Justification Document for the Selection of a CoRAP Substance

-Update-

Substance Name (public name): 1,1,1,3,5,5,5-heptamethyltrisiloxane

EC Number: 217-496-1

CAS Number: 1873-88-7

Authority: NO CA

PO CA

Date: 22/03/2016 (UK)

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

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

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

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 and Poland

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1 IDENTITY OF THE SUBSTANCE

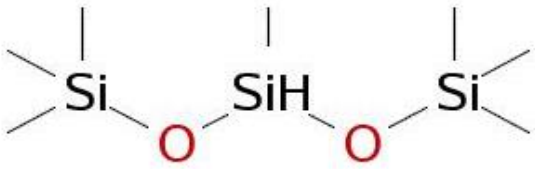
1.1 Other identifiers of the substance

Table: Other Substance identifiers

EC name (public):	1,1,1,3,5,5,5-heptamethyltrisiloxane
IUPAC name (public):	1,1,1,3,5,5,5-heptamethyltrisiloxane
Index number in Annex VI of the CLP Regulation:	Not applicable
Molecular formula:	$C_7H_{22}O_2Si_3$
Molecular weight or molecular weight range:	222.51
Synonyms:	*BLUESIL HEPTAMETHYLTRISILOXANE*

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

Structural formula:

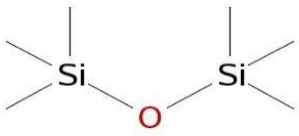
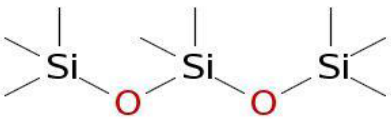
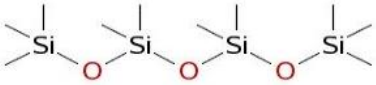
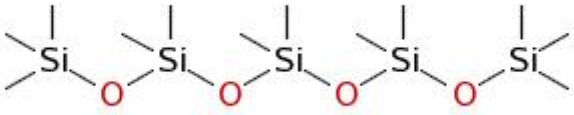
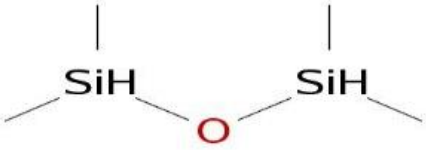


1.2 Similar substances/grouping possibilities

The structurally related chemicals hexamethyldisiloxane, octamethyltrisiloxane, decamethyltetrasiloxane and dodecamethyltetrasiloxane could be included to form a category for evaluation. The registrant has also proposed to use data generated on 1,1,3,3-tetramethyldisiloxane.

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
1,1,3,3-tetramethyldisiloxane	3277-26-7	221-906-4	Registered – read across proposed

Structural formula:

Hexamethyldisiloxane (L2)	
Octamethyltrisiloxane (L3)	
Decamethyltetrasiloxane (L4)	
Dodecamethyltetrasiloxane (L5)	
1,1,3,3-tetramethyldisiloxane	

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 undergoing substance evaluation. Information from these processes are expected to be relevant for the substance evaluation of 1,1,1,3,5,5,5-heptamethyltrisiloxane.

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 registrations:

Flam. Liq. 2 H225

The following hazard classes are in addition notified among the aggregated self-classifications in the C&L Inventory:

Flam. Liq. 3 H226

Flam. Liq. 3 H225

Skin Irrit. 2 H315

Eye Irrit. 2 H319

STOT SE 3 H335

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
☒ 1000+ tpa		☐ Confidential
Joint submission – full registration		

***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:

Manufacture and on- site use as an intermediate. There is also off-site use as a monomer/intermediate and laboratory chemical. These cover manufacture, industrial and professional use. There are no known consumer uses.

Part 1:

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

[1] Dissemination site was accessed on 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 criteria for persistence (vP) in the sediment compartment are met". Characteristics of other siloxanes such as D4, D5 and HMDS (L2) suggest potential to be persistent in sediment. Therefore as well as clarifying P properties, sediment risks will also be investigated.

In a compliance check decision (decision number CCH-D-2114362615-47-01/F) a sediment simulation study (OECD TG 308) with the registered substance was required. The deadline for submitting the information was 28. January 2019. As far as we can see the registration dossier has not been updated to include the study.

Bioaccumulation data is read-across from octamethyltrisiloxane (L3), which has a high measured bioconcentration factor in fish (BCF = 7730 L/kg).

The read-across for toxicity data from L3 to fulfill the chronic aquatic data for the T endpoints was rejected by ECHA in the compliance check decision. In this decision a long-term toxicity testing on fish (Fish, early-life stage (FELS) toxicity test, OECD TG 210) and a long-term toxicity testing on aquatic invertebrates (Daphnia magna reproduction test, EU OECD TG 211) with the registered substance was required. The deadline to send in the data was 28. January 2019. As far as we can see the registration dossier has not been updated to include these studies yet.

It is not known if 1,1,1,3,5,5,5-heptamethyltrisiloxane could be a potential replacement for D4 and D5, but the supply volume may increase if uses of those substances will be restricted. In addition, the CSRs will be examined to see how uses of the substances made from it have been considered (exposure scenarios should be included if the substance is an impurity or degradation product in products such as polymers).

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.

In the compliance check decision it was decided that an EOGRTS study had to be performed with the registered substance. The deadline to send in the data was 26. July 2019. As far as we can see the registration dossier has not been updated to include such a study yet.

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.