

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
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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	Name and other identifiers of the substance	3
2	CLASSIFICATION AND LABELLING	4
2.1	Harmonised Classification in Annex VI of the CLP	4
2.2	Proposal for Harmonised Classification in Annex VI of the CLP	4
2.3	Self classification	4
3	JUSTIFICATION FOR THE SELECTION	5
3.1	Legal basis for the proposal	5
3.2	Grounds for concern	5
3.3	Information on aggregated tonnage and uses	5
3.4	Other completed/ongoing regulatory processes	6
3.5	Information to be requested to clarify the suspected risk	6
3.6	Potential follow-up and link to risk management	6

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 ₆ H ₁₈ OSi ₂
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

- Article 44(1) (refined prioritisation criteria for substance evaluation)
 Article 45(5) (Member State priority)

3.2 Grounds for concern

<input checked="" type="checkbox"/> (Suspected) CMR	<input type="checkbox"/> Wide dispersive use	<input type="checkbox"/> Cumulative exposure
<input type="checkbox"/> (Suspected) Sensitiser	<input checked="" type="checkbox"/> Consumer use	<input type="checkbox"/> High RCR
<input type="checkbox"/> (Suspected) PBT	<input type="checkbox"/> Exposure of sensitive populations	<input checked="" type="checkbox"/> Aggregated tonnage
<input type="checkbox"/> Suspected endocrine disruptor	<input type="checkbox"/> 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

<input type="checkbox"/> 1 - 10 tpa	<input type="checkbox"/> 10 - 100 tpa	<input type="checkbox"/> 100 - 1000 tpa	
<input checked="" type="checkbox"/> 1000 - 10,000 tpa	<input type="checkbox"/> 10,000 - 100,000 tpa		
<input type="checkbox"/> 100,000 - 1000,000 tpa	<input type="checkbox"/> > 1000,000 tpa		
<input type="checkbox"/> Confidential			
The tonnage band is given on the dissemination site.			
<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input checked="" type="checkbox"/> Consumer use	<input checked="" type="checkbox"/> 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

<input type="checkbox"/> Compliance check final decision	<input type="checkbox"/> Dangerous substances Directive 67/548/EEC
<input 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
<input type="checkbox"/> Annex XIV (Authorisation)	<input checked="" type="checkbox"/> Other (provide further details below)
<input type="checkbox"/> Annex XVII (Restriction)	
The substance has been assessed in the OSPAR programme (UK rapporteur) owing to its high toxicity to aquatic organisms and potential for bioaccumulation.	

3.5 Information to be requested to clarify the suspected risk

<input checked="" type="checkbox"/> Information on toxicological properties	<input type="checkbox"/> Information on physico-chemical properties
<input type="checkbox"/> Information on fate and behaviour	<input checked="" type="checkbox"/> Information on exposure
<input type="checkbox"/> Information on ecotoxicological properties	<input type="checkbox"/> Information on uses
<input type="checkbox"/> 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

<input type="checkbox"/> Restriction	<input type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Authorisation	<input type="checkbox"/> 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.			