# Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name):	Hexamethyldisiloxane
Chemical Group:	Organic
EC Number:	203-492-7
CAS Number:	107-46-0
Submitted by:	UK CA
Published:	20/03/2013

#### NOTE

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

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# **1 IDENTITY OF THE SUBSTANCE**

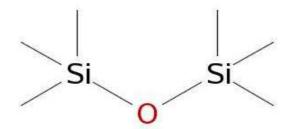
#### 1.1 Name and other identifiers of the substance

#### **Table 1: Substance identity**

Public Name:	hexamethyldisiloxane
EC number:	203-492-7
EC name:	hexamethyldisiloxane
CAS number (in the EC inventory):	107-46-0
CAS number:	107-46-0
CAS name:	Disiloxane, 1,1,1,3,3,3-hexamethyl-
IUPAC name:	hexamethyldisiloxane
Index number in Annex VI of the CLP Regulation	Not applicable
Molecular formula:	C <sub>6</sub> H <sub>18</sub> OSi <sub>2</sub>
Molecular weight or molecular weight range:	162.38
Synonyms:	Disiloxane, hexamethyl-, 2,2,4,4-Tetramethyl-3- oxa-2,4-disilapentan HMDSO Bis(trimethylsilyl) ether disiloxane, 1,1,1,3,3,3-hexamethyl- alpha- (Trimethylsilyl)-omega- methylpoly(oxy(dimethylsilylene)) Trade names: DOW CORNING 200(R) FLUID, 0.65 CST., DOW CORNING(R) ENDBLOCK B INT, DOW CORNING(R) 2-1077 FLUID M2, MM, 81798D(L-313)

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

#### **Structural formula:**



# **2** CLASSIFICATION AND LABELLING

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

No harmonised classification available.

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

None

#### 2.3 Self classification

From the dissemination site:

#### CLP:

Flam. Liquid 2; H225; Highly flammable liquid and vapour

Aquatic Acute 1; H400; Very toxic to aquatic life

#### DSD:

F; R11; Highly flammable

N; R50; dangerous for the environment; very toxic to aquatic organisms

(Some self classifications on the dissemination site include classification for carcinogenicity due to an impurity dichloromethane)

Additional classifications notified in C&L inventory;

Aquatic chronic 1; H410; very toxic to aquatic life with long lasting effects

Acute tox 3; H301; toxic if swallowed

Acute tox 4; H332; harmful if inhaled

Car cat 2; H351; suspected of causing cancer

Skin irrit 2; H315; causes skin irritation

Eye irrit 2; H319; causes serious eye irritation

Asp tox 1; H304; may be fatal if swallowed and enters airways

Flam sol 1; H220; flammable solid

Flam Liq. 3; H226; Flammable liquid & vapour

Water react 1; H260; in contact with water releases flammable gas which may spontaneously ignite

#### **3 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CORAP** SUBSTANCE

#### **3.1 Legal basis for the proposal**

 $\boxtimes$  Article 44(1) (refined prioritisation criteria for substance evaluation)

Article 45(5) (Member State priority)

#### **3.2 Grounds for concern**

ig i (Suspected) CMR	☐ Wide dispersive use	Cumulative exposure
(Suspected) Sensitiser	🖾 Consumer use	High RCR
(Suspected) PBT	Exposure of sensitive populations	Aggregated tonnage
Suspected endocrine disruptor	Other (provide further details below)	

Tumours were observed in a carcinogenicity study conducted on hexamethyldisiloxane. These tumours have been dismissed as not relevant to humans. As this substance is used in personal care products, evaluation is required to confirm the substance is not carcinogenic to humans.

## 3.3 Information on aggregated tonnage and uses

🗌 1 – 10 tpa		🗌 10 – 100 tpa		🗌 100 – 1000 tpa	
🖾 1000 – 10,000 tpa	⊠ 1000 – 10,000 tpa □ 10,000 – 100,000 tpa		,000 tpa		
□ 100,000 - 1000,000 tpa □ > 1000,000 tpa		ра			
Confidential					
The tonnage band is given on the dissemination site.					
☐ Industrial use	Industrial use 🛛 Professional use 🖾 Consumer us				Closed System
Industrial uses:					
manufacture of electronics/semi-conductors laboratory chemical personal care products, including formulation cleaning of optical wear medical adhesives other reactant (end blocker) for silicone polymers/resins use as a monomer or other reactant in the production of polysiloxanes/silicone polymers/ resins use as a chemical intermediate Use in automotive care products Use in ore heat-transfer systems Sealant formulations					
Professional use: of personal care products of automotive care products of sealant formulations					

Consumer exposure use: personal care products automotive care products

# **3.4 Other completed/ongoing regulatory processes that may affect suitability for substance evaluation**

Compliance check final decision		
Testing proposal	Existing Substances Regulation 793/93/EEC	
Annex VI (CLP)	□ Plant Protection Products Regulation 91/414/EEC	
Annex XV (SVHC)	Biocidal Products Directive 98/8/EEC	
Annex XIV (Authorisation)	$oxed{intermation}$ Other (provide further details below)	
Annex XVII (Restriction)		
The substance has been assessed in the OSPAR programme (UK rapporteur) owing to its high		

# 3.5 Information to be requested to clarify the suspected risk

toxicity to aquatic organisms and potential for bioaccumulation.

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

Information may be required to determine whether or not the tumors observed in the combined chronic toxicity/carcinogenicity study are relevant to humans.

Information on both environmental and human health exposure may be required.

Given the ecotoxicological profile of this substance, further studies investigating the effect of adsorbance to sediment on the substance's rate of hydrolysis may be considered.

#### **3.6 Potential follow-up and link to risk management**

Restriction	Harmonised C&L	Authorisation	$\Box$ Other (provide further details)			
Depending on the outcome of the evaluation there may be a need for a harmonised classification and labeling proposal for carcinogenicity.						
Possible refinement of the RCR may require other risk reduction measures to be considered.						