Justification Document for the Selection of a CoRAP Substance

-Update-

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: NO CA

Date: 22/03/2016 (UK)

20/03/2018 (1. update) (UK)

19/03/2019 (2. update) (NO)

18/03/2020 (3. update) (NO)

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.

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1 IDENTITY OF THE SUBSTANCE

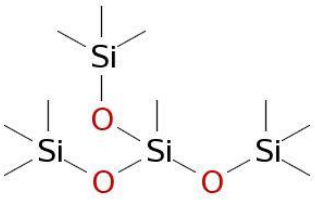
1.1 Other identifiers of the substance

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:	$C_{10}H_{30}O_3Si_4$
Molecular weight or molecular weight range:	310.69
Synonyms:	TMF-1.5

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

Structural formula:

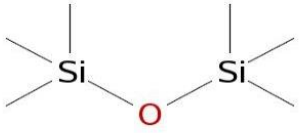
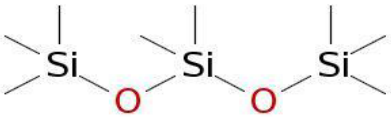
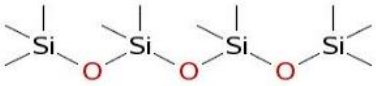
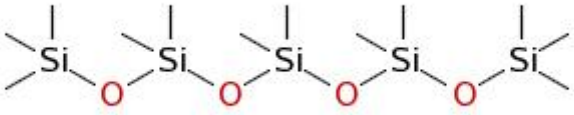


1.2 Similar substances/grouping possibilities

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

D4 and D5 have been agreed to meet the PBT/vPvB criteria and an Annex XV restriction dossier for D4, D5, D6 is in progress, 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:

Flam. Liq. 3	H226
STOT RE 2	H373

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 August 2019).

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES[1]

4.1 Tonnage and registration status

Table: Tonnage and registration status

From ECHA dissemination site		
☒ Full registration(s) (Art. 10)	☐ Intermediate registration(s) (Art. 17 and/or 18)	
Tonnage band (as per dissemination site)		
☐ 1 – 10 tpa	10 – 100 tpa	☒ 100 – 1000 tpa
☐ 1000 – 10,000 tpa	☐ 10,000 – 100,000 tpa	☐ 100,000 – 1,000,000 tpa
☐ 1,000,000 – 10,000,000 tpa	☐ 10,000,000 – 100,000,000 tpa	☐ > 100,000,000 tpa
☐ <1 . . . . . >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		☐ Confidential
Joint submission		

*the total tonnage band has been calculated by excluding the intermediate uses, for details see the Manual for Dissemination and Confidentiality under REACH Regulation (section 2.6.11): https://echa.europa.eu/documents/10162/22308542/manual_dissemination_en.pdf/7e0b87c2-2681-4380-8389-cd655569d9f0

4.2 Overview of uses

The following uses are identified on the ECHA dissemination site: cosmetics and 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 cosmetics and 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, D5 and D6(restriction dossier).

Table: Uses

Part 1:

☐ Manufacture	☒ Formulation	☒ Industrial use	☒ Professional use	☒ Consumer use	☐ Article service life	☐ Closed system

[1] Based on ECHA dissemination site accessed 28.08.2019.

5. JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

5.1. Legal basis for the proposal

☒ Article 44(2)
☐ Article 45(5)

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 ☐ C ☐ M ☐ R	Suspected CMR[2] ☐ C ☐ M ☐ R	☐ Potential endocrine disruptor
☐ Sensitiser	☐ Suspected Sensitiser[2]	
☐ PBT/vPvB	☒Suspected PBT/vPvB[2]	☐ Other (please specify below)

Exposure/risk based concerns		
☒ Wide dispersive use	☐ Consumer use	☐ Exposure of sensitive populations
☐ Exposure of environment	☐ Exposure of workers	☐ Cumulative exposure
☐ High RCR	☐ High (aggregated) tonnage	☐ 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 that the substance "meets screening criterion for persistence (P/vP) in the sediment compartment." However, a request to waive the environmental simulation studies for water has 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. A sediment simulation study OECD 308 with the registered substance is ongoing and should be taken into account for the evaluation of the P/vP criterion. However, only interim results are currently available. A soil simulation test OECD 307 with the registered substances was requested in the compliance check decision (decision number CCH-D-2114359638-34-01/F) within 26. November 2018. As far as we can see the registration has not been updated to include this study yet.

The measured bioconcentration factor in fish at steady state is 3500 L/kg with a range of BCF results between 1500-9600 L/kg according to the registration dossier. This exceeds the Annex XIII B criterion. According to the compliance check decision a robust study summary was required for bioaccumulation in fish: aqueous and dietary exposure, OECD TG 3O5. The deadline for submitting the information was 26. November 2018 but as far as we can see the registration dossier has not been updated to include these studies yet.

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. The read-across for toxicity data from L4 to fulfill the chronic aquatic data for the T endpoints was rejected by ECHA in the compliance check decision. Hence a long-term toxicity testing on fish (Fish, early-life stage (FELS) toxicity test, OECD TG 210)) with the registered substance was required within 26. November 2018. The information has not been included in the updated registration dossier yet.

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. It seems that the T-criterion may be fulfilled with a new 90 study in rats from 2019. The registrant has proposed a classification of STOT RE 2 based on a NOAEL at 20 mg/kg bw/day for male rats due to pigment deposition in the bile duct at higher dose levels. A classification of STOT RE 2 fulfills the criteria for T in PBT according to annex XIII of REACH. A classification of STOT RE 2 has not yet been notified in the C&L inventory.

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

☐ Information on toxicological properties	☐ Information on physico-chemical properties
☒Information on fate and behaviour	☒ Information on exposure
☒ Information on ecotoxicological properties	☐ Information on uses
☐ Information ED potential	☐ Other (provide further details below)

Testing to assess persistency. Further information on releases from relevant parts of the life cycle Further data to clarify any sediment risks.

5.5 Potential follow-up and link to risk management

☐ Harmonised C&L	☐ Restriction	☐ Authorisation	☐ Other (provide further details)
To be determined following substance evaluation.			