Annex 15 Report
Proposal for identification of a substance of very high concern (SVHC)

Octamethyltrisiloxane (L3)

EC Number: 203-497-4

CAS Number: 107-51-7

November 2026

Contents

1 Proposal **5**

2 Justification **8**

2.1 Identity of the substance and physical and chemical properties 8

2.2 Mandatory classification and labelling 10

2.3 Environmental fate properties 10

2.4 Conclusions on the SVHC properties 26

3 Information on use, exposure and alternatives **28**

3.1 UK and EU REACH registration status and tonnage 28

3.2 General description of uses and exposure 28

3.3 Alternatives 29

References **30**

Tables

Table 1: Substance identity....8
Table 2: Constituents other than impurities/additives....9
Table 3: Overview of physicochemical properties of L3....10
Table 4: Summary of abiotic degradation data....11
Table 5: Calculated hydrolysis half-lives of L3....12
Table 6: Summary of screening test results for L3....13
Table 7: Summary of simulation test results for L3....13
Table 8: Distribution of ^{14}C (%) between compartments for each sediment system at day 140....14
Table 9: Average chemical speciation (%) in the two sediment systems at day 140 as fractions of applied radioactivity....15
Table 10: Summary of aquatic bioaccumulation data....19
Table 11: Approximate steady-state concentrations of L3 in fish and resultant $BCF_{SS,L}$ values....21
Table 12: Values of the uptake and depuration rate constants and resultant BCF_{KgL} values, for the simultaneous and sequential methods of determining rate constants....22
Table 13: Calculated BMF values using the standard OECD TG 305 approach....23
Table 14: Relevant parameters and re-calculated BMF values according to OECD TG 305....24

List of abbreviations

B	Bioaccumulative
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
DFOP	Double first-order parallel
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
L3	Octamethyltrisiloxane
LOD	Limit of detection
LOQ	Limit of quantification
MCL	Mandatory classification and labelling
NER	Non-extractable residue
MSC	Member State Committee
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	Theoretical 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: Octamethyltrisiloxane

EC number: 203-497-4

CAS number: 107-51-7

Octamethyltrisiloxane, which is also known as L3, 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, 2024a). 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 provides an independent scientific assessment by the Agency[1] on whether L3 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, 2024b). Relevant observations on studies made in the EU MSC support document have been summarised and Agency comments have been added. Prior to exiting the EU, the UK Competent Authority conducted a Substance Evaluation of L3 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 not performed because the existing information is considered to be sufficient for decision making.

It is proposed to identify L3 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 has been used to identify L3 as vPvB.

[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

A hydrolysis half-life of around 50 days at pH 7 and 12°C can be estimated from a study carried out according to OECD Test Guideline (TG) 111. Hydrolysis is more rapid at pH 5 and 9. However, L3 is highly adsorptive to organic matter, and this is likely to reduce the influence of hydrolysis on environmental fate.

L3 did not fulfil the criteria for ready biodegradability as no mineralisation was observed over 28 days in an OECD TG 310 study (which is suitable for volatile substances). L3 therefore is potentially persistent (P) and very persistent (vP).

A water-sediment aerobic degradation study performed according to OECD TG 308 reported an extrapolated overall system half-life of 416 days or longer at 12°C. There were some 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). Despite the volatility of L3, long half-lives were observed in sediment, and the high adsorption of the substance to organic carbon within the sediment is likely to be a significant factor in this. The Agency considers the study reliable with restrictions and concludes that the half-life in the freshwater sediment was > 180 days. This exceeds the P and vP criteria for freshwater sediment (half-life >120 or >180 days, respectively).

The Agency concludes from the evidence available that L3 fulfils the P and vP criteria of Annex 13 of UK REACH.

Bioaccumulation

L3 screens as potentially bioaccumulative (B) and very bioaccumulative (vB) in aquatic organisms based on a measured n-octanol–water partition coefficient (log K_{OW}) of 6.6 (log K_{OW} > 4.5).

The key data come from an aquatic exposure study performed to OECD TG 305 and GLP, which provided valid growth-corrected, lipid-normalised kinetic values for the bioconcentration factor (BCF). The BCF_{KgL} for *Pimephales promelas* range from 9,615 to 17,146 L/kg.

Further evidence indicative of very bioaccumulative properties is provided by valid growth-corrected, lipid-normalised kinetic BMF_{KgL} values from two dietary exposure studies (conducted in accordance with OECD TG 305) on *Oncorhynchus mykiss.* These ranged from 0.32 to 0.86, resulting in modelled BCF values in the range of 9,087 to 27,833 L/kg. The laboratory-derived dietary BMF values <1 cannot be directly compared to the B/vB criteria, and there are some study limitations (including excessively high fish growth in one study). However, the modelled BCF values are consistent with L3 fulfilling the vB criteria (all estimated values were > 5,000 L/kg). Additionally, depuration rate constant values were lower than those obtained in the aquatic exposure study, suggesting that the BCF of L3 in *O. mykiss* may be higher than in *P. promelas* (assuming similar uptake rates). Based on valid kinetic BCF_{KgL} values for *P. promelas* and the supporting evidence from the

dietary studies, the Agency concludes that L3 meets the criteria for B and vB set out in Annex 13 of UK REACH (BCF > 2,000 and > 5,000 L/kg, respectively). This is consistent with an earlier Substance Evaluation decision by the UK Competent Authority under EU REACH (ECHA, 2017).

Conclusion

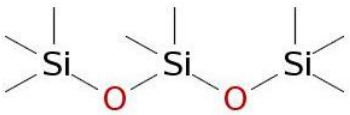
Based on the information available, the Agency concludes that L3 fulfils the vPvB criteria of Annex 13 of UK REACH and can therefore be identified as a SVHC in accordance with Article 57(e).

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:	203-497-4
EC name:	Octamethyltrisiloxane
SMILES[a]	C[Si](C)(C)O[Si](C)(C)O[Si](C)(C)C
CAS number:	107-51-7
IUPAC[b] name:	2,2,4,4,6,6-hexamethyl-3,5-dioxa-2,4,6 trisilaheptane
Index number in GB Mandatory Classification and Labelling (MCL) List[c]:	No mandatory classification
Molecular formula:	$C_8H_{24}O_2Si_3$
Molecular weight range:	236.53 g/mol
Synonyms:	1,1,1,3,3,5,5,5-Octamethyltrisiloxane; dimethyl-bis(trimethylsilyloxy)silane; Trisiloxane Acronyms: L3; MDM
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 Britain

2.1.2 Composition of the substance

Substance type: mono-constituent

Table 2: Constituents other than impurities/additives

Constituents	Typical concentration
L3	≥ 80% w/w

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

No transformation products were considered in ECHA (2024b).

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)

No structurally related substances were considered in ECHA (2024b).

The Agency does not consider it necessary to consider structurally related products due to the findings for the parent substance.

2.1.5 Physicochemical properties

Physicochemical property information reported in ECHA (2024b) are summarised in Table 3. The data have been collated from publicly available sources. The Agency has not independently verified the reliability of this information unless otherwise stated.

L3 is highly volatile and has a vapour pressure of 530 Pa at 25°C (OECD TG 104).

The water solubility of L3 is 0.034 mg/L at 23°C. This was measured in a 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).

Predictive models for physico-chemical (and other) data were used in the SVHC assessment of an analogue as part of a category approach that included L3 (ECHA, 2024b). However, the Agency considers that measured data are preferable. The predictions for L3 have therefore not been considered further by the Agency.

Table 3: Overview of physicochemical properties of L3

Property	Description/value	Method
Physical state at 20°C and 101.3 kPa	Colourless liquid	-
Melting/freezing point (°C)	-87.8 at 101.3 kPa	OECD TG 102 (differential scanning calorimetry; DSC)
Boiling point (°C at 101 325 Pa)	152.4	OECD TG 103 (DSC)
Vapour pressure (Pa at 25°C)	530	OECD TG 104 (static method, ebulliometer)
Water solubility (mg/L at 23°C)	0.034	Non-guideline study
Partition coefficient n-octanol–water (log K_{OW})	6.6 at 25.3°C	OECD TG 123 (slow-stirring method)
Partition coefficient n-octanol–air (log K_{OA})	3.79 ± 0.01 at 20.8°C	High-performance liquid chromatography (HPLC), no method stated (Unpublished study report, 2010a)

2.2 Mandatory classification and labelling

L3 is not listed on the GB 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 (2024b) is summarised in Table 4.

Table 4: Summary of abiotic degradation data

Abiotic degradation process	Information presented	Results
Hydrolysis	Unpublished study (2007) OECD TG 111	Hydrolysis half-life was calculated to be 44.1 days at 12°C and pH 7 (relevant to the freshwater environment)
Oxidation	No data presented	-
Phototransformation	US EPA (2017) Estimated values using AOPWIN	K_{OH} (cm^3 $molecule^{-1}$ s^{-1}): 1.25 x 10^{-12} $kdeg_{air}$ (d^{-1}): 0.054 Estimated DT_{50} of 13 days in air
	Markgraf and Wells (1997)	K_{OH} (cm^3 $molecule^{-1}$ s^{-1}): 1.83 x 10^{-12} $kdeg_{air}$ (d^{-1}): 0.079 Estimated DT_{50} of 8.8 days in air
	Kim and Xu (2017)	K_{OH} (cm^3 $molecule^{-1}$ s^{-1}): 2.15 x 10^{-12} $kdeg_{air}$ (d^{-1}): 0.093 Estimated DT_{50} of 7.5 days in air
	Bernard *et al.* (2018)	K_{OH} (cm^3 $molecule^{-1}$ s^{-1}): 1.72 x 10^{-12} $kdeg_{air}$ (d^{-1}): 0.074 Estimated DT_{50} of 9.3 days in air
	Alton and Browne (2020)	K_{OH} (cm^3 $molecule^{-1}$ s^{-1}): 1.7 x 10^{-12} $kdeg_{air}$ (d^{-1}): 0.073 Estimated DT_{50} of 9.4 days in air

Hydrolysis: ECHA (2024b) presented a study carried out according to OECD TG 111 and GLP. The test was performed at pH 5, 7 and 9, at 10°C, 25°C and 35°C. At pH 5 and pH 9, the half-lives of L3 at 10°C were 0.64 and 2.9 days, respectively. At pH 7 and 10°C, L3 has a relatively long hydrolysis half-life of around 61 days; the interpolated half-life at 12°C was 44.1 days (see Table 5). The study was considered reliable with restrictions (Klimisch score 2) due to some deviations from the guideline.

The Agency calculates a hydrolysis half-life of around 49.7 days at pH 7 and 12°C using the Arrhenius equation and the same values for activation energy and pre-exponential constant as reported in ECHA (2024b). This is also the half-life value reported in the Substance Evaluation for L3 in 2021 (ECHA, 2021). ECHA (2024b) acknowledged that the values differ due to a “new interpretation of the study”, but no further information is provided.

Additionally, L3 is highly adsorptive to organic matter in suspended solids, sediment and soils (Section 2.3.2), which may limit the rate of hydrolysis, increasing the abiotic half-life. This means that the hydrolysis half-life values are given a low weight in this assessment.

Table 5: Calculated hydrolysis half-lives of L3

pH	Temperature (°C)	Half-life (days)	k_{obs} (day^{-1})
6	9	7	0.099
	12	5.5	0.126
	25	2.1	0.330
7	9	58	0.012
	12	44.1	0.016
	25	13.5	0.051
8	9	31.9	0.022
	12	21	0.033
	25	3.9	0.178

Phototransformation in air: A predicted half-life in air of 13 days using the AOPWIN (v1.92) model in EpiSuite™. Academic studies are also available (ECHA 2024b). The predicted value is slightly higher than half-lives measured in four academic studies. The half-life values calculated from the studies ranged from 7.5 to 9.4 days. The four measured values provide a mean DT_{50} in air of 8.75 days.

ECHA (2024b) concluded that the available information demonstrates that L3 is hydrolytically stable. The 13-day half-life from AOPWIN was considered a reasonable and conservative value as it was relatively similar to values provided in academic studies. The measured values are preferred and therefore a DT_{50} of 8.75 days is more relevant. 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 the aquatic environment

2.3.1.2.1.1 Screening tests

One biodegradability screening test for L3 is presented in ECHA (2024b) (summarised in Table 6).

Table 6: Summary of screening test results for L3

Reference	Study type	Results
Unpublished study (2009)	OECD TG 310 study, GLP Pre-adapted inoculum 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.

- Ready biodegradation study (Unpublished study, 2009)

ECHA (2024b) presented a study conducted according to OECD TG 310 and GLP, using domestic activated sludge from a wastewater treatment facility mainly treating residential wastewater. The Agency considers this a suitable test guideline for volatile substances since it involves closed bottles. The study used an L3 concentration of 20 mg/L which is above its water solubility (0.034 mg/L). No biodegradation (CO_2 evolution) was observed over the 28-day test. 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.

ECHA (2024b) concluded that the study is reliable without restriction. The Agency agrees with this conclusion and concludes that L3 is not readily biodegradable.

2.3.1.2.1.2 Biodegradation studies (simulation tests)

The results from a water-sediment simulation study (ECHA 2024b) are summarised in Table 7.

Table 7: Summary of simulation test results for L3

Reference	Study type	Results
Unpublished study (2021b)	OECD TG 308 study, GLP 2 sediment types 12 °C for 140 days, using radiolabelled L3, under aerobic and anaerobic conditions	No significant degradation was observed after 140 days in either sediment.

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

The test was performed according to OECD TG 308 and to GLP. The study was conducted at 12°C for 140 days under aerobic and anaerobic conditions, using radiolabelled L3. Spiking the sediment provided a nominal concentration of 150 ng ^{14}C L3 per g of sediment (dry weight, dw). Only methods and results from the aerobic tests were reported in ECHA (2024b). Two UK-based sediments were used (Calwich Abbey Lake and Emperor Lake, with organic carbon 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 (14% between day 0 to day 7 and 10% between day 7 and day 14 in the Calwich Abbey system, 9.3% between day 0 and day 7 and 3.8% between day 7 and day 14 in the Emperor Lake system). This was attributed to the high 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 8.

Table 8: Distribution of ^{14}C (%) between compartments for each sediment system at day 140

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 (used to dissolve and apply L3) but no solvent controls were included in the study. 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 (trimethyl silanol (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 the support document and is summarised in Table 9.

Table 9: Average chemical speciation (%) in the two sediment systems at day 140 as fractions of applied radioactivity

Media	Substance	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

Non-extractable residues (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 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 its 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 Agency notes that 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.

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 (Klimisch score 2), 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 therefore given a high weight in this assessment.

2.3.1.2.1.3 Biodegradation in soil

One non-standard soil simulation study is included in ECHA (2024b), which is considered to not be reliable (Klimisch score 3).

- Biodegradation in soil (Unpublished study, 2010b)

The study was not performed in accordance with OECD TG 307 or GLP. There was uncertainty around the moisture content of the soil. The soil was air-dried and microbial activity was not measured during the test. Tests were carried out with variable temperature and humidities which resulted in $DegT_{50}$ values ranging from a few days to over 200 days. Due to the use of 100% relative humidity in the study, it is not known how this equates to moisture content in the OECD TG 307. As the study does not allow derivation of reliable half-lives, the study was considered not reliable, and the Agency agrees with this conclusion. Therefore, the study was given no weight in this assessment.

2.3.1.2.1.4 Monitoring data

ECHA (2024b) includes the results of several studies that determined the presence of L3 in a variety of matrices including wastewater treatment plant (WWTP) influent and effluent (<limit of detection (LOD) to 4.6 µg/L), WWTP sludge (<limit of quantification (LOQ) to ~800 ng/g dry weight (dw)), sediment (<LOD to 15.4 ng/g dw), soil (<LOD to 1.16 ng/g dw), dust (<LOQ to 261 ng/m^3), air (<LOD to 743 ng/m^3), and surface freshwater (<LOD to 59.9 ng/L). Biota concentrations are summarised in Section 0. In most cases, sample collection and analytical methods were not described in detail, so the Agency notes that the reliability of this information is unclear.

There were no Environment Agency monitoring data available for the substance.

The presence of L3 in environmental matrices 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 Agency has not considered the monitoring data further.

2.3.1.4 Summary and discussion of degradation

A reliable OECD TG 111 hydrolysis study for L3 in pure water determined a half-life of 49.7 days at 12°C and pH 7, representing freshwater and marine water respectively. Half-lives may be longer in the environment due to sorption to organic matter. Atmospheric degradation half-lives derived from experimental data and QSARs ranged from 7.5 to 13 days.

L3 is not readily biodegradable with 0% biodegradation observed after 28 days in a study carried out to OECD TG 310 that was considered reliable without restriction.

Very little degradation was observed in a water-sediment partially aerobic degradation study performed according to OECD TG 308, with $DegT_{50}$ values of 416 days or longer at 12°C. This study was considered to be reliable with restrictions as there were some 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). However, the Agency considers that the half-life in freshwater sediment was > 180 days.

Degradation half-lives in soil are unknown since only an unreliable non-guideline, non-GLP study has been reported.

L3 has been detected 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 (2024b) provided a brief summary of an OECD TG 106 study (Unpublished study, 2010c). Individual soil organic carbon–water partition coefficient (log K_{OC}) values were 4.28, 4.37 and 4.38 (mean log K_{OC} of 4.34) which indicates a high potential to adsorb to organic matter in sediment and soils. The similarity of K_{OC} values and isotherms derived in the test indicate that L3 partitioning into soil organic matter dominated the overall sorption from water.

2.3.2.2 Volatilisation

L3 has a high vapour pressure (530 Pa at 25°C) and low water solubility (0.034 mg/L at 23°C).

ECHA (2024b) calculated the Henry's Law constant as 3.59 x 10^6 Pa m^3/mole at 25°C and 1.72 x 10^6 Pa m^3/mole at 12°C ECHA (2024b) also presented Henry's Law constant of 2.68×106 Pa m^3 mol^{-1} at 20.8°C and 1.62×106 Pa m^3 mol at 12°C based on a log K_{AW} of 3.04 obtained from an OECD TG 117 study, rated by the EU REACH registrants as 'reliable with restrictions' (Klimisch score 2).

The relatively high Henry's Law constant indicates that the substance will be volatile in the environment, transferring readily from the water phase to air unless already adsorbed to organic carbon.

2.3.2.3 Distribution modelling

The environmental distribution of L3 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 (2024b) presents level III fugacity modelling for L3 (from US-EPA EPI Suite (v4.11))) using loading rates for air, soil, and water of 1,000 kg/h:

- Equal release of L3 to air, soil and water is predicted to result in 27.5% in air, 38.4% in water, 0.858% in soil, and 33.3% in sediment.
- L3 released entirely into water is expected to partition roughly equally to the sediment (43.1%) and water (49.7%).
- L3 released entirely into soil is expected to mainly partition to air (92.7%) with the

rest remaining in soil (7.27%).

- L3 released into air is expected to remain there (100%).

2.3.2.4 Estimation of long-range transport potential (LRTP)

ECHA (2024b) used the OECD P_{OV} and LRTP screening tool version 2.213 (Wegmann *et al*., 2009) to conclude that L3 is able to undergo long-range atmospheric transport in air. 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 6.6 at 25.3°C (see Section 2.1.5) suggests the potential for bioaccumulation. The EU REACH registrant considered this study 'reliable without restriction' (Klimisch 1).

The measured log K_{OA} for L3 of 3.79 at 20.8°C (see Section 2.1.5) does not exceed the screening criteria for bioaccumulation in air breathing organisms (log K_{OW} > 2 and log K_{OA} > 5).

2.3.3.2 Aquatic bioaccumulation data

Three aquatic bioaccumulation studies are presented in ECHA (2024b), as summarised in Table 10.

Table 10: Summary of aquatic bioaccumulation data

Reference	Study type	Results / comments
Unpublished study (2006)	OECD TG 305, GLP Aqueous exposure over 42 days using *Pimephales promelas* (Fathead Minnow) Reliable with restrictions (Klimisch score 2)	Exposure concentration 1.7 µg/L BCF_{KgL} = 9,615 L/kg Exposure concentration 21 µg/L BMF_{KgL} = 17,146 L/kg

Reference	Study type	Results / comments
Unpublished study (2010d)	OECD TG 305, GLP Dietary exposure over 65 days using *Oncorhynchus mykiss* (Rainbow Trout) carried out broadly in line with OECD TG 305. Reliable with restrictions (Klimisch score 2)	BMF_{KgL} = 0.86 BCF values calculated from the depuration rate constant (k_2 = 0.0404 d^{-1}) using the OECD BCF estimation tool: Method 1: Median $BCF_{kinetic}$ 11,399 L/kg (with outliers removed) Method 2: $BCF_{kinetic}$ 9,087 L/kg Method 3: BCF 11,635 L/kg
Cantu and Gobas (2024)	OECD TG 305 Dietary exposure over 95 days using *O. mykiss* Reliable with restrictions (Klimisch score 2)	BMF_{KgL} = 0.315 BCF values calculated from the depuration rate constant (k_2 = 0.0212 d^{-1}) using the OECD BCF estimation tool: Method 1: Median $BCF_{kinetic}$ 13,034 L/kg Method 2: $BCF_{kinetic}$ 27,833 L/kg Method 3: BCF 5,065 L/kg

- Unpublished study (2006), OECD TG 305 with aqueous exposure

The study was carried out according to OECD TG 305 and to GLP, with some minor deviations. The validity criteria specified in the test guideline were fulfilled. *P. promelas* were exposed to 1.7 and 21 µg/L L3 (mean measured concentrations, from stock solutions of ^{14}C-labelled L3 in dimethylformamide) over a 42-day uptake phase, followed by a 10-day depuration phase.

Radioactivity in the fish was 97.7% L3, 1.4% unknown transformation product, and 0.9% not extracted; reported concentrations were corrected to reflect L3 only. Concentrations were measured on a whole fish basis.

ECHA (2024b) noted that only the 1.7 µg/L treatment group reached a 95% reduction in body burden at the end of the depuration phase as specified in OECD TG 305, with a 91.5% reduction for the 21 µg/L treatment group. In addition, the concentrations of L3 in fish showed a high variability at some timepoints, and trace amounts (1.19 to 3.71 µg/L) of L3 were detected in the water for the 21 µg/L treatment group during the depuration phase, indicating potential contamination. No positive controls were applied.

Steady-state BCF (BCF_{SS}) values were determined in the original study, but one of the criteria for confirming steady state was not fulfilled in either treatment group (concentrations were not within ± 20% of one another). Normalisation to 5% lipid content

provided $BCF_{SS,L}$ values of 18,292 and 26,916 L/kg for the 1.7 and 21 µg/L treatment groups, respectively, using the mean lipid value recorded at the end of the uptake phase. However, as a significant decrease in lipid content was observed over the duration of the study, lipid-normalised BCF values accounting for the change in lipid content were also calculated in ECHA (2024b), resulting in $BCF_{SS,L}$ values (normalised to 5% lipid content) of 12,381 and 21,819 L/kg for the 1.7 and 21 µg/L treatment groups, respectively. Detailed calculation methods are described in ECHA (2024b).

Relevant data are summarised in Table 11.

Table 11: Approximate steady-state concentrations of L3 in fish and resultant BCFSS,L values

Treatment group	Mean "steady state"[a] L3 concentration in fish (µg/kg ww)	Mean "steady state"[a] L3 concentration in water (µg/L)	Mean lipid content at end of uptake phase (%)	$BCF_{SS,L}$ (L/kg)	$BCF_{SS,L}$ accounting for changing lipid content (L/kg)
1.7 µg/L	8,543	1.68	1.39	18,292	12,381
21 µg/L	161,226	21.68	1.39	26,916	21,819

[a] Steady state BCFs were determined, but one of the criteria for confirming steady state was not fulfilled in both treatment groups (concentrations were not within ± 20% of one another).

It was noted in ECHA (2024b) that kinetic BCF values are preferred given that steady state could not be confirmed. As a decrease in fish weight was observed over the course of the study, growth-corrected depuration rate constants (k_2) were calculated and used to derive growth-corrected lipid-normalised kinetic BCF values (BCF_{KgL}). ECHA (2024b) stated that the study report provided no explanation for the decrease and does not inform about any observed abnormalities in the fish. Using values of BCF_K determined in the EU REACH registration dossier using the simultaneous method resulted in values of BCF_{KgL} of 12,880 and 19,869 L/kg for the 1.7 and 21 µg/L treatment groups, respectively.

Given the variability in fish concentrations at the end of the uptake phase and potential L3 contamination, BCF_K values were also determined using the sequential method in ECHA (2024b). This resulted in BCF_{KgL} values of 13,716 and 22,496 L/kg for the 1.7 and 21 µg/L treatment groups, respectively. When accounting for changing lipid content over time, the BCF_{KgL} values were determined as 9,615 and 17,146 L/kg. Relevant data are summarised in Table 12.

Table 12: 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					
1.7 µg/L	1,213	0.336	-0.002	12,880	Not determined
21 µg/L	1,042	0.186	-0.002	19,869	Not determined
Sequential method					
1.7 µg/L	1,196	0.311	-0.002	13,716	9,615
21 µg/L	1,257	0.199	-0.002	22,496	17,146

From the results of the study, it was concluded that all kinetic BCF values were above 5,000 L/kg (when lipid-normalised). It was noted that although the k_2 values indicated relatively rapid depuration (0.199 to 0.311 day^{-1}), the k_1 values were higher than expected, resulting in high BCF values.

ECHA (2024b) concluded that the study was reliable with restrictions (Klimisch score 2). The Agency agrees with this assessment and the study interpretation.

- Unpublished study (2010d), OECD TG 305 with dietary exposure

The study was carried out prior to the dietary exposure part of OECD TG 305 being published, but was broadly in line with the TG, and most validity criteria were fulfilled. The study was performed in accordance with GLP. However, there were some test guideline deviations:

- The dissolved oxygen levels fell below 60% of the air saturation from day 47 until study end (day 65), though no mortality or adverse effects were observed as a result.
- It could not be concluded whether the concentration of test substance in fish food at the start of the experiment and end of the uptake phase was within ± 20%, as the concentrations were not measured at the start and end of the uptake phase (day 0 and 35). However, it was noted that the concentration 21 days before the start of the experiment were within ± 20% of the concentrations 10 days before and after the end of the uptake phase. Additionally, this was based on duplicate samples as opposed to recommended triplicate samples at both time points.
- A feeding rate of 3% was applied rather than 1 to 2% as recommended in the OECD TG 305, and excessive growth of the fish was reported (average weight increased from 0.64 to 7.81 g).

O. mykiss were exposed to 436 µg/g radiolabelled L3 in food for a 35-day uptake phase, followed by a 30-day depuration phase. Fish and their gastrointestinal tracts were removed

and analysed separately during the uptake phase. Fish livers were analysed separately during the depuration phase. It was not clear whether liver and gastrointestinal tract concentrations were added to the total concentrations. Steady state was reached on day 21 of the test (all criteria fulfilled).

A 5% lipid-normalised steady-state biomagnification factor ($BMF_{SS,L}$) was calculated as 0.38 (based on a mean steady state fish concentration of 45.9 µg/g, a time-weighted mean fish lipid content of 5.2%, and food lipid content of 17.9%).

The assimilation efficiency (α) was presented as 0.32 in the study report, but was not calculated according to the method recommended in the OECD TG. ECHA (2024b) recalculated the assimilation efficiency as 0.37. These values were used with a k_2 of 0.085 day^{-1} to determine 5% lipid-normalised kinetic BMF values corrected for a growth dilution rate constant (k_g) of 0.0404 day^{-1}, according to the OECD TG 305. The resultant BMF_{KgL} values are summarised in Table 13.

Table 13: 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})	Lipid correction factor	α	BMF_{KgL}
0.03	0.085	0.0404	0.29	0.32	0.75
				0.37	0.86

BMF_{KgL} values were also determined with incorporation of the change in lipid content in fish over time (the method was stated to be the same as that applied for the aquatic exposure study). Resultant BMF_{KgL} values for α of 0.32 and 0.37 were 0.60 and 0.69, respectively. BMF_{KgL} values for L3 ranged from 0.69 to 0.86.

BCF values were also determined using the OECD Dietary BCF Estimation Tool. The most relevant estimates were derived from method 1, ranging from 8,019 to 18,959 L/kg with a median BCF of 11,399 L/kg (excluding outliers as recommended in the OECD TG 305). From method 2, a BCF of 9,087 L/kg was derived. The BCF provided from method 3 was 11,635 L/kg. It was 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 L3, but that caution should be applied given that training set compounds are dominated by aromatics and halogenated aromatics, so L3 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. The potential hydrolysis of L3 at the low pH in fish stomachs was also discussed, as this may result in lower concentrations of L3 in the digested food.

Overall, the modelled BCF values significantly exceed 5,000 L/kg. ECHA (2024b) notes that further support to this finding is the k_{2g} values measured for *O. mykiss* in the study. These were lower than those observed in the aquatic exposure study for *P. promelas*, suggesting that BCF may be higher in *O. mykiss* (assuming a similar uptake rate constant)

and therefore also > 5,000 L/kg.

ECHA (2024b) concluded that the study is reliable with restrictions (Klimisch score 2). The Agency agrees with this conclusion and the interpretation.

- Cantu and Gobas (2024), OECD TG 305 with dietary exposure

Bioaccumulation in *O. mykiss* was assessed according to a modified OECD TG 305 method, with dietary exposure to L3 together with 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. The contents of fish gastrointestinal tracts were removed before analysis. Different equations to those given in the OECD TG were used by the study authors to derive a k_2 of 0.03 day^{-1} and a lipid-normalised BMF of 0.24 (kg lipid kg^{-1} fish) for L3. The study fulfilled the OECD TG 305 validity criteria, except that dissolved oxygen concentrations were not reported.

BMF values were re-calculated in ECHA (2024b) according to OECD TG 305. Relevant parameters and results are summarised in Table 14.

Table 14: Relevant parameters and re-calculated BMF values according to OECD TG 305

k_2 (day^{-1})	Concentration in food (mg/kg)	Feeding rate (%)	α	k_g (day^{-1})	Lipid correction factor	BMF_{KgL}
0.031	998	1.25	0.1467	0.0099	0.275	0.315

A BCF was also calculated by the study authors from k_1 and k_2, but it was noted in ECHA (2024b) that this calculation is not in line with REACH R.11 guidance (ECHA, 2016) or OECD TG 305. The OECD Dietary BCF Estimation Tool was therefore applied, resulting in estimated BCF values. For method 1, the median BCF was 13,022 L/kg (with a range of 8,923 to 47,340 L/kg) and for method 2, the BCF was 27,800 L/kg. 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.

Overall, the modelled BCF values indicate a high bioaccumulation potential for L3 (BCF > 5,000). The Agency notes that the growth-corrected k_2 of 0.0212 day^{-1} for *O. mykiss* is the slowest depuration rate of all three bioaccumulation studies for L3. The two dietary exposure studies on *O. mykiss* had slower depuration rates compared with the depuration rates observed in the aqueous exposure study which resulted in a BCF above 5,000 L/kg.

ECHA (2024b) concluded that this study is reliable with restrictions. The Agency agrees with this conclusion and the interpretation of the study.

2.3.3.3 Toxicokinetics

ECHA (2024b) included a toxicokinetic study that suggests an approximate elimination half-life < 24 hours in rats (Unpublished study, 2017), although this may be unreliable.

2.3.3.4 Field data

ECHA (2024b) stated that levels of L3 have been reported in phytoplankton (6.1 to 88 pg/g dw), invertebrates (<LOD to 10.7 ng/g dw) and fish (<LOD to 0.33 ng/g wet weight (ww)). The highest observed concentration of L3 in biota reported in ECHA (2024b) is 10.7 ng/g dw, for bivalves from South Korea. In most cases, sample collection and analytical methods were not described in detail so the reliability of this information is unclear.

No studies reporting field BMF or trophic magnification factor (TMF) values were provided in ECHA (2024b).

The presence of L3 in biota shows that it is bioavailable, but the absence of contemporary exposure concentrations means this information cannot be used in the assessment of bioaccumulation potential. Given the availability of laboratory data that can be directly compared with the Annex 13 criteria, the monitoring data have not been examined further.

2.3.3.5 Summary and discussion of bioaccumulation

Based on the experimental log K_{OW} of 6.6 (OECD TG 123; slow-stirring method), L3 has the potential for bioaccumulation in aquatic species.

Valid growth-corrected, lipid-normalised kinetic BCF values from an aquatic exposure study (OECD TG 305) on *P. promelas* range from 9,615 to 17,146 L/kg (when corrected for changes in fish lipid content over time); the data are reliable with restrictions.

Valid growth-corrected, lipid-normalised kinetic BMF values from two dietary exposure studies (OECD TG 305) on *O. mykiss* range from 0.32 to 0.86, resulting in modelled BCF values ranging from 9,087 to 27,833 L/kg (a lower value was derived using a less reliable model method 3 of 5,065 L/kg which is still above the 5,000 criterion). The Agency notes that these two studies have some limitations, including excessively high fish growth in one. However, the depuration rate constant values are lower than those obtained in the aquatic exposure study, suggesting that the BCF of L3 in *O. mykiss* may be higher than in *P. promelas* (assuming similar uptake rates). L3 has been detected in biota.

The available toxicokinetic data are insufficient to conclude on the bioaccumulation potential of L3 in air-breathing organisms, although the substance does not screen as potentially bioaccumulative as it is volatile.

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 L3 as vPvB.

Persistence

A hydrolysis half-life of around 50 days at pH 7 and 12°C can be estimated from a study carried out according to OECD TG 111. Hydrolysis is more rapid at pH 5 and 9. However, L3 is highly adsorptive to organic matter, and this is likely to reduce the influence of hydrolysis on environmental fate.

L3 did not fulfil the criteria for ready biodegradability as no mineralisation was observed over 28 days in an OECD TG 310 study (which is suitable for volatile substances). L3 therefore is P and vP.

A water-sediment aerobic degradation study performed according to OECD TG 308 reported an extrapolated overall system half-life of 416 days or longer at 12°C. There were some 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). Despite the volatility of L3, long half-lives were observed in sediment, and the high adsorption of the substance to organic carbon within the sediment is likely to be a significant factor in this. The Agency considers the study reliable with restrictions and concludes that the half-life in the freshwater sediment was > 180 days. This exceeds the P and vP criteria for freshwater sediment (half-life >120 or >180 days, respectively).

The Agency concludes from the evidence available that L3 fulfils the P and vP criteria of Annex 13 of UK REACH.

Bioaccumulation

L3 screens as potentially B and vB in aquatic organisms based on a measured log K_{OW} of 6.6 (log K_{OW} > 4.5).

The key data come from an aquatic exposure study performed to OECD TG 305 and GLP, which provided valid growth-corrected, lipid-normalised kinetic values for the BCF. The BCF_{KgL} for *P. promelas* range from 9,615 to 17,146 L/kg.

Further evidence indicative of very bioaccumulative properties is provided by valid growth-corrected, lipid-normalised kinetic BMF_{KgL} values from two dietary exposure studies (conducted in accordance with OECD TG 305) on *O. mykiss.* These ranged from 0.32 to 0.86, resulting in modelled BCF values in the range of 9,087 to 27,833 L/kg. The laboratory-derived dietary BMF values <1 cannot be directly compared to the B/vB criteria, and there are some study limitations (including excessively high fish growth in one study).

However, the modelled BCF values are consistent with L3 fulfilling the vB criteria (all estimated values were > 5,000 L/kg). Additionally, depuration rate constant values were lower than those obtained in the aquatic exposure study, suggesting that the BCF of L3 in *O. mykiss* may be higher than in *P. promelas* (assuming similar uptake rates). Based on valid kinetic BCF_{KgL} values for *P. promelas* and the supporting evidence from the dietary studies, the Agency concludes that L3 meets the criteria for B and vB set out in Annex 13 of UK REACH (BCF > 2,000 and > 5,000 L/kg, respectively). This is consistent with an earlier Substance Evaluation decision drawn by the UK Competent Authority under EU REACH (ECHA, 2017).

2.4.2 Overall conclusions on the vPvB properties

Based on the information available, the Agency concludes that L3 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

Under UK REACH, the substance is registered with an aggregated tonnage of 100-1,000 tonnes per annum (tpa).

A total 58 Downstream User Import Notifications (DUINs[2]) have been submitted under UK REACH.

Under EU REACH, the substance is registered with an aggregated tonnage of 1,000 – 10,000 (nine active EU registrants).

3.2 General description of uses and exposure

L3 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 certain 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, other cleaning and maintenance products, adhesives, sealants, coatings, inks and toners. In addition to being a direct additive, L3 may also be present in such products as an impurity where silicone polymers or related siloxane materials containing residual L3 are incorporated into the formulation. Other reported uses include specialty industrial and electronics applications.

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, 2024c).

[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.

3.3 Alternatives

Potential alternatives to L3 have been identified, although their suitability depends on the intended use. It is recognised that substitution may be easier for some applications than others and it is unlikely that the full range of properties provided by L3 could be replaced by a single alternative substance. In practice, alternatives are likely to be selected to replace specific functions provided by L3 and reformulation may require a combination of other substances to achieve comparable performance. As an example, ECHA (2024c) noted that when used in cosmetics, linear siloxanes such as L3 could be replaced with a mixture of vegetable oils owing to their similar physicochemical properties. Alternatives for use in cleaning agents, where L3 is used for its antifoaming properties or to provide gloss or surface finishing properties, have been more difficult to identify.

References

Alton, M. W. & Browne, E. C. (2020). Atmospheric chemistry of volatile methyl siloxanes: Kinetics and products of oxidation by oh radicals and cl atoms. Environ Sci Technol, 54(10), 5992-5999. 10.1021/acs.est.0c01368

Bernard, F., Papanastasiou, D. K., Papadimitriou, V. C. & Burkholder, J. B. (2018). Temperature dependent rate coefficients for the gas-phase reaction of the oh radical with linear (l(2), l(3)) and cyclic (d(3), d(4)) permethylsiloxanes. J Phys Chem A, 122(17), 4252-4264. 10.1021/acs.jpca.8b01908

Cantu, M. A. & Gobas, F. (2024). Bioaccumulation of linear siloxanes in fish. Environ Toxicol Chem, 43(1), 42-51. 10.1002/etc.5760

European Chemicals Agency (ECHA). (2016). Chapter R.11: PBT and vPvB assessment, Guidance on Information Requirements and Chemical Safety Assessment. European Chemicals Agency. Helsinki, Finland. https://data.europa.eu/doi/10.2823/515110

ECHA. (2017). Decision on substance evaluation. European Chemicals Agency. Helsinki. https://chem.echa.europa.eu/api-activity-list/v1/substanceEvaluation/documents?name=7fb84b3653b2a19c2b337ecca80c9c07_SEV-203-497-4-1_DEC_Final_REG_PUBLIC_en.pdf

ECHA. (2021) Substance Evaluation Conclusion As Required By Reach Article 48 And Evaluation Report for Octamethyltrisiloxane (L3) Available at: https://chem.echa.europa.eu/api-activity-list/v1/substanceEvaluation/documents?name=7fb84b3653b2a19c2b337ecca80c9c07_SEV-203-497-4-1_conclusion_public.pdf

ECHA. (2024a). Member State Committee support document for identification of octamethyltrisiloxane as a substance of very high concern because of its vPvB (Article 57e) properties. European Chemicals Agency. Available at: https://echa.europa.eu/documents/10162/c93548a0-e826-f7aa-00b6-e0f06c0c4e0d

ECHA. (2024b). Inclusion of substances of very high concern in the Candidate List for eventual inclusion in Annex XIV. [D(2024)7663-DC]. European Chemicals Agency. Helsinki. Available at: https://echa.europa.eu/documents/10162/fe683d44-f2a2-cd2c-d2fd-a714cb339f69

ECHA. (2024c) Proposal for identification of a substance of very high concern on the basis of the criteria set out in REACH Article 57 for Octamethyltrisiloxane. European Chemicals Agency. Available at: https://echa.europa.eu/documents/10162/50af4c82-3704-5444-c958-f8d7f2cab589

ECHA. (2024d) Comments on an Annex XV dossier for identification of a substanceas SVHC and responses to these comments for Octamethyltrisiloxane. European Chemicals Agency. Available at https://chem.echa.europa.eu/api-obligation-

list/v1/candidateList/documents?name=8115da88b7dda58868f5e7bdf4d68c9d_svhc_msc_rcom_octamethyltrisiloxane_pub_en.rtf

FOCUS. (2014). Generic guidance for estimating persistence and degradation kinetics from environmental fate studies on pesticides in EU registration. Report of the FOCUS work group on degradation kinetics. Available at: https://esdac.jrc.ec.europa.eu/public_path/projects_data/focus/dk/docs/FOCUSkineticsvc1.1Dec2014.pdf

Kim, J. & Xu, S. (2017). Quantitative structure-reactivity relationships of hydroxyl radical rate constants for linear and cyclic volatile methylsiloxanes. Environ Toxicol Chem, 36(12), 3240-3245. 10.1002/etc.3914

Markgraf, S. J. & Wells, J. R. (1997). The hydroxyl radical reaction rate constants and atmospheric reaction products of three siloxanes. International Journal of Chemical Kinetics, 29(6), 445-451. 10.1002/(sici)1097-4601(1997)29:6<445::Aid-kin6>3.0.Co;2-u

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.: European Commission. Available at: http://data.europa.eu/eli/reg/2006/1907/2022-12-17

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance). European Commission. Available at: http://data.europa.eu/eli/reg/2008/1272/2026-05-01

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance). UK Government. Available at: https://www.legislation.gov.uk/eur/2008/1272/contents

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (Text with EEA relevance). UK Government. Available at: https://www.legislation.gov.uk/eur/2006/1907/contents

Unpublished study report (2006). Bioaccumulation in fish: aqueous exposure of L3. OECD TG 305.

Unpublished study report (2007). Hydrolysis of L3 as a function of pH. OECD TG 111.

Unpublished study report (2009b). Ready biodegradability of L3 - CO_2 in sealed vessels (headspace test). OECD TG 310.

Unpublished study report (2010a). Adsorption – desorption of L4 using a batch equilibrium method OECD TG 106.

Unpublished study report (2010b). Study on the effect of temperature and relative humidity in air on the degradation of L3. Non guideline study.

Unpublished study report (2010c). Partition Coefficient of L4 (n-octanol / water), HPLC method OECD TG 117.

Unpublished study report (2010d). Bioaccumulation in fish: dietary exposure of L3 OECD TG 305.

Unpublished study report (2017). L3 study partly based on OECD TG 414 prenatal developmental toxicity study.

Unpublished study report (2021b). Study on L3 - aerobic and anaerobic transformation in aquatic sediment systems. OECD TG 308.

Varaprath, S., Frye, C. L. & Hamelink, J. (1996). Aqueous solubility of permethylsiloxanes (silicones). Environmental Toxicology and Chemistry, 15(8), 1263-1265. 10.1002/etc.5620150803

Wegmann, F., Cavin, L., MacLeod, M., Scheringer, M., & Hungerbühler, K. (2009). The OECD software tool for screening chemicals for persistence and long-range transport potential. Environmental Modelling & Software, 24(2), 228-237.

Further information

For information about health and safety, or to report inconsistencies or inaccuracies in this guidance, visit the HSE website.

You can order HSE priced publications at the HSE books website.

HSE priced publications are also available from bookshops.

This publication is available on the HSE website here

© Crown copyright If you wish to reuse this information visit the HSE website for details. First published [11/26].

Published by the Health and Safety Executive [11/26].