (Klimisch score 2).

Predictions using COSMOTherm provide predicted values of 0.0107 mg/L and 0.0106 mg/L at 20°C and 25°C, respectively (Glüge and Scheringer, 2023). The Agency notes that water solubility is usually higher at higher temperatures, but input parameters for these predictions are not stated so it is not possible to check.

An OECD TG 123 study reported a measured log K_{OW} value of 8.21 at 25.1°C (Unpublished study report, 2008a). The EU REACH registrant considered this ‘reliable without restriction’ Klimisch 1. The predicted value in COSMOTherm was 7.42 at 25°C (Glüge and Scheringer, 2023).

The COSMOTherm predictions are theoretical, so are useful for illustrating expected trends in properties, but measured data are preferable. They have therefore not been considered further by the Agency.

2.2 Mandatory classification and labelling

L4 is not listed on the GB (Great Britain) mandatory classification and labelling (MCL) list nor on Annex 6 of Regulation (EC) No 1272/2008.

2.3 Environmental fate properties

2.3.1 Degradation

2.3.1.1 Abiotic degradation

The information on abiotic degradation presented in ECHA (2025b) is summarised in Table 5.

Table 5: Summary of abiotic degradation data

Abiotic degradation process	Information presented	Results
Hydrolysis	OECD TG 111 study (Unpublished study report, 2009a)	Hydrolysis half-life was calculated as 165 days at 10 °C and pH 7, and 30.3 days at 25 °C and pH 7
Oxidation	No data presented	
Phototransformation	AOPWIN (US EPA, 2017)	K_{OH} (cm^3 $molecule^{-1}$ s^{-1}): 1.5×10^{-12} $kdeg_{air}$ (d^{-1}): 0.065 Estimated DT_{50} of 10.7 days in air
	Markgraf and Wells (1997)	K_{OH} (cm^3 $molecule^{-1}$ s^{-1}): $2.66 \pm 0.13\ 10^{-12}$ $kdeg_{air}$ (d^{-1}): 0.115 Estimated DT_{50} of 6.0 days in air
	Kim and Xu (2017)	K_{OH} (cm^3 $molecule^{-1}$ s^{-1}): $3.37 \pm 0.4\times 10^{-12}$ $kdeg_{air}$ (d^{-1}): 0.146 Estimated DT_{50} of 4.8 days in air
	Alton and Browne (2020)	K_{OH} (cm^3 $molecule^{-1}$ s^{-1}): $2.5 \pm 0.2 \times 10^{-12}$ $kdeg_{air}$ (d^{-1}): 0.108 Estimated DT_{50} of 6.4 days in air

Hydrolysis: ECHA (2025b) presented a study carried out according to OECD TG 111 and GLP (Unpublished study report, 2009a). The test was performed at pH 5, 7 and 9 at 10°C, 25°C and 35°C. In the pH 5 and 9 treatments, recovery ranged from 76 to 90%. Low recovery rates were reported at pH 7 (in the range of 55 to 70%). According to ECHA (2025b), the study report attributed this to the partitioning of the substance in the headspace of the tubes over time due to the longer study duration compared to the other treatment groups. The study duration for each pH treatment group is not however specified. ECHA (2025b) suggested that losses from adsorption to the test vessel may have occurred. The extrapolated half-life at 12°C and pH 7 relevant to the freshwater environment was 132 days. As L4 is highly adsorptive to organic matter with a log K_{OC} of 5.16 (see Section 2.3.2.1), the hydrolysis $DegT_{50}$ values for L4 may be longer in natural waters with higher amounts of dissolved organic carbon than this study. The study was

considered reliable with restrictions (Klimisch score 2) due to some deviations from the guideline.

ECHA (2025b) compared the hydrolysis half-life ($DegT_{50}$) of L4 with those of the analogues mentioned in Section 2.1.4 (repeated in Table 6).

Table 6: Comparison of hydrolysis $DegT_{50}$ values at pH 7 for L2, L3, and M3T

L2	L3	M3T
4.8 days at 25°C 17.4 at 10°C (Unpublished study report, 2006b)	14 days at 25°C 52 days at 12°C OECD TG 111 (Unpublished study report, 2007)	26.5 d at 25°C (QSAR prediction) (Unpublished study report, 2015c)

L4 is more hydrolytically stable than L2 and L3, demonstrating that hydrolysis half-lives increase with increasing chain length and molecular weight.

Phototransformation in air: ECHA (2025b) presented estimates for the phototransformation of L4 in air. A predicted half-life in air determined using the AOPWIN (v1.92) model (US-EPA EPISuite™) was 13 days for L3 and 10.7 days for L4. The half-life values calculated from studies reported in the academic literature ranged from 7.5 to 9.4 days for L3 and 4.8 to 6.4 days for L4. These data are not subject to the Annex 13 criteria so are not considered further in this assessment.

2.3.1.2 Biodegradation

2.3.1.2.1 Biodegradation in aqueous media or aqueous environment

2.3.1.2.1.1 Screening tests

No studies investigating the ready biodegradability of L4 were presented in ECHA (2025b). Instead, a read-across for ready biodegradability study using L2, L3 and M3T was presented (Table 7).

Table 7: Summary of screening test results for L2, L3 and M3T

Reference	Substance	Study type	Results
Unpublished study (1994)	L2	OECD TG 301C study L2 initial concentration: 100 mg/L Duration: 28 days Reliable without restriction (Klimisch score 1)	2% mineralisation to CO_2 observed by day 28 Positive control (aniline) showed 91% biodegradation after 14 days
Unpublished study (2009b)	L3	OECD TG 310 study L3 initial concentration: 20 mg/L Duration: 28 days Reliable without restriction (Klimisch score 1)	No biodegradation observed as CO_2 evolution Positive control (sodium benzoate) showed 86.6% CO_2 evolution after 28 days
Unpublished study (2011a)	M3T	OECD TG 301F study M3T initial concentration: 24.4 mg/L Duration: 28 days Reliable without restriction (Klimisch score 1)	No biodegradation was observed as O_2 consumption Positive control (sodium benzoate) showed 61.2% biodegradation after 14 days

- Ready biodegradation study, L2 (Unpublished study, 1994)

ECHA (2025b) presented a study conducted according to OECD TG 301C and GLP. The study used a mixture of both domestic and industrial sewage sludge. An L2 concentration of 100 mg/L was used, which is noted to be significantly above the water solubility of 0.93 mg/L. The method is suitable for poorly soluble and adsorbing compounds, and is generally acceptable for volatile compounds. The positive control (aniline) reached 91% degradation by day 14 of the study, whereas 2% mineralisation of L2 occurred after 28 days. Gas chromatography-mass spectrometry (GC-MS) analysis of the parent substance during the test showed that volatile losses were minimal. The degradation product trimethylsilanol (TMS) comprised up to 18% of the mass balance in the biotic and abiotic control test vessels. This transformation product was thought to be a product of hydrolysis. The Agency concludes that L2 is not readily biodegradable.

- Ready biodegradation study, L3 (Unpublished study, 2009)

ECHA (2025b) presented a study conducted according to OECD TG 310 and GLP, using domestic activated sludge from a wastewater treatment facility mainly treating residential

wastewater. This is a suitable test guideline for volatile substances. Further study details are presented in ECHA (2024b). The study used an L3 concentration of 20 mg/L which is significantly above its water solubility limit (0.034 mg/L), but all validity criteria were met. No biodegradation was observed over the 28-day test (CO_2 evolution). The positive control used sodium benzoate, which showed 86.6% degradation after 28 days. The mean theoretical inorganic carbon (ThIC) was 2.9 mg C/L at the end of the study, fulfilling the criteria that the total inorganic carbon (TIC) must be below 3 mg C/L. The Agency concludes that L3 is not readily biodegradable.

- Ready biodegradation study, M3T (Unpublished study, 2011a)

The study presented in ECHA (2025b) was performed according to OECD TG 301F and GLP. The study used activated sludge from a domestic wastewater treatment plant which treated mainly residential wastewater. An initial test substance concentration of 24.4 mg/L was used which is significantly above the solubility of M3T (0.002 mg/L). The method is suitable for poorly soluble and adsorbing compounds, and is generally acceptable for volatile compounds. All validity criteria were met. No biodegradation was observed during the study (as oxygen consumption) over 28 days. The positive control (sodium benzoate) degraded by 61.2% by day 14 and no inhibition was observed in the toxicity control. The Agency concludes that M3T is not readily biodegradable.

The Agency considers that the three studies are ‘reliable with restriction’ (Klimisch score 2) due to the high volatility of the substances and the concentrations above water solubility used. The structurally similar substances L2, L3 and M3T are not readily biodegradable. These studies provide suitable supporting evidence that L4 is unlikely to be readily biodegradable. This is because there is no reason to expect the longer chain homologue L4 to be more biodegradable than L2 or L3. Although M3T is branched, this appears to have had little impact on ready biodegradation. L4 also has lower solubility in water than L2 and L3 with a longer hydrolysis half-life (see Sections 2.1.5 and 2.3.1.1), making it less bioavailable, which also supports the likelihood of it being less biodegradable. In conclusion, L4 is not readily biodegradable.

2.3.1.2.2 Biodegradation studies (simulation tests)

ECHA (2025b) provided information on three water-sediment simulation studies for L2, L3 and M3T as no studies were available for L4. The results are summarised in Table 8.

Table 8: Summary of simulation test results for L2, L3 and M3T

Reference	Substance	Study type	Results
Unpublished study (2019)	L2	OECD TG 308 study, GLP 2 sediment types 12°C for 99 days (Calwich Abbey Lake) and 108 days (Emperor Lake), using radiolabelled L2, under aerobic conditions	Distribution of 77.3% in Calwich Abbey Lake sediment after 99 days and 34.3% in Emperor Lake sediment after 108 days Whole system $DegT_{50}$ values of 360 days and 54 days at 12°C
Unpublished study (2021b)	L3	OECD TG 308 study, GLP 2 sediment types 12°C for 140 days, using radiolabelled L3, under aerobic conditions	No significant degradation was observed after 140 days. For Calwich Abbey Lake sediment, the degradation rate was not significantly different from zero, resulting in $DegT_{50}$ values > 10,000 days
Unpublished study (2021a)	M3T	OECD TG 308 study, GLP 2 sediment types 12°C for 100 days, using radiolabelled M3T, under aerobic conditions	No significant degradation was observed in 100 days. For Calwich Abbey Lake sediment, the degradation rate was not significantly different from zero, resulting in $DegT_{50}$ values > 10,000 days

- Aquatic sediment simulation study, L2 (Unpublished study, 2019)

A study on aerobic transformation in aquatic sediment systems was performed according to OECD TG 308 and to GLP using radiolabelled L2. The study used two UK-based sediments; Calwich Abbey Lake and Emperor Lake (with organic carbon (OC) contents of 4.8 and 1.73% ww, respectively) for a duration of 99 days and 108 days, respectively. ECHA (2025b) noted that the Emperor Lake study ran beyond the duration of 100 days recommended in the OECD TG 308, but highlighted that no explanation was provided regarding the extension.

Redox potentials were not determined and no observations regarding formation of aerobic and anaerobic layers were made. Oxygen levels were measured during the test, but the target oxygen saturation level was not specified. At the start of the test after the substance was added, the oxygen saturation in the control vessels was 42% for Calwich Abbey Lake and 72% for Emperor. The average oxygen saturation measurements of control replicates test vessels ranged from 4 to 69% during exposure. This is below the 7–10 mg oxygen/L recommended in OECD TG 308 (65 to 93%). ECHA (2025b) noted that no redox potential measurements within the sediment profile were carried out. This is of particular importance

as the dissolved oxygen concentrations measured in the overlying water were substantially lower than recommended in the OECD TG 308. Therefore, it is not clear whether degradation rates were limited by oxygen availability. The impact of low oxygen content on microbial activity in the sediment cannot be determined as microbial biomass measurements were not carried out.

For the chemical analysis, liquid scintillation counting (LSC) was used and radio-high-performance liquid chromatography (HPLC) was performed for speciation. Oxygen and pH were only measured in the control vessels. At each sampling point, volatiles were captured in a series of traps; a dry ice/acetone bath, vials containing non specified scintillation cocktails and a carbon dioxide trap. A further trap was added early in the study as it was suspected that there was a passage of air drawing volatiles into the carbon dioxide trap.

There were significant initial losses from the test systems, with nearly 50% of the ^{14}C activity lost from the Calwich Abbey Lake system on day 1 and 33% lost from the Emperor Lake system.

The radioactivity associated with each compartment at day 99 and 108, calculated relative to the total applied radioactivity, was reported in ECHA (2025b) and is summarised in Table 9.

Table 9: Distribution of ^{14}C (%) between compartments for each sediment system at the end of the OECD TG 308 test for L2

Media	Calwich Abbey Lake (day 99)	Emperor Lake (day 108)
% Air	<0.1	<0.1
% Water	22.7	65.7
% Sediment	77.3	34.3
% Recovery	52.9	68.9

Chemical speciation in the overlying water and sediment at day 99 and 108, calculated relative to the initial L2 concentration (applied amount), was reported in ECHA (2025b) and is summarised in Table 10.

Table 10: Average chemical speciation (%) as fractions of applied radioactivity in the two sediment systems at the end of the OECD TG 308 test for L2

Media	Component	Calwich Abbey Lake (day 99)	Emperor Lake (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 system	L2	57.7 %	13.8 %
	TMS	41.2 %	85.4 %
	Other	1.1 %	0.8 %

Mass spectrometry identified L2 and degradation product TMS. TMS was the major transformation product (resulting from hydrolysis). Whilst ECHA (2025b) stated that there was a low amount of CO_2 which is consistent with the slow mineralisation of L2, the proportion of CO_2 is not quantified in the report.

Table 11: Total radioactivity and contribution from L2 in the two sediments in the OECD TG 308 study

Sample day	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

The EU REACH registrant initially performed the kinetics assessment using a single first order kinetic model according to the FOCUS guidance (FOCUS, 2014). However, the

kinetics were revised to account for the observed volatilisation with L2 assumed to be the only compound in the volatilisation traps. This degradation of L2 was biphasic, and the hockey-stick (HS) model was used to calculate half-lives.

According to ECHA (2025b), in the test report measured values were normalised against the total applied radioactivity (AR) of the test systems which were set as 100% AR. The day 1 values were considered to represent the effective dose of the study as day 0 values include losses occurring through vessel dosing and volatile loss as the system re-equilibrated. Total AR was used as the starting concentration at day 0.

The break point for the HS model set to day 7 for the Emperor Lake system provided a good visual fit and Chi^2. For the Calwich Abbey Lake system, a break point at day 7 did not provide a good fit and day 1 was used instead. However, the measured and modelled values did not show good agreement in the second phase of degradation. The modelled values for volatility loss at day 1 for Calwich Abbey Lake were optimised by adjusting the kinetics curves to achieve a better Chi^2 fit for the second phase (k_2). According to ECHA (2025b), the test report justified this approach as the k_2 is more important than k_1 when biphasic degradation occurs and there is more uncertainty around measurements in k_1 due to the high amount of volatilisation at the start of the study.

The EU REACH registrant's amended HS model led to an increase in the half-life of the substance in the Calwich Abbey Lake sediment (from 192 days to a whole system $DegT_{50}$ of 360 days) but made little difference to the half-life in the Emperor Lake sediment (increased from 53 days to a whole system $DegT_{50}$ of 54 days). Non-extractable residues (NERs) were not taken into consideration as they would likely increase the $DegT_{50}$ which does not affect the overall outcome, as $DegT_{50}$ values were already >180 days.

Table 12: First-order kinetics for two sediments in OECD TG 308 study using L2

	Calwich Abbey Lake	Emperor Lake
Total system rate constant ($days^{-1}$)	3.61×10^{-3}	1.31×10^{-2}
Total system $DegT_{50}$ (days)	192 (90% CI ± 56 d)	53 (90% CI ± 17 d)

The Agency notes that sediment $DegT_{50}$ values would be preferred over total system $DegT_{50}$ values. Due to the volatilisation, a significant proportion of the substance was lost from the sediment-water system (39 to 54.8% AR by end of study). The parent substance that had partitioned to sediment only degraded slowly. The L2 remaining in water hydrolysed to TMS (94.6 to 99.2% by end of study).

ECHA (2025b) considered this study to be reliable with restrictions (Klimisch score 2), as the endpoints are suitable for comparison with the persistence criteria despite the study not meeting the validity criteria for mass balance due to volatility losses.

The Agency agrees with the interpretation of the results and study validity. Due to the rapid losses via volatilisation at the study start, and extrapolation beyond the study period (108 days), there are uncertainties around the $DegT_{50}$ values derived. Nevertheless, the parent substance that had partitioned to sediment only degraded slowly and the Agency concludes that the half-life in the Calwich Abbey Lake sediment is highly likely to be > 180 days. The study is given a high weight in the persistence assessment.

- Aquatic sediment simulation study, L3 (Unpublished study, 2021b)

The details of this study were presented in ECHA (2024b). The test was performed according to OECD TG 308 and to GLP. The study was conducted at 12°C for 140 days, using radiolabelled L3. Spiking the sediment provided a nominal concentration of 150 ng ^{14}C L3 per g of sediment dry weight (dw) under aerobic and anaerobic conditions. Only methods and results from the aerobic tests were reported in ECHA (2024b). Two sediments were used (Calwich Abbey Lake and Emperor Lake, with OC contents of 4.7 and 2.0% w/w, respectively).

Test systems were set up in duplicate for each analysed timepoint. Rapid initial losses of ^{14}C were observed. In the Calwich Abbey Lake system, a 14% decrease was observed from the from day 0 to day 7 and 10% from days 7 to 140. In the Emperor Lake system, a 9.3% loss occurred from day 0 to 7 and 3.8% from days 7 to 140. The losses were attributed to the volatility of L3. The radioactivity associated with each compartment at day 140, calculated relative to the total applied radioactivity, was reported in ECHA (2024b) and is summarised in Table 13.

Table 13: Distribution of ^{14}C (%) between compartments for each sediment system at day 140 in the sediment simulation study for L3

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

Several deviations from the test guideline were noted in ECHA (2024b). The test duration was extended from 100 to 140 days. Some samples were outside the required recovery range of 90 to 110% (recovery was between 81.6 to 89.1%). These values were considered reasonable due to the volatility and low solubility of L3 and the proximity to the target range. The test guideline states that the typical oxygen saturation range should be 7–10 mg O_2/L (65 to 93%) in the aerobic layer. However, oxygen saturation was outside this range in the test sediments, with average values at the start and end of each aeration event of 4.5 and 53% for Calwich Abbey Lake, and 19 and 55% for Emperor Lake. The authors speculated that this was a result of biodegradation of the diethylene glycol methyl

ether solvent (DEGME) (used to dissolve and apply L3) but no solvent controls were included in the study. Further, no redox potential measurements within the sediment profile were reported. This is of particular importance as the dissolved oxygen concentrations measured in the overlying water were substantially lower than recommended in the OECD TG 308. Therefore, it is not clear whether degradation rates were limited by oxygen availability.

L3 and its metabolites TMS, dimethylsilanediol (DMSD), and pentamethyldisiloxanol (PMDS)) were measured by HPLC with flow scintillation detection after solid phase extraction. Chemical speciation in the overlying water and sediment at day 140, calculated relative to the initial L3 concentration (applied amount), was reported in ECHA (2025b) and is summarised in Table 14.

Table 14: Average chemical speciation (%) in the two sediment systems at day 140 as fractions of applied radioactivity in the sediment simulation study for L3

Media	Component	Calwich Abbey Lake	Emperor Lake
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 %	0.0 %
	PMDS	0.0 %	0.0 %
	DMSD	0.0 %	0.0 %
Total system	L3	89.9 %	75.7 %
	TMS	2.1 %	2.9 %
	PMDS	0.5 %	0.5 %
	DMSD	1.1 %	1.3 %

NERs in the two sediments ranged from 6.3 to 10.9% in the Calwich Abbey Lake systems, and 5.4 to 8.5% in the Emperor Lake systems. Some increases in NERs were observed in Calwich Abbey Lake systems from day 77.

Kinetic calculations were performed according to the FOCUS (2014) guidance using normalised concentrations of total radioactivity of L3 recovered at Day 0. It is not clear from the evaluation in ECHA (2024b) why the results were not normalised to the actual applied radioactivity on day 0.

Single first order (SFO), first-order multi-compartment (FOMC), double first-order in parallel (DFOP), and hockey-stick (HS) models were fitted. All models had an acceptable fit for Emperor Lake and resulted in $DegT_{50}$ values > 180 days; the SFO model and resultant $DegT_{50}$ of 416 days was selected as the key endpoint in ECHA (2024b). It was

noted that $DegT_{50}$ values were extrapolated beyond the study period (140 days) and should therefore be treated with caution.

For Calwich Abbey Lake, the degradation rate was not significantly different from zero, resulting in $DegT_{50}$ values > 10,000 days. However, it was noted that these values should be interpreted with care due to the lack of degradation.

The REACH R.11 guidance (ECHA, 2016) stated that non-characterised NERs should be treated as non-degraded parent substance. ECHA (2024b) noted that inclusion of the NERs according to this guidance would further extend the $DegT_{50}$ values. However, NER characterisation was not carried out to understand environmental significance. There is also no evidence of combustion of bound residues and whether direct determination of residual radioactivity was carried out. The study appears to move directly to extraction using tetrahydrofuran (THF) and it is not clear from ECHA (2024b) if sequential extraction procedures starting with less harsh aqueous extractions were performed.

The study does not provide sufficient information regarding analytical sensitivity, including method detection limits, limits of quantification and measurement uncertainty for parent compound and transformation product analyses. Furthermore, results are predominantly presented as percentages of applied radioactivity rather than as measured concentrations, despite significant losses, imperfect recoveries and normalisation to recovered radioactivity on day 0. This approach limits independent assessment of analytical reliability and makes it difficult to determine whether observed trends represent genuine degradation, analytical variability or artefacts of the normalisation procedure. Consequently, confidence in the derived kinetic parameters is reduced.

The half-lives in the two sediments are very different, which may be a result of the differences in rapid losses via volatilisation in the two test systems and the organic carbon content of the sediments (Calwich Abbey Lake 4.8%; Emperor Lake 1.73%). Nonetheless, despite being a volatile substance, L3 only degraded very slowly in sediment, most likely as a consequence of being highly adsorptive to organic matter. The study duration of 140 days is longer than the 100 days recommended in the test guidelines and this may have impacted the microorganism viability of the study. However, given the low levels of degradation occurring prior to 100 days this is unlikely to significantly affect the results. There were also uncertainties due to issues with L3 recovery and a low oxygen saturation in the test systems, and the $DegT_{50}$ was extrapolated beyond the study period (140 days).

ECHA (2024b) acknowledged the uncertainty associated with the direct parent measurements and so, as an alternative, degradation products detected in the water phase were used to estimate parent degradation kinetics. This could potentially be used as supporting evidence. However, this introduces additional uncertainties such as pathway completeness, analytical accuracy and quantification of the transformation products.

ECHA (2024b) concluded that the fitted values are reliable with restrictions and the EU REACH lead registrant considers the study as reliable without restriction (Klimisch score 1)

with a sediment half-life of 1,280 days and 2,520 days (3.50 and 6.91 years) at 12°C for the two test systems. Despite the uncertainties highlighted above, the Agency agrees that the degradation half-life under partially aerobic conditions in both sediments is highly likely to be > 180 days. The study is given a high weight in the persistence assessment.

- Aquatic sediment simulation study, M3T (Unpublished study, 2021a)

The study was performed according to OECD TG 308 and GLP. The study used ^{14}C-radiolabelled M3T (53 µg/L) under aerobic and anaerobic conditions at 12 °C. Only methods and results from the aerobic tests were reported in ECHA (2025b). The sediments and water were collected from Calwich Abbey Lake (OC content of 5.16% w/w) and Emperor Lake (OC content of 2.15% w/w). Sampling was performed at day 0, 1, 3, 7, 14, 28, 45, 62 and 100 for both test systems. Test system flasks were prepared in accordance with recommendations in OECD TG 308. Diethylene glycol methyl ether (DEGME) was used as a spiking solvent and was used at approximately 1% v/v in the study. No solvent control was used in the study.

Oxygen levels were recorded using two control flasks for each test system. ECHA (2025b) stated that it was not clear from the study report whether these flasks had any of the test substance or solvent added to the flasks. The test guideline states that the typical oxygen saturation range should be 7–10 mg oxygen/L (65 to 93%) in the aerobic layer. However, oxygen saturation was outside this range in the test sediments, with several of the measurements in the Calwich Abbey Lake samples below 1 mg oxygen/L. ECHA (2025b) suggested that this could be due to inconsistencies in the measurements and the depth at which the electrode was placed in the surface water of the test system. Redox measurements in sediment indicated that the sediment was anaerobic during the 100-day study (measurements ranged from -415.4 to -580.1mV in Calwich Abbey Lake sediment and -403.6 to -592.4mV in Emperor Lake sediment).

Microbial biomass was measured at the start and end of the study using a fumigation extraction method. However, high levels of organic carbon in all samples were reported at the study start. The study authors attributed this to the addition of a blank solvent DEGME to the biomass samples before sampling, therefore it is not known whether microbial activity remained stable for the study duration. Microbial biomass of 65.6 mg carbon/100 g dry sediment (equivalent to 2.8% as sediment OC) and 8.7 mg carbon/100 g dry sediment (0.9% as sediment OC) at the study end was reported for Calwich Abbey Lake and Emperor Lake, respectively.

AR measured by LSC in the dosing solution ranged from 85.5 to 103.8% in the Calwich Abbey Lake sediment, and 92.7 to 99% in the Emperor Lake sediment. AR recoveries in the study were generally within the recommended 90 to 110% range. There were six exceptions for the Calwich Abbey Lake test system where recoveries ranged from 83.3 to 89.4% AR, and two exceptions in the Emperor Lake test system where recoveries ranged

from 86.4 to 88.1% AR. Therefore, ECHA (2025b) states that the study does not fulfil all validity criteria. However, this was considered acceptable given the low aqueous solubility and volatility of M3T.

M3T partitioned rapidly from water to sediment. In both test systems, 3-5% AR was present in water after 14 days and 1% after 100 days. The concentration in the water phase was too low to identify the test compound after 28 days and onwards. Where concentrations were above detection limits, most of the AR in extractable sediment and water was identified as the parent substance via gas chromatography. In five test vessels, an unidentified minor component was detected at 1.4 to 10.6% AR. Traps containing sodium hydroxide (NaOH) and diol captured 3.4% and 7.6% AR at day 100 for Calwich Abbey Lake and Emperor Lake, respectively. TMS was identified in the initial NaOH traps via liquid chromatography-mass spectrometry (LC-MS), and is likely to be a hydrolysis product of L4 as it is for L2 and L3.

A large proportion of radioactivity was claimed to be methane (CH_4) in the study report (17% for Calwich Abbey Lake and 42.6% for Emperor Lake), but this was not analytically verified. ECHA (2025b) speculated that the radioactivity may be the hydrolysis product TMS. Table 15 presents the radioactivity associated with water, sediment and air compartments.

Table 15: Distribution of ^{14}C in the two sediments at the end of the sediment simulation study

Media	Calwich Abbey Lake	Emperor Lake
% Air (CO_2 +CH_4 + PU plug + ^{14}C volatiles)	20.8	51.5
% Water	0.7	1.1
% Sediment	72.7+5.4 (NER)	45.5+1.5 (NER)
% Recovery	99.5	98.4

M3T was measured by HPLC with flow scintillation detection after solid phase extraction. For information on recovery in the systems, the data was normalised using the total AR residue to the test systems at day 0. The values at day 0 suggest losses occurring through vessel dosing and volatile loss as the system re-equilibrated. The Agency notes that as the overlying water concentration was not analysed, a full mass balance is not possible.

Chemical speciation in the overlying water and sediment after 100 days, calculated relative to the initial M3T concentration (applied amount), was reported in ECHA (2025b) and is summarised in Table 16. In the Calwich Abbey Lake sediment, total AR was 29.3% and 33.5% in the two replicates at day 0, increasing to a maximum of 91.2% and 82.2% at day 7 and then decreasing to 75.7% and 69.6% at day 100. In the Emperor Lake sediment,

total AR was 73.3% and 62.5% at day 0 and slowly decreased over the study duration to 45.3 and 43.4% at day 100 (parent and degradation products).

Table 16: Average chemical speciation (%) in the two sediment systems at day 100 as fractions of applied radioactivity

Media	Component	Calwich Abbey Lake	Emperor Lake
Overlying water	M3T	Not analysed	Not analysed
	Sum of minor components	Not analysed	Not analysed
Sediment	M3T	72.6 %	41.9 %
	Sum of minor components	<LOQ	Not detected
Total system	M3T	72.6 %	41.9 %
	Sum of minor components	<LOQ	Not detected

LOQ = limit of quantification

NERs in sediments were determined via extraction with THF in a shaker for 1 hour. NERs were determined by combustion and LCS analysis of remaining sediment samples. NERs were 5.4% of total AR in Calwich Abbey Lake system and 1.5% of total AR in Emperor Lake after 100 days. The Agency also notes that the study appears to move directly to extraction using THF and it is not clear from ECHA (2025b) if sequential extraction procedures starting with less harsh aqueous extractions were performed. NER characterisation was not carried out to provide information on the environmental significance.

ECHA (2025b) stated that the kinetic calculations in the study report were performed according to FOCUS (2014) guidance using normalised concentrations of total radioactivity of M3T. The SFO, FOMC, DFOP, and HS models were fitted. NERs were not included in the kinetics assessment in the study report.

For Emperor Lake, the FOMC model provided the best fit based on Chi^2 error and visual assessment and provided a $DegT_{50}$ of 75.3 days. For Calwich Abbey Lake, the biphasic models provided a better fit, based on visual assessment and Chi^2 error, which gave a k2 value of >10,000 days. The Agency notes that the $DegT_{50}$ value for Calwich Abbey Lake was extrapolated beyond the study duration (100 days) and should therefore be treated with caution. However, due to the lack of observed degradation, it is reasonable to conclude that the $DegT_{50}$ was > 180 days.

ECHA (2025b) stated that the exclusion of NERs is not in line with the PBT/vPvB assessment guidance under EU REACH (Chapter R.11; ECHA, 2016). Therefore, ECHA (2025b) presented the kinetics assessment with the inclusion of NERs. The inclusion of NERs led to an increase in $DegT_{50}$ for both test systems:

- For Emperor Lake, the best fit was determined to be the HS model based on visual fit and Chi^2 error. The k_1 and k_2 values were statistically significant ($p<0.1$). The $DegT_{50}$ values were k_1 = 20.2 days and k_2 = 126 days. The fit was also good for the DFOP model with a low Chi^2 error resulting in $DegT_{50}$ values of k_1 = 3.74 and k_2 =136 days.

- For Calwich Abbey Lake, the water-sediment system $DegT_{50}$ with the inclusion of NERs led to an acceptable fit for all models and a high $DegT_{50}$ value was derived ($DegT_{50}$ > 180 days). The visual fit was better for the DFOP and HS models than for the SFO model. ECHA (2025b) concluded that the HS model provided the best fit.

As there was uncertainty in the identity of the volatiles in the traps, ECHA (2025b) also performed a kinetics assessment with AR in volatiles assumed to be the parent M3T. This method is conservative and therefore lengthened the $DegT_{50}$ values. Re-calculated k_2 $DegT_{50}$ values for the Emperor Lake system were 133 days and 141 days for the HS and DFOP models, respectively. The Calwich Abbey Lake system k_2 $DegT_{50}$ values did not change as a result of the recalculations (>10,000 days).

ECHA (2025b) considered the study ‘reliable with restrictions’ (Klimisch score 2) and gives a high weight in the persistence assessment. The Agency agrees with the study validity, and concludes that the half-life in the Calwich Abbey Lake sediment is highly likely to be > 180 days. The redox measurements and oxygen levels in sediment imply that the test systems were anaerobic, and so methane formation would be expected. It is not possible to conclude that this half-life is representative of aerobic conditions, and so it might not be definitive.

2.3.1.2.3 Biodegradation in soil

One non-standard soil simulation study is included in ECHA (2025b).

- Biodegradation in soil (Unpublished study, 2014a)

A non-standard set of soil degradation experiments were carried out using varying temperatures and humidities. The study was not performed in accordance with OECD TG 307 or GLP. It used a single soil from Michigan, USA (22% clay, 28% silt, 50% sand, 2.4% OC). The moisture content of the soil was not reported. Due to the use of relative humidity in the study, it is not known how this equates to moisture content in the OECD TG 307. The soil was air-dried, but other preparatory methods such as sieving or grinding the soil prior to the test were not stated in ECHA (2025b). The distribution of the test substance in the system is also unknown. The duration of the study was not reported and microbial activity was not measured during the test.

The study determined $DegT_{50}$ values ranging from a few days to over 280 days, however ECHA (2025b) did not consider the test to be reliable (Klimisch score 3). The Agency

agrees with this conclusion, and so the study is not used in the weight-of-evidence (WoE) assessment for persistence.

2.3.1.3 Monitoring data

ECHA (2025b) included the results of several studies that determined the presence of L4 in a variety of matrices including wastewater treatment plant (WWTP) influent and effluent (<limit of detection (LOD) to 0.148 µg/L), WWTP sludge (<LOQ to 3.4 mg/kg dw), sediment (<LOD to 52.4 µg/kg dw), soil (not detected to 0.45 µg/kg dw), air (not detected to 37 ng/m^3), and surface freshwater (<LOD to 24 ng/L). Biota concentrations are summarised in Section 2.3.3.2. In most cases, sample collection and methods have not been described in full detail.

Monitoring data are also available from the Environment Agency. The analytical method was gas chromatography-mass spectrometry (GC-MS), the data are semi-quantitative, and the sites are distributed throughout England, including both rural and urban locations. The data for 2019 to 2020 show detection in 0.06% of freshwater samples with a maximum detection of 0.016 µg/L. The limit of detection was stated to be 0.01 µg/L.

The presence of L4 in the environment may in certain circumstances be considered as indirect supporting evidence of persistence. However, given the availability of laboratory data that can be directly compared with the Annex 13 criteria, the monitoring data cited in ECHA (2025b) were not examined in detail for this report.

2.3.1.4 Summary and discussion of degradation

A reliable OECD TG 111 study resulted in a hydrolysis half-life of 165 days at 10°C and pH 7 in pure water. This equated to a half-life of 132 days at 12°C and pH 7, representing the freshwater environment. These half-lives are expected to be longer in the presence of OC. L4 is more hydrolytically stable than L2 and L3, indicating that hydrolysis half-lives increase with increasing chain length and molecular weight.

No biodegradation screening tests are available for L4. ECHA (2025b) presented three ready biodegradation studies for the structurally similar substances L2, L3 and M3T. None were readily biodegradable, with 0% biodegradation observed after 28 days for L3 and M3T (in OECD TG 310 and OECD TG 301F studies, respectively), and 2% mineralisation observed after 28 days for L2 (in an OECD TG 301C study). All three studies meet the relevant validity criteria, although degradation may have been limited by dissolution kinetics since the test concentrations significantly exceeded the water solubility limit for all three. Nevertheless, due to the similarity in structure to L2, L3 and M3T, it is highly unlikely that L4 would be readily biodegradable in these test systems, as it will be less bioavailable than L2 and L3 (it is less water soluble and more hydrophobic).

No water-sediment simulation studies are available for L4. ECHA (2025b) presented three

reliable sediment simulation studies for L2, L3 and M3T:

- For L2, whole system $DegT_{50}$ values of 360 days and 54 days at 12°C were derived in the two test sediments in a water-sediment aerobic degradation study performed according to OECD TG 308. Despite some uncertainties, the parent substance that had partitioned to sediment degraded slowly. In conclusion, the half-life in the Calwich Abbey Lake sediment is highly likely to be > 180 days.

- For L3, very little degradation was observed over 100 days in a water-sediment aerobic degradation study performed according to OECD TG 308. $DegT_{50}$ values of 416 days or longer were derived at 12°C. Despite some uncertainties, it is concluded that the degradation half-life was >180 days in both sediments tested.

- No significant degradation of M3T was observed over 100 days in a water-sediment aerobic degradation study performed according to OECD TG 308. The half-life in the Calwich Abbey Lake sediment is highly likely to be > 180 days. A low weighting was assigned in the persistence assessment due to the anaerobic test conditions.

L4 is more adsorptive than L2 and L3 (see Section 2.3.2.1), so is expected to partition more to sediment, reducing potential losses via hydrolysis and volatilisation. It is also expected to be less degradable due to its lower water solubility and higher hydrophobicity. The half-lives for L2 and L3 therefore represent the “best case” for L4. It can therefore be concluded that the half-life of L4 in freshwater sediment is >180 days.

L4 has been detected at low concentrations in a wide range of environmental compartments including sediment, soil, air and surface water. However, this does not provide any evidence that is relevant to the assessment of persistence.

2.3.2 Environmental distribution

2.3.2.1 Adsorption/desorption

ECHA (2025b) provided a brief summary of an OECD TG 106 study (Unpublished study, 2010a). Individual log K_{OC} values ranged from 4.95 to 5.28 (mean log K_{OC} of 5.16) at 23.7°C. The similarity of K_{OC} values and isotherms derived in the test indicate that L4 partitioning into soil organic matter is likely to dominate the overall sorption from water.

A predicted log K_{OC} of 4.5 at 25°C using the COSMOTherm model is presented in ECHA (2025b). The reliability of this information is not commented on. As noted in Section 2.1.5, the Agency prefers measured data.

For comparison, the measured log K_{OC} for L3 is 4.34 (OECD TG 106; Unpublished study report, 2010b). Only predicted data are presented for L2 and M3T in ECHA (2025b), so these have not been considered by the Agency, but it is noted that adsorption increases with chain length.

The high log K_{OC} for these substances indicate a high potential to adsorb to organic matter in sediment and soils. ECHA (2025b) stated that the siloxy backbone is the important fragment that drives the level of adsorption.

2.3.2.2 Volatilisation

L4 has a high vapour pressure (73 Pa at 25°C) and low water solubility (0.0067 mg/L at 23°C). ECHA (2025b) calculated the Henry's Law constant as 2.59 x 10^6 Pa m^3 mol at 12°C and 6.39 x 10^6.Pa m^3 mol^{-1} at 25°C based on a log K_{AW} of 3.22 obtained from an OECD TG 117 study, rated by the EU REACH registrants as 'reliable with restrictions' (Klimisch score 2). The Henry's Law constant is 1.09 x 10^4 calculated using the vapour pressure and water solubility.

For comparison, ECHA (2025b) presented Henry's Law constants for L2, L3 and M3T, and this information is provided in Table 17.

Table 17: Comparison of Henry's Law constants for L2, L3, and M3T

L2	L3	M3T
0.78x10^6 at 25°C 0.37x10^6 at 12°C (Unpublished study report, 2010e)	3.85×10^6 at 25°C 1.62×10^6 at 12°C (Unpublished study report, 2010e)	3.35×10^7 at 25°C 1.61×10^7 at 12°C (EUSES estimation)

Note: Units are Pa m^3 mol^{-1}

Vapour pressure and water solubility both decline with increasing molecular weight (see Section 2.1.5). All four substances are likely to be volatile in the aquatic environment, transferring readily from the water phase to the atmosphere unless already adsorbed to organic carbon (OC).

2.3.2.3 Distribution modelling

The environmental distribution of L4 is expected to be determined by its low water solubility, high volatility and high log K_{OC} value, along with its degradability in environmental media.

ECHA (2025b) presented level III fugacity modelling for L4 (from US-EPA EPISuite™ (v4.11)) using loading rates for air, soil, and water of 1,000 kg/h:

- Equal release of L4 to air, soil and water is predicted to result in 13.8% in air, 42.7% in water, 1.33% in soil, and 42.2% in sediment.
- L4 released entirely into water is expected to partition roughly equally to the sediment (49.2%) and water (49.8%).
- L4 released entirely into soil is expected to mainly partition to air (83%) with the rest (17%) remaining in soil.
- L4 entirely released into air is expected to remain there (100%).

2.3.2.4 Estimation of long-range transport potential (LRTP)

ECHA (2025b) used the OECD P_{OV} and LRTP screening tool version 2.213 (Wegmann *et al.*, 2009) to conclude that L4 is able to undergo long-range atmospheric transport. The Agency has not assessed this information.

2.3.3 Bioaccumulation

2.3.3.1 Bioaccumulation in aquatic organisms (pelagic & sediment organisms)

2.3.3.1.1 Screening data

A log K_{OW} of 8.21 at 25.1°C (see Section 2.1.5) suggests the potential for bioaccumulation.

The measured log K_{OA} of 4.85 at 19.7°C (see Section 2.1.5) means that L4 approaches but does not exceed the screening criteria for bioaccumulation in air breathing organisms (log K_{OW} > 2 and log K_{OA} > 5).

2.3.3.1.2 Aquatic bioaccumulation data

Three aquatic bioaccumulation studies for L4 are presented in ECHA (2025b), as summarised in Table 18.

Table 18: Summary of aquatic bioaccumulation data for L4

Reference	Study type	Results / comments
Unpublished study report (2006a)	OECD TG 305. 63-day test: aqueous exposure using *Pimephales promelas (Fathead Minnow)* Reliable with restrictions (Klimisch score 2)	High exposure concentration (5.3 µg/L): BCF_{KgL} = 3,007 L/kg Low exposure concentration (0.43 µg/L): BCF_{KgL} = 8,080 L/kg (based on both replicates) or 7,282 L/kg (based on Replicate B only) The Agency prefers a BCF of 6,201 and 2,713 L/kg calculated at the end of the uptake phase for the low and high exposure group, respectively – see main text for further details
Unpublished study report (2011b)	OECD TG 305. 67-day test: dietary exposure using *Oncorhynchus mykiss (Rainbow Trout)* Reliable with restrictions (Klimisch score 2)	BMF_{KgL} = 0.355 BCF values calculated from the depuration rate constant (growth corrected k_{2g} = 0.0092 d^{-1}) using the OECD BCF estimation tool (adjusted for lipid content over time): $BCF_{kinetic}$: 1,124 to 140,701 L/kg (Method 1) $BCF_{kinetic}$: 60,550 L/kg (Method 2) $BCF_{ss,L}$: 10,959 L/kg (Method 3)

Reference	Study type	Results / comments
Cantu and Gobas (2024)	OECD TG 305. 95-day test: dietary exposure using *Oncorhynchus Mykiss (Rainbow Trout)* Reliable with restrictions (Klimisch score 2)	BMF_{KgL}= 0.355 BCF values calculated from the depuration rate constant (growth corrected k_{2g} = 0.0092 d^{-1}) using the OECD BCF estimation tool: $BCF_{kinetic}$: 1,139 to 142,654 L/kg (Method 1) $BCF_{kinetic}$: 61,579 L/kg (Method 2) $BCF_{ss,L}$: 5,592 L/kg (Method 3)

- Unpublished study report (2006a), L4 aqueous exposure study

A study conducted according to OECD TG 305 and GLP was carried out with L4 using *Pimephales promelas* (Fathead Minnow). The Agency has previously evaluated the unpublished study report as part of the Substance Evaluation of L4 which was finalised by the Norwegian Competent Authority (ECHA, 2021). The study was performed for a total of 63 days at 22 ± 2ºC under flow through conditions. The uptake phase was 35 days with water and tissue samples collected on days 0, 3, 7, 14, 21, 28 and 35. The depuration phase was 28 days, with sampling on days 1, 3, 7, 10, 14, 21 and 28. Fish were collected from each aquarium in duplicate (four fish per treatment) and one fish was collected on days 0, 35 and 63 for lipid analysis.

Stock solutions of the ^{14}C radiolabelled L4 in dimethylformamide (DMF) were made. The water was dosed with L4 prior to test start and water samples were taken on eight occasions prior to the start of the study to ensure equilibrium of the solutions in the test chambers. The test item was detected in fish at day 0, but only in the high and low treatments, not in the solvent control. This is therefore an indication of exposure starting before day 0 fish samples were taken, and not contamination.

Determination of the concentrations was performed by LSC. The low treatment (nominal concentration of 0.67 µg/L) had mean measured concentrations of 0.43 µg/L and the high treatment (nominal concentration of 6.7 µg/L) had mean measured concentrations of 5.3 µg/L. The mean-measured high concentration is very close to the L4 water solubility of 6.7 µg/L at 23 °C (see Section 2.1.5). The concentration of L4 was measured in the whole fish, with water samples taken on the same days. No characterisation of degradation products was performed.

The study report stated that fish concentrations plateaued after day 14 of the uptake period. A 95% reduction in body burden was reached at the end of the depuration phase, as recommended in the OECD TG 305.

ECHA (2025b) stated that most validity criteria were met. However, mortality was higher than recommended in the OECD TG 305. Mortality in the solvent control, low and high exposure groups was 8.5%, 10.65% and 10.65%, respectively. ECHA (2025b) adjusted these values to mortality per month (30 days). The mortality rate per month equated to 4.04% in the solvent control and 5.07% in both the low and high treatment group. The Agency notes that both treatment groups exceed the 5% per month mortality threshold as stated in the current OECD TG 305. No reasons for the mortality rates were suggested in the study report, and no sub-lethal effects were reported in ECHA (2025b). ECHA (2025b) stated that when comparing the cumulative mortality, there was no significant difference between treatment group and solvent control. Additionally, it was noted that the validity criteria were only exceeded in one out of the two replicates for both the low and high treatment groups, as well as one replicate of the solvent control. At the end of the uptake period mortality across all controls and treatments did not exceed 10%. Therefore, ECHA (2025b) concluded that mortality is likely not caused by toxicity of the test item, but instead due to the experimental set-up.

ECHA (2025b) stated that there was potential contamination of analytical equipment as L4 was detected in water for the high concentration treatment during the depuration phase (0.240 to 0.442 µg/L at day 1 and 3). There were no further detections of L4 in the water during the depuration phase in any treatment group or replicate.

The contamination and mortality issues have an impact on the reliability of replicate A for the low treatment group (mortality in replicate A: 13%, mortality in replicate B: 8.3%) and both replicates for the high treatment group (mortality in replicate A: 8.3% and contamination in replicate A, mortality in replicate B: 13%). The BCF values were therefore recalculated by ECHA (2025b) using just replicate B of the low treatment group (i.e. excluding replicate A and the high treatment group replicates).

The study report calculated steady-state BCF (BCF_{SS}) values using the geometric mean of fish concentrations on day 14, 21, 28 and 35 (7,946 and 1,477 µg/kg for the low and high exposure groups, respectively). Normalisation to 5% lipid content provided $BCF_{SS,L}$ values of 6,201 and 2,713 L/kg for the low and high treatment groups, respectively, using the mean lipid value recorded at the end of the uptake phase. However, the concentration increases between uptake sampling points were significant for both treatment groups, which indicates that steady state had not in fact been reached. Therefore, the Agency considers that the BCF_{SS} values derived in the study are likely to be an underestimate. Steady state was, however, reached for replicate B of the low exposure group, and the $BCF_{SS,L}$ was 5,976 L/kg.

Due to the variation in lipid content across the study period, another method was used to calculate $BCF_{SS,L}$ recommended in OECD TG 305. This was a linear regression of log normal per cent lipid content plotted against time to derive the change in lipid content each day. The change in lipid content over time could not be differentiated between treatment

groups, but a single rate in change in lipid content was used for normalisation of the measured concentrations. The approach resulted in a slight change to the $BCF_{SS,L}$ values: 6,112 L/kg for replicate B for the low exposure group, 6,343 L/kg for the combined replicates of the low exposure group and 2,778 L/kg for the combined replicates of the high exposure group. Detailed calculation methods are described in ECHA (2025b), and relevant data are summarised in Table 19.

Table 19: Approximate $BCF_{SS,L}$ values for L4 based on the fish and water concentrations at the end of uptake

Treatment group	Mean L4 concentration in fish (µg/kg) on day 35	Mean L4 concentration in water (µg/L) on day 35	Mean lipid content at end of uptake phase (%)	$BCF_{SS,L}$ (L/kg)	$BCF_{SS,L}$ accounting for changing lipid content (L/kg)
Low	2,648	0.427	2.79	6,201	6,343
High	14,241	5.25	2.79	2,713	2,778
Low Replicate B only	2,552	0.427	2.79	5,976	6,112

There was no significant growth observed over the course of the study in the treatment groups, including at a replicate level for the low exposure group. However, a significant decrease in fish weight was observed in the solvent control between day 0 and 63 ($p = 0.0331$), although the raw data for fish wet weight were not provided in ECHA (2025b).

This was investigated further by considering whether there were any differences in growth between the uptake and depuration phases of the study. The solvent control group showed a significant difference in growth rate between these phases (growth rate (k_g) of -0.0073 during the uptake phase and -0.0224 during the depuration phase). According to OECD TG 305, if there is a statistically significant difference between the growth rate constants derived for the uptake phase and depuration phase, then the depuration phase rate constant is preferred. The growth during the uptake and depuration phase were pooled for each treatment respectively. There was no statistical significance in growth rate between the high and low exposure treatments, nor between them and replicate B in the low treatment group.

The growth rate for replicate B in the low treatment group was dealt with separately, as it was the only treatment group considered reliable by ECHA (2025b). The growth-corrected depuration rate constants (k_2) were calculated and used to derive growth-corrected lipid-normalised kinetic BCF values (BCF_{KgL}). Using values of BCF_K determined in the EU REACH registration dossier derived from the simultaneous method resulted in BCF_{KgL} values of 6,184 and 2,899 L/kg for the low and high treatment groups, respectively. The k_2 value was derived from the linear regression of log normal measured fish concentration

against time during the depuration phase (day 35 to 63), which gave the value 0.0983 as the slope of the plot which is significantly different to zero ($p<0.05$). The k_1 value was obtained from least squares fitting of the uptake curve, providing a value of 416.03 L/kg/day.

BCF_K values were also determined using the sequential method in ECHA (2025b). This resulted in BCF_{KgL} values of 8,080.3 and 3,007 L/kg for the low and high treatment groups, respectively. When accounting for changing lipid content over time, the BCF_{KgL} values were determined as 8,439 and 3,093 L/kg. ECHA (2025b) states that as the change in lipid concentration over time was not significant, the standard OECD TG lipid normalisation to 5% is preferred (though the Agency notes that the BCF_{SS} values are reported using the lipid normalisation over time). The Agency recognises that the BCF_{KgL} values using the two approaches are similar and are all above 5,000 L/kg for the low concentration treatment group. Relevant data are summarised in Table 20.

Table 20: Values of the uptake and depuration rate constants and resultant BCF_{KgL} values, for the simultaneous and sequential methods of determining rate constants

Treatment group	k_1 (L kg^{-1} day^{-1})	k_2 (day^{-1})	Growth rate (day^{-1})	BCF_{KgL} (L/kg)	BCF_{KgL} accounting for changing lipid content (L/kg)
Simultaneous method					
Low	764.7	0.221	-0.0006	6,184	6,177
High	268.8	0.166	-0.0006	2,899	2,975
Low Replicate B only	1,015.6	0.312	-0.0040	5,826	5,845
Sequential method					
Low	413.74	0.0910	-0.0006	8,080	8,439
High	246.7	0.1462	-0.0006	3,007	3,083
Low Replicate B only	416.03	0.0983	-0.0040	7,282	7,560

From the results of the study, ECHA (2025b) concluded that the lipid- and growth-corrected kinetic BCF values are 7,282 L/kg based on the sequential method and 5,826 L/kg based on the simultaneous method for replicate B of the low exposure treatment group. These values were taken forward for the WoE assessment.

Aside from the drawbacks identified by ECHA (2025b), the Agency has the following observations:

- If only one replicate is considered valid, a study cannot be rated as “reliable with restrictions” for the purpose of calculating a kinetic BCF. The choice of the BCF_{KgL} value

for replicate B of the low exposure treatment group is therefore not supported.

- The level of mortality observed during the study was only marginally above the 10% threshold for the whole study, and even closer to the mortality threshold when applied to tests exceeding 30 days (5.07% versus 5%). Therefore, it is questionable whether the low exposure group as a whole should be considered invalid.
- The growth rate was very small and negative, so it is debatable whether growth correction was necessary in this case. For the high concentration treatment group, the BCF_K was 1,687 L/kg compared to growth corrected BCF_{Kg} of 1,680 L/kg. The low concentration treatment group BCF_K was 4,546 L/kg compared to a growth corrected BCF_{Kg} of 4,514 L/kg. The negative growth rate might possibly indicate some level of sub-lethal effect, but this cannot be determined with confidence.

Overall, it is difficult to draw definitive conclusions about the most appropriate numerical BCF value from this study given the uncertainties. Aside from marginally failing the mortality criteria, steady state was not reached, there appears to have been some contamination of the water during the early stages of depuration, and the corrections made for growth and lipid variation by ECHA (2025b) may have been unnecessary. The lipid-normalised BCF values derived using fish concentrations at day 35 of uptake (6,201 and 2,713 L/kg for the low and high exposure group, respectively) are likely to represent a ‘best case’ (i.e. the BCF may have been higher if the uptake phase had been extended). The mortality up to the end of uptake was within the validity criteria of the OECD TG, so these values can be considered “reliable with restrictions”. It is not unusual for the BCF of hydrophobic substances to decrease with increasing exposure concentration, since this reflects bioavailability differences. The highest BCF (6,201 L/kg) is therefore selected for the WoE assessment.

- Unpublished study report (2011b), L4 dietary exposure study

The Agency has previously evaluated the unpublished study report as part of the Substance Evaluation of L4 which was finalised by the Norwegian Competent Authority (ECHA, 2021). The study was conducted prior to the dietary exposure part of the OECD TG 305 being published; however, the study was carried out broadly in line with the test guideline and was GLP compliant. The study used a 42-day uptake phase followed by a 25-day depuration phase, with *Oncorhynchus mykiss* (Rainbow Trout) at 12 ± 2°C. Triplicate samples were collected for each test chamber (totalling six fish per treatment) at regular intervals. A feeding rate of 3% was applied (as opposed to 1 to 2% recommended in the OECD TG 305) and fish grew significantly during the study (average weight increased from 0.81 to 11.33 g).

The study fulfils most of the TG validity criteria. The dissolved oxygen concentration fell below 60% of the air saturation from day 25 with a steady decrease until day 42 (end of uptake phase). The Agency notes that no dissolved oxygen values are reported as percentages so it is not clear what the extent of the decrease is by day 42. The study

reported no mortality or adverse effects as a result of the reduced dissolved oxygen levels. No mortalities were observed for the first 66 days of the test. However, on day 67 the study report noted that the majority of the fish died due to a diluter malfunction, and the test was terminated as a result.

Steady state was not reached by day 42 as the mean concentrations in fish on days 28, 35 and 42 were statistically different. The mean concentration in water on day 42 was 78.0 µg/L based on parent compound analysis. The Agency notes that this is an order of magnitude above the water solubility of L4 (6.7 µg/L). The BMF was estimated as 0.15 on day 42 (not lipid normalised) or 0.44 (lipid normalised using time weighted average lipid content of the fish) in the study report.

The fish digestive tracts were removed for analysis with no transformation products of the parent compound detected. In the liver, the difference between total radioactivity and parent L4 total radioactivity suggested the presence of some non-identified transformation products. However, further analysis with High-performance liquid chromatography with radioactivity detection (HPLC/RAD) failed to confirm this.

In the study report, the dietary uptake rate constant (k_1) and depuration rate constant (k_2) were derived from curve fitting via minimising the residual between the model output and the experimental data, using Berkeley Madonna software. The resulting k_1 was 0.0072 day^{-1} and the k_2 was 0.0057 day^{-1}.

The mean lipid content of the food was 17.7%. This is high compared to constituent quantities of a suitable commercial fish food stated in OECD TG 305. The lipid content of the fish increased from a mean of 2.3% at day 0 to 7.44% at day 67. As this was significant, a mean time-weighted value of 5.93% was used in the study report. With an assimilation efficiency (α) of 0.24, the study report calculated a BMF_K of 1.3 and lipid adjusted BMF_K (BMF_{KL}) of 3.8.

ECHA (2025b) recalculated the k_2 value which was obtained from the slope of the plot of log normal fish concentration versus time over the depuration phase, providing a k_2 value of 0.0494 day^{-1}. As there was no significant difference in the growth rates for the uptake and depuration phase for the treatment group, these rates were pooled. The rate constant for growth dilution (k_g) was 0.0383 day^{-1} based on the individual weight data in the study report from the exposed group. The growth-corrected depuration rate was 0.0111 day^{-1}.

ECHA (2025b) recalculated the time-weighted mean lipid content as 6.99%, and calculated two alternative assimilation efficiency values to the one in the study report (0.275 from the end of uptake phase, and 0.277 extrapolated to the start of depuration phase). No further details were provided on how these assimilation efficiency values were calculated.

The resulting lipid-normalised kinetic BMF values using both lipid content values, and the

three assimilation efficiencies are summarised in Table 21.

Table 21: Calculated BMF values using the standard OECD TG 305 approach

Food ingestion rate constant (g food/g fish/day)	k_2 (day^{-1})	k_g (day^{-1})	α	BMF_{KgL} (5% lipid content)	BMF_{KgL} (time weighted lipid content of 6.99%)
0.03	0.0494	0.0383	0.240	0.70	1.64
			0.275	0.80	1.88
			0.277	0.81	1.90

BCF values were determined using the OECD Dietary BCF Estimation Tool. When the output from the standard OECD TG 305 approach is used, estimated BCF values ranged from 778 to 97,371 L/kg in method 1 (median BCF of 39,418 L/kg with outliers removed), while methods 2 and 3 gave estimated BCF values of 38,615 and 22,233 L/kg, respectively.

BCF values were also determined in the Tool using the fish concentration that had been adjusted for lipid content over time. This provided a growth-corrected k_{2g} of 0.0261. The resulting values were generally within a similar range to the standard lipid normalisation values presented above, ranging from 1,124 to 140,701 L/kg for method 1 (median BCF of 24,241 L/kg with outliers removed), while method 2 and 3 gave estimated BCF values of 60,550 and 10,959 L/kg, respectively.

ECHA (2025b) noted that the k_{2g} values derived in the aquatic bioconcentration study with *P. promelas* were 0.0916 to 0.1468 day^{-1} (which equate to a BCF above 5,000 L/kg). These k_{2g} values can be compared with the k_{2g} value derived from the dietary study (0.0111 to 0.0261 day^{-1}). L4 appears to be depurated more rapidly from *P. promelas* than *O. mykiss*, suggesting that the BCF in *O. mykiss* may be higher than determined for *P. promelas*, assuming a similar uptake rate constant.

ECHA (2025b) noted that the methods function fairly well for non-polar compounds with log K_{OW} > 3.5 and α > 0.1, as is the case for L4, but that caution should be applied given that training set compounds are dominated by aromatics and halogenated aromatics, so L4 is not entirely within the model applicability domains. The significant growth of the fish during the study may have also introduced errors to predicted k_1 values.

ECHA (2025b) concluded that the study is reliable with restrictions. The Agency agrees with this, and that the modelled BCF values significantly exceeded 5,000 L/kg.

- Cantu and Gobas (2024), L4 dietary exposure study

Bioaccumulation in *O. mykiss* was assessed according to a modified OECD TG 305 method, with dietary exposure to L4 and seven reference chemicals combined (tri-, tetra-, penta-, and hexachlorobenzene, and PCB-52, PCB-153 and PCB-209). Most of the validity criteria were fulfilled, however, mortality was not reported in the publication. It is noted that the contents of fish gastrointestinal tracts were removed before analysis. Different equations to those given in the test guideline were used by the study authors to derive a k_2 of 0.018 day^{-1} and a lipid-normalised BMF of 0.24 (kg lipid kg^{-1} fish) for L4.

BMF values were re-calculated in ECHA (2025b) according to OECD TG 305. Relevant parameters and results are summarised in Table 22.

Table 22: Relevant parameters and re-calculated BMF values according to OECD TG 305 (Cantu and Gobas, 2024)

k_2 (day^{-1})	Concentration in food (mg/kg)	Feeding rate (%)	α	k_g (day^{-1})	Lipid correction factor	BMF_{KgL}
0.018	515	1.25	0.0864	0.0088	0.331	0.355

A BCF was also calculated by the study authors from k_1 and k_2, but it was noted in ECHA (2025b) that this calculation is not in line with REACH PBT guidance (ECHA, 2016) or OECD TG 305. The OECD Dietary BCF Estimation Tool was therefore applied by ECHA (2025b), resulting in estimated BCF values of 23,810 L/kg (median value) and 61,579 L/kg from methods 1 and 2, respectively. Method 3 resulted in a BCF of 5,065 L/kg, but was considered less relevant due to a lack of similar substances to L3 in the training set.

ECHA (2025b) concluded that the study is reliable with restrictions. The Agency agrees with this, and that the modelled BCF values significantly exceeded 5,000 L/kg.

2.3.3.2 Field data

ECHA (2025b) stated that L4 has been detected in a wide range of organisms, from phytoplankton (<LOD to 17 ng/kg dw) to invertebrates (<0.12 to 1.75 µg/kg dw) to fish (<LOD to 5.165 µg/kg ww). The highest observed concentration of L4 in biota reported in ECHA (2025b) is 5.165 µg/kg ww measured in cod liver in Norway (Ruus *et al*., 2023). In one study, L4 was detected in human breast milk up to concentrations of 0.013 µg/L (Kaj *et al*., 2005b). However, ECHA (2025b) stated that the analytical method is not sufficiently described.

The presence of L4 in biota may in certain circumstances be considered as indirect supporting evidence of bioaccumulation. However, given the availability of laboratory data that can be directly compared with the Annex 13 criteria, the Agency has not examined the monitoring data cited in ECHA (2025b) in detail for this report.

No studies reporting field BMF or TMF values were provided in ECHA (2025b).

2.1.1.1 Summary and discussion of bioaccumulation

Based on the measured log K_{OW} of 8.21 at 25.1ºC (unpublished study report, 2008a), L4 has the potential for bioaccumulation in aquatic organisms.

A valid lipid-normalised BCF value of 6,184 L/kg was obtained at the end of the uptake period in an aquatic exposure study (OECD TG 305) on *P. promelas*. Although mortality exceeded the TG validity criteria over the course of the whole study, the criteria were fulfilled for this portion. Steady state was not achieved so the BCF may be a minimum value. It is considered 'reliable with restrictions' (Klimisch score 2), but given the uncertainties in the study, is only assigned a medium weight for the WoE assessment.

There are also two dietary exposure studies (OECD TG 305) on *O. mykiss.* The valid growth-corrected, lipid-normalised kinetic BMF values range from 0.355 to 0.81, and resulting modelled BCF values ranged from 5,592 to 61,579 L/kg. These two studies have some limitations including excessively high fish growth in one study. However, overall, the studies are considered 'reliable with restrictions' (Klimisch score 2), and are given a high weighting in the WoE assessment.

There is evidence of the presence of L4 in a variety of aquatic wildlife and human breast milk at low concentrations, although the reliability of this information is unknown.

2.4 Conclusions on the SVHC properties

2.4.1 PBT and vPvB assessment

A weight-of-evidence determination according to the provisions of Annex 13 of UK REACH has been used to identify L4 as vPvB. This involved a read-across approach using L2, L3 and M3T for some endpoints. They are all structurally similar substances with clear patterns in physicochemical properties (including volatility, water solubility, and hydrophobicity) based on chain length and molecular weight.

Persistence

No biodegradation screening or simulation studies are available for L4. A read-across approach using L2, L3 and M3T was therefore used to assess the biodegradation potential of L4.

These three substances are not readily biodegradable. Due to the similarity in structure, it is highly unlikely that L4 would be readily biodegradable in these test systems, as it will be less bioavailable than L2 and L3 (it is less water soluble and more hydrophobic). It therefore screens as P and vP.

Three water-sediment aerobic degradation studies performed according to OECD TG 308 were presented in ECHA (2025b) and rated as 'reliable with restrictions':

- For L2, whole system $DegT_{50}$ values of 360 days and 54 days at 12°C were derived in the two test sediments. Despite some uncertainties, the parent substance that had partitioned to sediment degraded slowly. The half-life in one of the test sediments is highly likely to be > 180 days.

- For L3, very little degradation was observed over 100 days. $DegT_{50}$ values of 416 days or longer were derived at 12°C. The degradation half-life was >180 days in both sediments tested.

- M3T showed no significant degradation over 100 days. The half-life in one of the test sediments is highly likely to be > 180 days. Due to the anaerobic test conditions, it is not possible to conclude that this half-life is representative of aerobic conditions, and so it might not be definitive, and is therefore given a low weighting in the persistence assessment by the Agency.

L4 is more adsorptive than L2 and L3, so is expected to partition more to sediment, reducing potential losses via hydrolysis and volatilisation. It is also expected to be less degradable due to its lower water solubility and higher hydrophobicity. The half-lives for L2 and L3 therefore represent the “best case” for L4. It can therefore be concluded that the half-life of L4 in freshwater sediment is >180 days.

The Agency concludes from the evidence available that L4 fulfils the P and vP criteria of Annex 13 of UK REACH (freshwater sediment half-life > 120 or > 180 days, respectively).

Bioaccumulation

L4 screens as potentially B and vB in aquatic organisms based on a measured log K_{OW} of 8.21 at 25.1°C (log K_{OW} > 4.5).

An aquatic exposure study performed to OECD TG 305 using *P. promelas* yielded a lipid-normalised bioconcentration factor (BCF) of 6,201 L/kg calculated at the end of uptake at the lower exposure concentration. This is considered to be a best-case value (i.e. the BCF may be higher) and the most reliable result from the study (the reliability of the kinetic BCF values preferred by ECHA (2025b) is uncertain). However, given the overall uncertainties with this study, the information only has a medium weighting in the assessment.

Further evidence is provided in two dietary exposure studies performed to OECD TG 305 on *O. mykiss*. BMF_{KgL} values ranged from 0.355 to 0.81. Although the laboratory dietary BMF values were < 1, they cannot be directly compared to the B/vB criteria. Modelled BCF values ranged from 5,592 to 61,580 L/kg. Despite some limitations of the studies (including excessively high fish growth in one study), the modelled BCF values are considered to be sufficiently reliable for regulatory purposes, and are given a high weighting in this assessment.

Based on modelled BCF values of 5,592 to 61,580 L/kg derived from dietary BMF data for *O. mykiss*, with a lipid-normalised BCF of 6,201 L/kg from an aquatic exposure study with *P. promelas* as supporting evidence, it is concluded that L4 meets the B and vB criteria (BCF > 2,000 or > 5,000 L/kg, respectively) set out in Annex 13 of UK REACH.

2.4.2 Overall conclusions on the vPvB properties

Based on the information available, the Agency concludes that L4 fulfils the vPvB criteria of Annex 13 of UK REACH and can therefore be identified as an SVHC in accordance with Article 57(e).

3 Information on use, exposure and alternatives

3.1 UK and EU REACH registration status and tonnage

L4 is not currently registered under UK REACH.

A total of 64 Downstream User Import Notifications (DUINs[2]) have been submitted under UK REACH.

Under EU REACH, the substance is registered with an aggregated tonnage of 1000-10,000 (12 active EU registrants).

3.2 General description of uses and exposure

L4 is a linear siloxane that is primarily used in the production of silicone polymers, resins and rubbers. It is also used as a direct additive in formulations to provide properties such as lubrication, surface wetting, heat transfer, antifoaming or water repellence. Reported uses cover a broad range of industrial, professional and consumer applications including formulation of cosmetics and personal care products, automotive care products, polishes, wax blends and other cleaning formulations. Other reported uses include specialty industrial and electronics applications. In addition to being a direct additive, L4 may also be present in such products as an impurity where silicone polymers or related siloxane materials containing residual L4 are incorporated into the formulation.

The broad range of reported uses indicates the potential for releases throughout the life cycle of the substance, including during professional and consumer uses of the formulated products (ECHA 2025c).

3.3 Alternatives

No information on alternatives to L4 is available (ECHA, 2025c).

[2] GB-based companies who imported substances from EU-based suppliers before UK REACH became law on 1 January 2021 had no EU REACH registration obligations as they were classed as Downstream Users (DUs). As they are now importers from outside of GB, they may have registration obligations under UK REACH. However, a transitional measure allows former DUs to suspend the registration until one of three deadlines (depending on tonnage and hazard). Where the identity of these imported substances was known, they could be included in a Downstream User Import Notification (DUIN) submitted to the Agency.

The Agency considers that the identification of alternatives is likely to be application and function specific, and it is unlikely that a single alternative substance would be capable of replacing L4 across all uses.

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Appendix A Structural read across

Table A1 presents the data matrix for L2, L3, L4 and M3T, based on ECHA (2025b).

Table A1: Data matrix for L2, L3, L4 and M3T

Substance	L2	L3	L4	M3T
Annex under EU REACH (based on tonnage)	10	10	9	9
No of Si atoms	2	3	4	4
Molecular weight (g/mol)	162.8	237	311	311
Vapour pressure (Pa)	5,500 at 25°C, OECD TG 104 (Abbas *et al*., 2011) 5081.8 at 25°C, COSMOTherm	530 at 25°C, OECD TG 104 (Abbas *et al*., 2011) 226 at 25°C, COSMOTherm	73 at 25°C, OECD TG 104 (Abbas *et al*., 2011) 19.1 at 25°C, COSMOTherm	210 at 25°C, and 120 at 20°C), (Unpublished study report, 2017) 35.9 at 25°C, COSMOTherm
Water solubility at 23 °C (mg/L)	0.93 (Varaprath *et al*., 1996) 10.476 at 25°C, COSMOTherm	0.034 (Varaprath *et al*., 1996) 0.51 at 25°C, COSMOTherm	0.0067 (Varaprath *et al*., 1996) 0.011 at 25°C, COSMOTherm	0.002 (Varaprath *et al*., 1996) 0.005 at 25°C, COSMOTherm
Log K_{OW}	5.06, QSAR (Unpublished study report, 2010d) 4.5 at 20°C, COSMOTherm	6.6, OECD TG 123 (Unpublished study report, 2008b) 5.8 at 20°C, COSMOTherm	8.21, OECD TG 123 (Unpublished study report, 2008a) 7.4 at 20°C, COSMOTherm	8.2, QSAR (Unpublished study report, 2015a) 7.6 at 20°C, COSMOTherm

The following similarities and trends in physicochemical properties are presented in ECHA (2025b):

- The physical state of L2, L3, M3T and L4 are all liquids at standard temperature and pressure.

- The substances are highly volatile, but vapour pressure decreases with increasing chain length. Experimental vapour pressure values for L2, L3, M3T and L4 are 5,500, 530, 210 and 73 Pa at 25°C, respectively, determined in a study performed according to OECD TG 104 (Abbas *et al*., 2011; Unpublished study report, 2017).
- The water solubility of the substances is generally low and decreases with chain length. Measured water solubility values for L2, L3, M3T and L4 are 0.93, 0.034 ,0.002 and 0.0067 mg/L at 23°C, respectively, determined in a study which used a method for preparing molecularly dispersed, colloid-free saturated aqueous solutions (Varaprath *et al*., 1996). This study was not performed according to test guidelines but was considered to be a reliable study by the EU REACH registrant as it was conducted according to generally accepted scientific principles.
- The substances all have high log K_{OW} values. L2 has a predicted log K_{OW} of 5.06 (Unpublished study report, 2010d). Measured log K_{OW} values for L3 and L4 of 6.6 and 8.21, respectively, were determined in two studies performed according to OECD TG 123 (Unpublished study reports, 2008a and 2008b). The predicted log K_{OW} value for M3T was 8.2 (Unpublished study report, 2015a

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