Annex 15 Report

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

1,1,1,3,5,5,5-Heptamethyl-3-[(trimethylsilyl)oxy]trisiloxane

EC Number: 241-867-7

CAS Number: 17928-28-8

November 2026

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List of abbreviations

AR	Applied radioactivity
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
DEGME	Diethylene glycol methyl ether
DFOP	Double first-order in parallel
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
DUIN	Downstream User Import Notifications
ECHA	European Chemicals Agency
EC	European Community
EU	European Union
FOMC	First-order multicompartment
GB	Great Britain
HPLC	High-performance liquid chromatography
HS	Hockey-stick model
IUPAC	International Union of Pure and Applied Chemistry
K_{ow}	n-Octanol–water partition coefficient
L2	Hexamethyldisiloxane
L3	Octamethyltrisiloxane
L4	Decamethyltetrasiloxane
LSC	Liquid Scintillation Counting
M3T	1,1,1,3,5,5,5-heptamethyl-3 [(trimethylsilyl)oxy]trisiloxane
MCL	Mandatory classification and labelling

MSC	Member State Committee
NER	Non-extractable residues
OC	Organic carbon
OECD	Organisation for Economic Cooperation and Development
P	Persistent
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
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: 1,1,1,3,5,5,5-heptamethyl-3-[(trimethylsilyl)oxy]trisiloxane

EC number: 241-867-7

CAS number: 17928-28-8

1,1,1,3,5,5,5-Heptamethyl-3-[(trimethylsilyl)oxy]trisiloxane, which is also known as M3T, 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 provides an independent scientific assessment by the Agency[1] on whether M3T should be identified as an 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), except where stated otherwise. Relevant observations on studies made in the EU MSC support document have been summarised and Agency comments have been added. The unpublished study reports were not available and therefore were not examined, unless stated otherwise. A literature search was considered unnecessary, as the existing information was considered to be sufficient for decision making.

It is proposed to identify M3T 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 M3T as vPvB. This involved a read-across approach using Decamethyltetrasiloxane (L4) for some endpoints. L4 is the linear isomer of M3T, with the same molecular weight and is expected to have very similar physicochemical properties to M3T.

Persistence

M3T did not fulfil the criteria for ready biodegradability (no mineralisation was observed over 28 days in an OECD TG 301F study) and therefore it is potentially persistent (P) and very persistent (vP).

A water-sediment aerobic degradation study performed according to OECD Test Guideline

[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.

(TG) 308, reported an extrapolated sediment half-life of 133 days and >10,000 days at 12°C in two sediments. There were some issues with M3T recovery, a low oxygen saturation in the test systems, and $DegT_{50}$ values were extrapolated beyond the study period (100 days). However, the study is considered to be reliable with restrictions and concludes that the half-life in one freshwater sediment was > 180 days. This exceeds the P and vP criteria for freshwater sediment (half-life > 120 days or 180 days, respectively).

The Agency concludes from the evidence available that M3T fulfils the P and vP criteria of Annex 13 of UK REACH.

Bioaccumulation

M3T screens as potentially bioaccumulative (B) and very bioaccumulative (vB) in aquatic organisms based on a likely n-octanol–water partition coefficient (log K_{OW}) of ~8 at 20°C (derived by read-across from L4 and predictions of unknown validity) (log K_{OW} > 4.5). It also screens as potentially bioaccumulative in air breathing organisms based on the log K_{OW} and a predicted log K_{OA} value of 5.09 at 20°C (log K_{OW} > 2 and log K_{OA} > 5), although the log K_{OA} value is based on a prediction of unknown reliability.

An aqueous exposure study was performed to OECD TG 305 using *Oncorhynchus mykiss* (Rainbow Trout). Several limitations were identified, including exposure concentrations above the water solubility limit. A steady state bioconcentration factor (BCF_{SS}) of 5,979 L/kg can be calculated assuming the fish were exposed at the water solubility limit. The Agency considers the study to have a medium weight in the bioaccumulation assessment.

Given the uncertainties in this study, a read-across approach has also been used, based on data for the close analogue L4:

- An aquatic exposure study performed to OECD TG 305 using *Pimephales promelas* (Fathead Minnow) yielded a lipid-normalised 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.

The Agency concludes from the evidence available, particularly the read-across approach to L4, that M3T fulfils the B and vB criteria (BCF > 2,000 or > 5,000 L/kg, respectively) of Annex 13 of UK REACH.

Conclusion

Based on the information available, the Agency concludes that M3T fulfils the vPvB criteria of Annex 13 of UK REACH and can therefore be identified as an SVHC in accordance with Article 57(e).

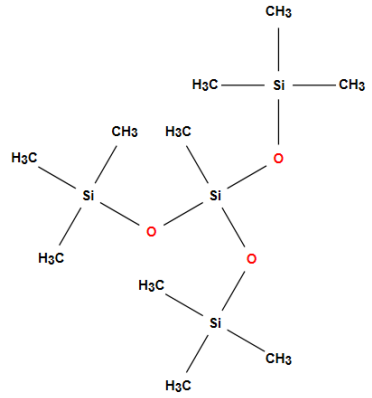
2 Justification

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:	241-867-7
EC name:	1,1,1,3,5,5,5-heptamethyl-3-[(trimethylsilyl)oxy]trisiloxane
CAS number:	17928-28-8
SMILES[a]	C[Si](C)(C)O[Si](C)(O[Si](C)(C)C)O[Si](C)(C)C
IUPAC[b] name:	2,2,4,6,6-pentamethyl-4-[(trimethylsilyl)oxy]-3,5 dioxa-2,4,6-trisilaheptane
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:	310.688 g/mol
Synonyms:	Trisiloxane; 1,1,1,3,5,5,5-heptamethyl-3-(trimethylsiloxy); Methyltris(trimethylsiloxy)silane; Tris(trimethylsiloxy)methylsilane Acronyms: M3T, TMF-1.5

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 retain Regulation (EC) No 1271/2008 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
M3T	≥ 80% w/w

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

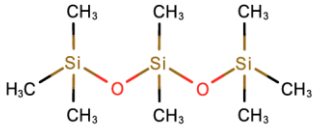
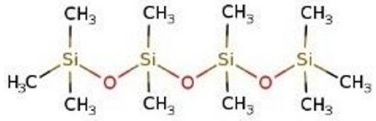
No transformation products were considered in ECHA (2025b). The Agency does not consider it necessary to consider transformation products as part of this assessment.

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 to Hexamethyldisiloxane (L2), Octamethyltrisiloxane (L3) and L4 following the ECHA Read-Across Assessment Framework (RAAF; ECHA, 2017), including a one-to-one read-across to L4. Substance identities are provided in Table 3.

Table 3: Structurally related substance(s) identity, L2, L3 and L4

EC name:	Hexamethyldisiloxane (L2)	Octamethyltrisiloxane (L3)	Decamethyltetrasiloxane (L4)
EC number	203-492-7	203-497-4	205-491-7
CAS number	107-46-0	107-51-7	141-62-8
IUPAC name:	trimethyl[(trimethylsilyl)oxy]silane	2,2,4,4,6,6-hexamethyl-3,5-dioxa-2,4,6-trisilaheptane	2,2,4,4,6,6,8,8-octamethyl-3,5,7-trioxa-2,4,6,8 tetrasilanonane
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

M3T 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.

M3T is a structural isomer of L4. L4 is linear, whereas M3T is a branched structure of four Si atoms, the longest chain contains three Si atoms and two O atoms, with the middle Si atom in the chain containing the Si-O branch. The Agency notes that branched substances can be more resistant to metabolism than linear equivalents.

Similarity in physicochemical properties

ECHA (2025b) provided a data matrix to support the reach-across approach (replicated in Appendix A). In addition to property data reported in the relevant EU REACH registration dossiers, the data matrix included the predicted physicochemical data using the COSMOTherm model 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 details on the COSMOTherm predictions (including a reliability assessment and model version) were provided in ECHA (2025b).

The table provided in ECHA (2025b) also provided a comparison of various environmental fate parameters. This is discussed in the 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 M3T and its isomer L4 due to the branched structure of M3T; L4 is slightly less volatile but slightly more water soluble. The Agency agrees that 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 M3T 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)	-78.7 to -76.3	OECD TG 102 (Unpublished study report, 2012)
Boiling point (°C at 101 325 Pa)	180	Unspecified QSAR (Unpublished study report, 2015a)
Boiling point (°C)	179.39	COSMOTherm (Glüge and Scheringer, 2023)
Vapour pressure (Pa at 25 °C)	210	OECD TG 104 (Unpublished study report, 2017)
Vapour pressure (Pa at 20 °C)	23.45	COSMOTherm (Glüge and Scheringer, 2023)
Vapour pressure (Pa at 25 °C)	35.89	COSMOTherm (Glüge and Scheringer, 2023)
Density (g/cm^3 at 20 °C)	0.91	Unspecified QSAR (Unpublished study report, 2015b)
Water solubility (mg/L at 23 °C)	0.002	(Varaprath *et al.*, 1996)
Water solubility (mg/L at 20 °C)	0.0049	COSMOTherm (Glüge and Scheringer, 2023)
Water solubility (mg/L at 25 °C)	0.005	COSMOTherm (Glüge and Scheringer, 2023)
Partition coefficient n-octanol–water (log K_{OW}) (at 20 °C)	8.2	Unspecified QSAR (Unpublished study report, 2015c)
Partition coefficient n-octanol–water (log K_{OW}) (at 20 °C)	7.64	COSMOTherm (Glüge and Scheringer, 2023)
Partition coefficient n-octanol–water (log K_{OW}) (at 25 °C)	7.66	COSMOTherm (Glüge and Scheringer, 2023)

Partition coefficient air–water (log K_{AW}) (at 20 °C)	2.78	COSMOTherm (Glüge and Scheringer, 2023)
Partition coefficient air–water (log K_{AW}) (at 25 °C)	2.96	COSMOTherm (Glüge and Scheringer, 2023)
Partition coefficient n-octanol–air (log K_{OA}) (at 20 °C)	5.09	COSMOTherm (Glüge and Scheringer, 2023)
Dissociation constant	No ionisable groups	No study performed. No ionic structure.

The water solubility of M3T is 0.002 mg/L based on a study performed at 23°C (Varaprath *et al*., 1996). No further details on the study are provided in ECHA (2025b). 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 rated the study as 'reliable with restrictions' (Klimisch score 2).

Predictions using COSMOTherm provide values of 0.049 and 0.05 mg/L at 20 and 25°C, respectively (Glüge and Scheringer, 2023).

There were no experimental K_{OW} data for M3T. Predicted log K_{OW} values range from 7.64 to 8.2 at 20°C. The reliability of these predictions is not discussed in ECHA (2025b), and the Agency has not been able to verify these values. However, an OECD TG 123 study for L4 reported a measured log K_{OW} value of 8.21 at 25.1°C (Unpublished study report, 2008a) is considered reliable by the EU REACH registrants of L4. The predicted value in COSMOTherm was 7.42 at 25°C (Glüge and Scheringer, 2023). This implies that the COSMOTherm model under-predicts the K_{OW}. Since L4 is an isomer of M3T, they are likely to have similar log K_{OW} values, i.e. ~8.

2.2 Mandatory classification and labelling

M3T 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

Table 5: Summary of abiotic degradation data

Abiotic degradation process	Information presented	Substance	Results
Hydrolysis	OECD TG 111 study (Unpublished study report, 2009a)	L4	Hydrolysis half-life was calculated to be 132 days at 12°C and pH 7 (relevant to the freshwater environment)
Oxidation	No data presented		
Phototransformation	AOPWIN	M3T	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
	AOPWIN	L4	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)	L4	K_{OH} (cm^3 $molecule^{-1}$ s^{-1}): 2.66 ± 0.13 10^{-12} $kdeg_{air}$ (d^{-1}): 0.115 Estimated DT_{50} of 6.0 days in air
	(Kim and Xu, 2017)	L4	K_{OH} (cm^3 $molecule^{-1}$ s^{-1}): 3.37 ± 0.4× 10^{-12} $kdeg_{air}$ (d^{-1}):0.146 Estimated DT_{50} of 4.8 days in air
	(Alton and Browne, 2020)	L4	K_{OH} (cm^3 $molecule^{-1}$ s^{-1}): 2.5 ± 0.2 × 10^{-12} $kdeg_{air}$ (d^{-1}): 0.108 Estimated DT_{50} of 6.4 days in air

Hydrolysis: No hydrolysis study was available for M3T. QSAR modelling provided in ECHA (2025b) estimated a hydrolytic half-life of 26.5 days at 25°C for M3T and the formation of hydrolysis products trimethylsilanol (TMS; CAS no. 1066-40-6, EC no. 213-914-1) and methysilanetriol (CAS no. 2445-53-6, EC no. 219-489-9). The Agency notes that no further information on the QSAR, including model or reliability, was provided.

ECHA (2025b) presented a read-across category approach using L2, L3 and L4. The Agency has only presented the studies for L4 as it is a structural isomer of M3T, with the same molecular weight and similar physicochemical properties (high log K_{OW} with low water solubility). L2, L3 and L4 all form the common hydrolysis product TMS. The TMS moiety is also present in M3T, so it is expected that hydrolysis will be similar to the non-

branched linear siloxanes (Figure 1). The OECD TG 308 study on M3T indicated slow degradation of M3T, which is hypothesised to be formed via hydrolysis.

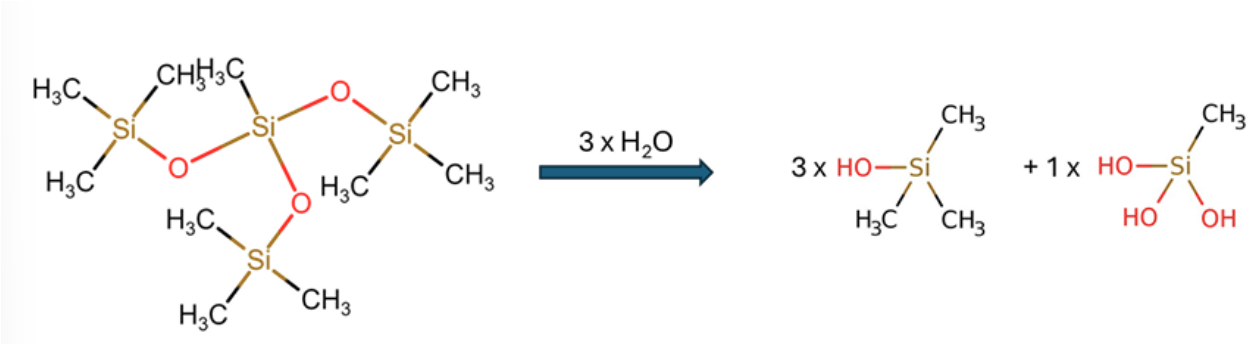


Figure 1 Hydrolysis reaction of M3T from ECHA (2025b)

ECHA (2025b) presented a study of the hydrolysis of L4. The study was performed to OECD TG 111 and GLP, and was considered reliable with restrictions (Klimisch score 2) due to some deviations from the guideline. The test was performed at pH 5, 7 and 9 at 10°C, 25°C and 35°C. For pH 5 and 9 treatments, recovery ranged from 76 to 90%. Low recovery rates were reported at pH 7 (ranging from 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 as the study duration was significantly longer for the pH 7. 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 half-life at 12°C at pH 7 relevant to freshwater environment was calculated to be 132 days.

The Agency agrees that the hydrolysis study is reliable with restrictions. However, L4 is highly adsorptive to organic matter in suspended solids, sediment and soils (Appendix A, Table A1) which may limit the rate of hydrolysis, increasing the abiotic half-life. The adsorption increases with increasing number of silicon atoms and molecular weight. Therefore, the hydrolysis $DegT_{50}$ value of M3T may be longer in natural waters containing dissolved organic carbon, and this information is given a low weight in this assessment.

Due to the similarity in structure to L4, and the common degradation product (TMS) formed, it is likely that M3T will hydrolyse slowly under natural conditions.

Phototransformation in air: ECHA (2025b) presents a predicted half-life in air of 10.7 days using the AOPWIN (v1.92) model in EpiSuite™.

ECHA (2025b) also presents a predicted half-life in air of 10.7 days for the linear isomer L4 using the AOPWIN (v1.92) model. Academic studies are also available for L4, with measured half-life values in the range of 4.8 to 6.4 days. This suggests that the predicted half-life of M3T is over-estimated. 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

ECHA (2025b) briefly summarised a ready biodegradability study for M3T (Table 6). The study 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. The test was carried out at 22 ± 1°C and a pH in the range of 7.44 to 8.50. 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.

Based on this information M3T is not readily biodegradable.

Table 6: Summary of screening test results for M3T

Reference	Study type	Results
Unpublished study (2011a)	OECD TG 301F study, GLP 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

2.3.1.2.1.2 Biodegradation studies (simulation tests)

ECHA (2025b) considers a water-sediment study for M3T, details of which are presented in Table 7.

Table 7: Summary of simulation test results for M3T

Reference	Study type	Results
Unpublished study (2021a)	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 in either sediment

- 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 UK-based sediment and water were collected from Calwich Abbey Lake (organic carbon (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 organic carbon) and 8.7 mg carbon/100 g

dry sediment (0.9% as sediment organic carbon) at the study end was reported for Calwich Abbey Lake and Emperor Lake, respectively.

Applied radioactivity (AR) measured by liquid scintillation counting (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) stated 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).

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 8 presents the radioactivity associated with water, sediment and air compartments.

Table 8: 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 (Non extractable residue (NER))	45.5+1.5 (Non extractable residue (NER))
% Recovery	99.5	98.4

M3T was measured by high-performance liquid chromatography (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 overlying water concentration was not analysed; therefore, a full mass balance could not be established.

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 9. 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 9: 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

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 Day-0 radioactivity. 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.

Non-extractable residues (NERs) in sediments were determined via extraction with tetrahydrofuran (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 study appears to move directly to extraction using tetrahydrofuran (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 single first order (SFO), first-order multi-compartment (FOMC), double first-order in parallel (DFOP), and hockey-stick (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 $DegT_{50}$ 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 DegT50 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.

2.3.1.2.1.3 Monitoring data

ECHA (2025b) included the results of one study which detected M3T in sediments in Asia (Horii *et al.*, 2022). Detections ranged from 0.03 to 72.8 µg/kg dw. However, sample collection and methods have not been described in full detail. There were no Environment Agency monitoring data available for the substance.

The presence of M3T in sediment 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 examined the monitoring data cited in ECHA (2025b) in detail for this report.

2.3.1.3 Summary and discussion of degradation

A reliable OECD TG 111 hydrolysis study determined a half-life of 14.3 days at 12°C and pH 7 for L4. ECHA (2017) stated that for biotic or abiotic degradation, it must be assessed from the documentation whether the source and target substances may be transformed (degraded) similarly based on their structure and whether the transformation occurs at the same rate or to the same extent. Due to the similarity in structure to L4, and the common degradation product (TMS) formed, it is likely that M3T will degrade abiotically at a similar rate to L4. However, as the studies were conducted under sterile conditions, they have limited environmental relevance and receive a low weighting in this assessment.

M3T is not readily biodegradable, with 0% biodegradation observed after 28 days in a study carried out to OECD TG 301F. The method is suitable for poorly soluble and adsorbing compounds, and is generally acceptable for volatile compounds so is considered reliable without restriction.

Very little degradation was seen in a water-sediment aerobic degradation study performed according to OECD TG 308, with $DegT_{50}$ values > 180 days in the Calwich Abbey Lake sediment at 12°C. This study was considered to be reliable with restrictions as there were some issues with M3T recovery, a low oxygen saturation in the test systems, and $DegT_{50}$ values were extrapolated beyond the study period (100 days). However, the half-life in one freshwater sediment was > 180 days.

M3T has been detected in sediment. 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

There are no experimental adsorption data for M3T. ECHA (2025b) presented a predicted log K_{OC} value of 5.3 from the EU REACH registration (Unpublished study report, 2015e). According to ECHA (2025b), M3T is within the applicability domain of the model, although no further details were provided. A predicted log K_{OC} of 4.6 was estimated using COSMOTherm (Glüge and Scheringer, 2023).

ECHA (2025b) provided a brief summary of the adsorption of structurally similar substance L4. An OECD TG 106 study on L4 derived K_{OC} values of 5.16 at 23.7 °C. The study was carried out to GLP and was considered 'reliable without restriction' Klimisch score 1. The substance is assumed to absorb to particles. Applying the read-across for L4 to M3T, it is assumed that M3T is also not mobile according to the CLP criteria. The COSMOTherm prediction for L4 (4.5 at 25°C) is lower than the measured value (mean log K_{OC} of 5.16) at 23.7°C, suggesting that the model under-estimates K_{OC} for this type of substance.

The Agency considers that M3T likely has a similar log K_{OC} (~5) to L4, since it has the same molecular weight and is structurally analogous. It therefore has a high potential to adsorb to organic matter in sediment and soils.

2.3.2.2 Volatilisation

M3T has a high vapour pressure (210 Pa at 25°C) and low water solubility (1.89×10^{-3} mg/L at 23°C) (see Section 2.1.5). ECHA (2025b) calculated the Henry's Law constant using the program EUSES v2.2.0 (Vermeire *et al*., 2005) as 3.35×10^{7} Pa m^3/mole at 25°C and 1.61×10^{7} Pa m^3/mole at 12°C. The dimensionless Henry's Law constant can be estimated as 13,500 at 25°C, 10,500 at 20°C and 6,770 at 12°C. The 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.

ECHA (2025b) presented a predicted log K_{AW} value at 2.78 and 2.96 at 20°C and 25°C, respectively, using COSMOTherm. The reliability of these values is unknown, but the model appears to underestimate other partition coefficients for this type of substance.

2.3.2.3 Distribution modelling

The environmental distribution of M3T 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 M3T (from US-EPA EPISuite™ (v4.11)) using loading rates for air, soil, and water of 1,000 kg/h:

- Equal release of M3T to air, soil and water is predicted to result in 12.5% in air, 39.1% in water, 8.23% in soil, and 40.1% in sediment.

- M3T released entirely into water is expected to partition roughly equally to the sediment (50.1%) and water (48.8%).
- M3T released entirely into soil is expected to partition to air (41.2%) with the rest (58.8%) remaining in soil.
- M3T entirely released into air is expected to remain there (99.8%).

2.3.3 Bioaccumulation

2.3.3.1 Bioaccumulation in aquatic organisms (pelagic & sediment organisms)

2.3.3.1.1 Screening data

M3T has a likely log K_{OW} of ~8 (see Section 2.1.5), which suggests that bioaccumulation in aquatic organisms is possible.

The Agency also notes the potential for M3T to bioaccumulate in air breathing organisms based on its log K_{OW} and the predicted log K_{OA} of 5.09 at 20°C using COSMOTherm (Glüge and Scheringer, 2023) (log K_{OW} > 2 and log K_{OA} > 5), although the reliability of the log K_{OA} value is unknown.

2.3.3.1.2 Aquatic bioaccumulation data

Four aquatic bioaccumulation studies are presented in ECHA (2025b), as summarised in Table 10. One aquatic bioaccumulation study is presented for M3T (Unpublished study, 1987). Three further bioaccumulation studies for L4 are provided as part of a read-across approach.

Table 10: Summary of aquatic bioaccumulation data

Reference	Substance	Study type	Results / comments
Unpublished study report (1987)	M3T	OECD TG 305. 58-day study. Aqueous exposure using *Oncorhynchus mykiss* (Rainbow Trout) Not assignable (Klimisch score 4)	Exposure concentration 32 µg/L: BCF_{SS} = 5,979 L/kg (calculated by ECHA assuming organisms were exposed at the water solubility limit)

Unpublished study report, (2006a)	L4	OECD TG 305. 63-day study. 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)	L4	OECD TG 305. 67-day study. Dietary exposure using *Onchorhynchus 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)
Cantu and Gobas (2024)	L4	OECD TG 305. 95-day study. Dietary exposure using *Onchorhynchus 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 (1987), OECD TG 305 with aqueous exposure, M3T

A non-GLP study was conducted using a protocol related to OECD TG 305 with test substance M3T. *Oncorhynchus mykiss* (Rainbow Trout) were exposed to M3T in a flow-through system with freshwater for 48 days, followed by a 10-day depuration period. The study authors claimed that steady state was achieved by day 28 based on concentrations in fish not significantly differing from concentrations in water on days 28, 35, 42 and 49.

The mean (± standard deviation) concentration of M3T in whole fish for days 35, 42 and 49 was 11,300 ± 4,100 µg/kg. The mean (± standard deviation) concentration in water prior to the introduction of the fish was 32 ± 54 µg/L, while for days 35, 42 and 49 it was measured as 3.2 ± 1.6 µg/L. The lower concentration was used to calculate the steady-state BCF (BCF_{SS}) (fish concentration/water concentration).

The non-lipid normalised BCF_{SS} was reported as 3,500 L/kg (ranging from 1,500 to 9,600 L/kg based on standard deviation). No significant reductions in M3T levels were observed during the 10-day depuration phase. This study was performed prior to the 1996 revision of OECD TG 305, so a kinetic BCF was not calculated. The depuration phase is significantly shorter than recommended in the current OECD TG 305, which suggests a period of half the duration of the uptake phase for substances following first order kinetics.

ECHA (2025b) highlighted several limitations with the study. Measured test concentrations were above the reported water solubility limit of M3T (1.89 µg/L; see Section 2.1.5). This led to fluctuating concentrations in water that did not stabilise over the test duration. ECHA (2025b) stated that as the analytical methods did not account for the exceedance of the test concentration above the water solubility limit, a more realistic BCF is 5,979 L/kg with a range of 3,810 to 16,296 L/kg. These values were calculated by dividing the concentration in fish by the water solubility.

ECHA (2025b) stated that there was no information on lipid content or growth rate and no tables with concentrations in fish or water were provided. The study was therefore deemed not assignable (Klimisch score 4). As *O. mykiss* can grow significantly during laboratory tests, growth dilution was potentially an issue (correcting for this would increase the BCF). The mean BCF value of 5,979 L/kg is considered the best estimate and, due to uncertainties around test concentrations above the water solubility of M3T and the lack of information on lipid and growth correction. It is assigned a medium weighting in the bioaccumulation assessment.

The lack of significant reduction in M3T levels during the 10-day depuration period suggests a slow depuration rate.

- Unpublished study report, (2006a), OECD TG 305 with aqueous exposure, L4

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 Appendix A). 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 treatment 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 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 the 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 11.

Table 11: 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)	Mean L4 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)
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 the 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 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					
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 high concentration treatment group BCF_K was 1,687.3 L/kg compared to growth corrected BCF_{Kg} 1,679.9 L/kg and for the low concentration treatment group BCF_K was 4546.1 L/kg compared to growth corrected BCF_{Kg} 4,514.2 L/kg. It might possibly indicate some level of sub-lethal effect, but this cannot be determined with confidence.

Overall, the Agency considers that 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 Agency considers that 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 be higher). The mortality up to the end of uptake was within the validity criteria of the 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), OECD TG 305 with dietary exposure, L4

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 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% which the Agency notes 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). ECHA (2025b) does not provide further details 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 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})	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 method 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 in 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), OECD TG 305 with dietary exposure, L4

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 14.

Table 14: 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 Summary and discussion of bioaccumulation

M3T has a likely log K_{OW} of ~8, which suggests that bioaccumulation in aquatic organisms is possible. M3T also has the potential to bioaccumulate in air breathing organisms based on its log K_{OW} and predicted log K_{OA} of 5.09 at 20°C (log K_{OW} > 2 and log K_{OA} > 5), although the reliability of the log K_{OA} value is unknown.

The aqueous exposure study performed to OECD TG 305 with M3T on *O. mykiss* was considered not reliable (Klimisch score 3) due to large variation in water concentrations which were above M3T water solubility. Additionally, concentrations measured in fish, lipid content and growth rates were not reported. The Agency considers the study to have a medium weight in the bioaccumulation assessment. Given the uncertainties in this study, a read-across approach has also been used, based on data for the close analogue L4.

Due to a lack of reliable studies with M3T, a read-across approach using L4 is used to assess the bioaccumulation potential of M3T. The Agency agrees that this approach is acceptable given that L4 is structurally similar to M3T, with same molecular weight and

similar water solubilities and adsorption. It is expected that branched substances like M3T are more resistant to metabolism compared with linear substances.

The key studies for the bioaccumulation of L4 are 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. The Agency notes that 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).

A valid growth-corrected, lipid-normalised steady state BCF value from an aquatic exposure study (OECD TG 305) on *P. promelas* was 6,184 L/kg in the low concentration treatment group (0.43 µg/L) supports the dietary exposure studies. It is noted that there were TG deviations, including high mortality exceeding TG validity criteria. However, the study report considered the mortality rates to be experimental-related (rather than treatment related) and notes that mortality rates are only marginally above the threshold. The Agency therefore agrees that the data are reliable with restrictions and, given the limitations of the study, consider the study as supporting evidence to the dietary exposure studies.

ECHA (2025b) stated that the mechanism of bioaccumulation for siloxanes is likely to be passive diffusion to lipids. L4 has very similar physicochemical properties to M3T:

- The molecular weight of M3T and L4 is identical (310.68 g/mol).
- The measured water solubility of M3T (0.002 mg/L) is similar to L4 (0.0067 mg/L)(See Appendix A).
- The log K_{OW} of both substances is expected to be ~8 (see Section 0).

The Agency notes that the main difference is that M3T has a branched structure. This will affect molecular volume, and branched substances are often more resistant to metabolism than linear equivalents (e.g. in the case of hydrocarbons).

The Agency considers L4 to be a suitable read-across analogue for M3T, in line with the ECHA read-across framework guidance document (ECHA, 2017). L4 is considered to have a BCF > 5,000 L/kg, so M3T is also likely to have a similar bioaccumulation potential. Despite its limitations the OECD TG 305 study for M3T is consistent with this conclusion.

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 M3T as vPvB. This involved a read-across approach using L4 for some endpoints. L4 is the linear isomer of M3T, with the same molecular weight and is expected to have very similar physicochemical properties to M3T.

Persistence

M3T did not fulfil the criteria for ready biodegradability (no mineralisation was observed over 28 days in an OECD TG 301F study) and therefore it is potentially P and vP.

A water-sediment aerobic degradation study performed according to OECD TG 308, reported an extrapolated sediment half-life of 133 days and >10,000 days at 12°C in two sediments. There were some issues with M3T recovery, a low oxygen saturation in the test systems, and $DegT_{50}$ values were extrapolated beyond the study period (100 days). However, the Agency considers the study to be reliable with restrictions and concludes that the half-life in one freshwater sediment was > 180 days. This exceeds the P and vP criteria for freshwater sediment (half-life > 120 days or 180 days, respectively).

The Agency concludes from the evidence available that M3T fulfils the P and vP criteria of Annex 13 of UK REACH.

Bioaccumulation

M3T screens as potentially B and vB in aquatic organisms based on a likely log K_{OW} of ~8 at 20°C (derived by read-across from L4 and predictions of unknown validity) (log K_{OW} > 4.5). It also screens as potentially bioaccumulative in air breathing organisms based on the log K_{OW} and a predicted log K_{OA} value of 5.09 at 20°C (log K_{OW} > 2 and log K_{OA} > 5), although the log K_{OA} value is based on a prediction of unknown reliability.

An aqueous exposure study was performed to OECD TG 305 using *Oncorhynchus mykiss* (Rainbow Trout). Several limitations were identified, including exposure concentrations above the water solubility limit. A BCF_{SS} of 5,979 L/kg can be calculated assuming the fish were exposed at the water solubility limit. The Agency considers the study to have a medium weight in the bioaccumulation assessment.

Given the uncertainties in this study, a read-across approach has also been used, based on data for the close analogue L4:

- An aquatic exposure study performed to OECD TG 305 using *Pimephales promelas* (Fathead Minnow) yielded a lipid-normalised 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.

The Agency concludes from the evidence available, particularly the read-across approach to L4, that M3T fulfils the B and vB criteria (BCF > 2,000 or > 5,000 L/kg, respectively) of Annex 13 of UK REACH.

2.4.2 Overall conclusions on the vPvB properties

Based on the information available, the Agency concludes that M3T 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

M3T is not currently registered under UK REACH.

A total of 12 Downstream User Import Notifications (DUINs[2]) have been submitted under UK REACH.

Under EU REACH, the substance is registered with an aggregated tonnage of 100-1000 tonnes/year. (There are currently 3 active EU registrants).

3.2 General description of uses and exposure

M3T is used as a formulation additive to provide properties such as lubrication, surface wetting and water repellence. It is used in consumer products including cosmetics, personal care products, fragrances and perfumes, where it functions as a carrier fluid, conditioning agent or emollient. Additional reported uses include laboratory and analytical applications as a reagent as well as in some other specialised formulations requiring surface modifying properties.

There is potential for release to the environment throughout the life cycle of the substance, including during professional and consumer uses of the formulated products (ECHA, 2025b).

3.3 Alternatives

No information available.

[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.

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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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