

Justification Document for the Selection of a CoRAP Substance

Substance Name (public name): 1,1,1,3,5,5,5-heptamethyl-3-
[(trimethylsilyl)oxy]trisiloxane

EC Number: 241-867-7

CAS Number: 17928-28-8

Authority: UK CA

Date: 22/03/2016

20/03/2018

Note

This document has been prepared by the evaluating Member State given in the CoRAP update 2017-2019. In CoRAP update 2018-2020 the evaluation of this substance has been reassigned to Norway.

Table of Contents

1	IDENTITY OF THE SUBSTANCE	3
1.1	Other identifiers of the substance	3
2	OVERVIEW OF OTHER PROCESSES / EU LEGISLATION	5
3	HAZARD INFORMATION (INCLUDING CLASSIFICATION)	6
3.1	Classification	6
3.1.1	Harmonised Classification in Annex VI of the CLP	6
3.1.2	Self classification	6
3.1.3	Proposal for Harmonised Classification in Annex VI of the CLP	6
4	INFORMATION ON (AGGREGATED) TONNAGE AND USES	7
4.1	Tonnage and registration status	7
4.2	Overview of uses	7
5.	JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CORAP SUBSTANCE	8
5.1.	Legal basis for the proposal	8
5.2.	Selection criteria met (why the substance qualifies for being in CoRAP)	8
5.3	Initial grounds for concern to be clarified under Substance Evaluation	8
5.4	Preliminary indication of information that may need to be requested to clarify the concern	9
5.5	Potential follow-up and link to risk management	9

1 IDENTITY OF THE SUBSTANCE

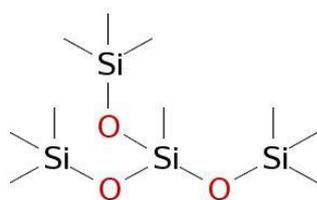
1.1 Other identifiers of the substance

Table: Other Substance identifiers

EC name (public):	1,1,1,3,5,5,5-heptamethyl-3-[(trimethylsilyl)oxy]trisiloxane
IUPAC name (public):	1,1,1,3,5,5,5-heptamethyl-3-[(trimethylsilyl)oxy]trisiloxane
Index number in Annex VI of the CLP Regulation:	Not applicable
Molecular formula:	C ₁₀ H ₃₀ O ₃ Si ₄
Molecular weight or molecular weight range:	310.69
Synonyms:	TMF-1.5

Type of substance Mono-constituent Multi-constituent UVCB

Structural formula:

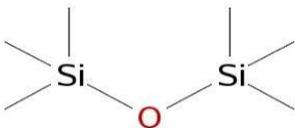
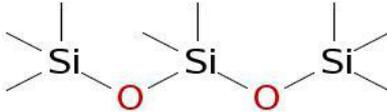
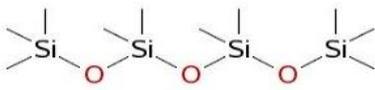
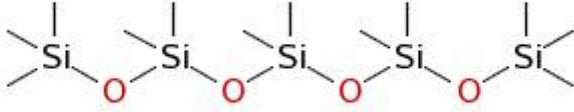


1.2 Similar substances/grouping possibilities

The structurally related chemicals hexamethyldisiloxane, octamethyltrisiloxane, decamethyltetrasiloxane and dodecamethyltetrasiloxane could be included to form a category for evaluation.

Name	CAS No	EC No	Comments
Hexamethyldisiloxane (L2)	107-46-0	203-492-7	Registered, SEV by UKCA in 2013
Octamethyltrisiloxane (L3)	107-51-7	203-497-4	Registered, SEV by UKCA in 2015
Decamethyltetrasiloxane (L4)	141-62-8	205-491-7	Registered, SEV by UKCA in 2015
Dodecamethyltetrasiloxane (L5)	141-63-9	205-492-2	Registered, SEV by UKCA in 2015

Structural formula:

Hexamethyldisiloxane (L2)	
Octamethyltrisiloxane (L3)	
Decamethyltetrasiloxane (L4)	
Dodecamethyltetrasiloxane (L5)	

2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table: Completed or ongoing processes

RMOA	<input type="checkbox"/> Risk Management Option Analysis (RMOA)	
REACH Processes	Evaluation	<input type="checkbox"/> Compliance check, Final decision
		<input type="checkbox"/> Testing proposal
		<input type="checkbox"/> CoRAP and Substance Evaluation
	Authorisation	<input type="checkbox"/> Candidate List
		<input type="checkbox"/> Annex XIV
	Restriction	<input type="checkbox"/> Annex XVII
Harmonised C&L	<input type="checkbox"/> Annex VI (CLP) (see section 3.1)	
Processes under other EU legislation	<input type="checkbox"/> Plant Protection Products Regulation Regulation (EC) No 1107/2009	
	<input type="checkbox"/> Biocidal Product Regulation Regulation (EU) 528/2012 and amendments	
Previous legislation	<input type="checkbox"/> Dangerous substances Directive Directive 67/548/EEC (NONS)	
	<input type="checkbox"/> Existing Substances Regulation Regulation 793/93/EEC (RAR/RRS)	
(UNEP) Stockholm convention (POPs Protocol)	<input type="checkbox"/> Assessment	
	<input type="checkbox"/> In relevant Annex	
Other processes / EU legislation	<input type="checkbox"/> Other (provide further details below)	

D4 and D5 have been agreed to meet the PBT/vPvB criteria, which may affect the supply of decamethyltetrasiloxane if this is used as a substitute in the future.

L2, L3, L4 and L5 are already subject to substance evaluation under REACH.

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

The substance is not classified in Annex VI of Regulation (EC) No 1272/2008

3.1.2 Self classification

- In the registration: not classified
- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:

Flam. Liq. 3 H226

Skin Irrit. 2 H315

Eye Irrit. 2 H319

STOT SE 3 H335 (target organ: "respiratory tract" or "not provided")

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

No proposal according to registry of intention (checked May 2015)

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES¹

4.1 Tonnage and registration status

Table: Tonnage and registration status

From ECHA dissemination site		
<input checked="" type="checkbox"/> Full registration(s) (Art. 10)	<input type="checkbox"/> Intermediate registration(s) (Art. 17 and/or 18)	
Tonnage band (as per dissemination site)		
<input type="checkbox"/> 1 - 10 tpa	<input checked="" type="checkbox"/> 10 - 100 tpa	<input type="checkbox"/> 100 - 1000 tpa
<input type="checkbox"/> 1000 - 10,000 tpa	<input type="checkbox"/> 10,000 - 100,000 tpa	<input type="checkbox"/> 100,000 - 1,000,000 tpa
<input type="checkbox"/> 1,000,000 - 10,000,000 tpa	<input type="checkbox"/> 10,000,000 - 100,000,000 tpa	<input type="checkbox"/> > 100,000,000 tpa
<input type="checkbox"/> <1 >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		<input type="checkbox"/> Confidential
Joint submission		

4.2 Overview of uses

The following uses are identified on the ECHA dissemination site: personal care products, and laboratory reagent. These cover industrial use, professional use and consumer use.

The primary interest in the substance evaluation is the use of personal care products as this is potentially a down-the-drain source of environmental exposure. The significance of the other use will be assessed as part of the evaluation. It is expected that there will be similarities with the exposure assessments of HMDS (L2) (already evaluated), L3-L5 (being evaluated in 2015) and the cyclic siloxanes D4 and D5 (both subject to a risk management options analysis).

Table: Uses

Part 1:

<input type="checkbox"/> Manufacture	<input checked="" type="checkbox"/> Formulation	<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input checked="" type="checkbox"/> Consumer use	<input type="checkbox"/> Article service life	<input type="checkbox"/> Closed system
--------------------------------------	---	--	--	--	---	--

¹ Based on ECHA dissemination site accessed 18th May 2015.

5. JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

5.1. Legal basis for the proposal

- Article 44(2) (refined prioritisation criteria for substance evaluation)

5.2. Selection criteria met (why the substance qualifies for being in CoRAP)

- Fulfils criteria as CMR/ Suspected CMR
- Fulfils criteria as Sensitiser/ Suspected sensitiser
- Fulfils criteria as potential endocrine disrupter
- Fulfils criteria as PBT/vPvB / Suspected PBT/vPvB
- Fulfils criteria high (aggregated) tonnage (*tpa* > 1000)
- Fulfils exposure criteria
- Fulfils MS's (national) priorities

5.3 Initial grounds for concern to be clarified under Substance Evaluation

Hazard based concerns		
CMR <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	Suspected CMR ² <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	<input type="checkbox"/> Potential endocrine disruptor
<input type="checkbox"/> Sensitiser	<input type="checkbox"/> Suspected Sensitiser ²	
<input type="checkbox"/> PBT/vPvB	<input checked="" type="checkbox"/> Suspected PBT/vPvB ²	<input type="checkbox"/> Other (please specify below)
Exposure/risk based concerns		
<input checked="" type="checkbox"/> Wide dispersive use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Exposure of sensitive populations
<input type="checkbox"/> Exposure of environment	<input type="checkbox"/> Exposure of workers	<input type="checkbox"/> Cumulative exposure
<input type="checkbox"/> High RCR	<input type="checkbox"/> High (aggregated) tonnage	<input type="checkbox"/> Other (please specify below)

² CMR/Sensitiser: known carcinogenic and/or mutagenic and/or reprotoxic properties/known sensitising properties (according to CLP harmonized or registrant self-classification or CLP Inventory)

Suspected CMR/Suspected sensitiser: suspected carcinogenic and/or mutagenic and/or reprotoxic properties/suspected sensitising properties (not classified according to CLP harmonized or registrant self-classification)

Suspected PBT: Potentially Persistent, Bioaccumulative and Toxic

The substance screens as vPvB based on the results from a ready biodegradation study and predicted log Kow. The registrant's PBT assessment indicates the substance "may be persistent and very persistent in sediment". However, a request to waive the environmental simulation studies for water, sediment and soil for the substance have been included in the registration dossier.

Characteristics of other siloxanes such as D4, D5 and HMDS (L2) suggest that this group of substances has the potential to be persistent in sediment. Therefore as well as clarifying P properties, sediment risks will also be investigated.

The measured bioconcentration factor in fish at steady state is 3500 L/kg according to the registration dossier. This exceeds the Annex XIII B criterion. It is not known if this value has been corrected for growth or lipid normalised, and it is possible that the value may be higher once this has been done. The range of BCF results is between 1500 – 9600 L/kg.

The chronic fish endpoint is fulfilled using read-across to a test that only investigated mortality. The validity of this test will be assessed as the endpoint is important for the T assessment.

1,1,1,3,5,5,5-heptamethyl-3-[(trimethylsilyl)oxy]trisiloxane is registered with uses including professional and consumer personal care products, which suggests a wide dispersive use pattern. As the substance could be a potential replacement for D4 and D5, the supply volume of 1,1,1,3,5,5,5-heptamethyl-3-[(trimethylsilyl)oxy] could increase if uses of those substances are restricted.

The evaluation will be targeted to the environment but during the PBT assessment the human health endpoints relevant to the T criterion will be assessed.

5.4 Preliminary indication of information that may need to be requested to clarify the concern

<input type="checkbox"/> Information on toxicological properties	<input type="checkbox"/> Information on physico-chemical properties
<input checked="" type="checkbox"/> Information on fate and behaviour	<input checked="" type="checkbox"/> Information on exposure
<input checked="" type="checkbox"/> Information on ecotoxicological properties	<input type="checkbox"/> Information on uses
<input type="checkbox"/> Information ED potential	<input type="checkbox"/> Other (provide further details below)

Testing to assess persistence in sediment, for example OECD 308 *Aerobic and Anaerobic Transformation in Aquatic Sediment Systems*.

Further information on releases from relevant parts of the life cycle (may include a request for monitoring data).

Further data to clarify any sediment risks.

5.5 Potential follow-up and link to risk management

<input type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Restriction	<input type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
---	--------------------------------------	--	--

To be determined following substance evaluation. However, if the PBT/vPvB concern is confirmed, it will not be desirable to allow the replacement of D4 and D5 by this substance in personal care products, so a similar restriction approach might be required.