

## Justification for the selection of a substance for CoRAP inclusion

<b>Substance Name (Public Name):</b>	Dodecamethylpentasiloxane
<b>Chemical Group:</b>	siloxanes
<b>EC Number:</b>	205-492-2
<b>CAS Number:</b>	141-63-9
<b>Submitted by:</b>	UK REACH CA
<b>Date:</b>	17/03/2015

### Note

This document has been prepared by the evaluating Member State given in the CoRAP update.

## Contents

1	IDENTITY OF THE SUBSTANCE.....	3
1.1	Other identifiers of the substance	3
1.2	Similar substances/grouping possibilities	3
2	CLASSIFICATION AND LABELLING.....	4
2.1	Harmonised Classification in Annex VI of the CLP	4
2.2	Self classification	4
2.3	Proposal for Harmonised Classification in Annex VI of the CLP	4
3	INFORMATION ON AGGREGATED TONNAGE AND USES .....	5
4	OTHER COMPLETED/ONGOING REGULATORY PROCESSES THAT MAY AFFECT SUITABILITY FOR SUBSTANCE EVALUATION.....	5
5	JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE ..	6
5.1	Legal basis for the proposal	6
5.2	Selection criteria met (why the substance qualifies for being in CoRAP)	6
5.3	Initial grounds for concern to be clarified under Substance Evaluation	6
5.4	Preliminary indication of information that may need to be requested to clarify the concern	7
5.5	Potential follow-up and link to risk management	7

## 1 IDENTITY OF THE SUBSTANCE

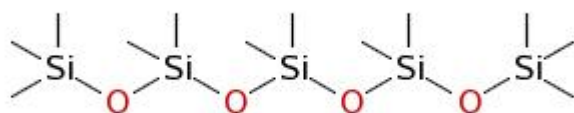
### 1.1 Other identifiers of the substance

**Table 1: Substance identity**

<b>EC name:</b>	Dodecamethylpentasiloxane
<b>IUPAC name:</b>	Dodecamethylpentasiloxane
<b>Index number in Annex VI of the CLP Regulation</b>	Not listed
<b>Molecular formula:</b>	C <sub>12</sub> H <sub>36</sub> O <sub>4</sub> Si <sub>5</sub>
<b>Molecular weight or molecular weight range:</b>	384.84
<b>Synonyms/Trade names:</b>	L5

**Type of substance**     Mono-constituent     Multi-constituent     UVCB

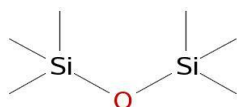
**Structural formula:**



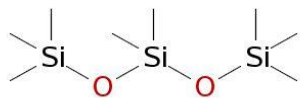
### 1.2 Similar substances/grouping possibilities

The structurally related chemical decamethyltetrasiloxane (CAS no. 141-62-8, also known as L4) has also been nominated to form a category for evaluation. Octamethyltrisiloxane (CAS 107-51-7, L3) is already nominated and is also proposed to form part of the category. Hexamethyldisiloxane (CAS no. 107-46-0, L2) was evaluated by the UK in the 2013 Substance Evaluation work.

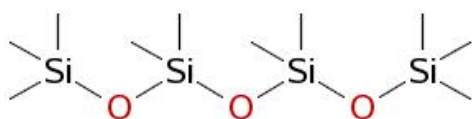
**Structural formula:**



Hexamethyldisiloxane (CAS no. 107-46-0, L2)



Octamethyltrisiloxane (CAS 107-51-7, L3)



Decamethyltetrasiloxane (CAS no. 141-62-8, L4)

## 2 CLASSIFICATION AND LABELLING

### 2.1 Harmonised Classification in Annex VI of the CLP

No harmonised classification.

### 2.2 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:

Not classified

Skin Irrit. 2;H315: causes skin irritation  
Eye Irrit. 2;H319: causes serious eye irritation  
STOT SE 3;H335: May cause respiratory irritation

### 2.3 Proposal for Harmonised Classification in Annex VI of the CLP

No proposal according to registry of intention.

### 3 INFORMATION ON AGGREGATED TONNAGE AND USES

From ECHA 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	
<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input checked="" type="checkbox"/> Consumer use	<input type="checkbox"/> Closed System
<p>The following uses are identified on the ECHA dissemination site: personal care products, polymer preparation - formulation of release agent, in-situ non-metal surface treatment, laboratory reagent. These cover industrial use, professional use and consumer use.</p> <p>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 other uses 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) and the cyclic siloxanes D4 and D5 (both covered by a notified restriction intention).</p>			

### 4 OTHER COMPLETED/ONGOING REGULATORY PROCESSES THAT MAY AFFECT SUITABILITY FOR SUBSTANCE EVALUATION

<input type="checkbox"/> Compliance check, Final decision	<input type="checkbox"/> Dangerous substances Directive 67/548/EEC
<input checked="" type="checkbox"/> Testing proposal	<input type="checkbox"/> Existing Substances Regulation 793/93/EEC
<input type="checkbox"/> Annex VI (CLP)	<input type="checkbox"/> Plant Protection Products Regulation 91/414/EEC
<input type="checkbox"/> Annex XV (SVHC)	<input type="checkbox"/> Biocidal Products Directive 98/8/EEC ; Biocidal Product Regulation (Regulation (EU) 528/2012)
<input type="checkbox"/> Annex XIV (Authorisation)	<input type="checkbox"/> Other (provide further details below)
<input type="checkbox"/> Annex XVII (Restriction)	
<p>Terrestrial toxicity testing has been proposed by registrant.</p> <p>D4 and D5 have been agreed to meet the PBT/vPvB criteria, which may affect the supply of dodecamethylpentasiloxane if this is used as a substitute in the future.</p>	

## 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)
- Article 45(5) (Member State priority)

### 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 <sup>1</sup> <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 <sup>1</sup>	
<input type="checkbox"/> PBT/vPvB	<input checked="" type="checkbox"/> Suspected PBT/vPvB <sup>1</sup>	<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 checked="" 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)

<sup>1</sup> 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

vPvB / PBT

Biodegradation data for dodecamethylpentasiloxane have been read-across from L3, which is not readily biodegradable, and under certain conditions appears to have a long half-life in soil. 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 is up to 1450 L/kg according to the registration dossier. 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 chronic fish endpoint is fulfilled using a test that only investigated mortality. The validity of this test will be assessed as the endpoint is important for the T assessment.

Dodecamethylpentasiloxane 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 dodecamethylpentasiloxane could increase if uses of those substances are restricted.

#### 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 checked="" 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 checked="" 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.