Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name):	Octamethyltrisiloxane
Chemical Group:	siloxanes
EC Number:	203-497-4
CAS Number:	107-51-7
Submitted by:	UK REACH CA
Published:	26/03/2014

Note

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

Contents

1 IDENTITY OF THE SUBSTANCE

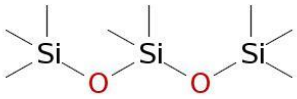
1.1 Other identifiers of the substance

Table 1: Substance identity

EC name:	Octamethyltrisiloxane
IUPAC name:	Octamethyltrisiloxane
Index number in Annex VI of the CLP Regulation	Not listed
Molecular formula:	C8H24O2Si3
Molecular weight or molecular weight range:	236.5
Synonyms/Trade names:	L3, Dow Corning 200 (r) fluid 1cst

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

Structural formula:



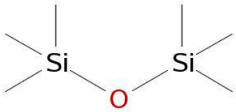
1.2 Similar substances/grouping possibilities

The structurally related chemical decamethyltetrasiloxane (CAS no. 141-62-8, also known as L4) could be included to form a category for evaluation.

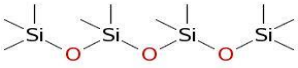
Hexamethyldisiloxane (CAS no. 107-46-0, L2) is currently being evaluated by the UK in the 2013 Substance Evaluation work.

Structural formula:

Hexamethyldisiloxane



Decamethyltetrasiloxane



2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

No harmonised classification.

2.2 Self classification

- In the registration:

  Flam. Liquid 3 H226: Flammable liquid and vapour.

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

  Aquatic Chronic 4; H413: May cause long lasting harmful effects to aquatic life.

  Not Classified

The following labelling is also notified without classification with hazard classes:

H304 May be fatal if swallowed and enters airways.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

2.3 Proposal for Harmonised Classification in Annex VI of the CLP

No proposal according to registry of intention (checked 9th August 2013)

3 INFORMATION ON AGGREGATED TONNAGE AND USES

From ECHA 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
Please provide further details if appropriate		

☒ Industrial use	☒ Professional use	☒ Consumer use	☐ Closed System

The following uses are identified on the ECHA dissemination site: personal care products, coatings, sealants, heat transfer fluid, non-metal surface treatment agent - in situ treatment, use in electronics and optical product manufacturing and laboratory reagent. These cover industrial use, professional use and consumer use.

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.

4 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

4.1 Legal basis for the proposal

☒ Article 44(2) (refined prioritisation criteria for substance evaluation)

☐ Article 45(5) (Member State priority)

4.2 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

4.3 Initial grounds for concern to be clarified under Substance Evaluation

Hazard based concerns		
CMR ☐C ☐M ☐R	Suspected CMR[1] ☐C ☐M ☐R	☐ Potential endocrine disruptor
☐ Sensitiser	☐ Suspected Sensitiser[1]	
☐ PBT/vPvB	☒ Suspected PBT/vPvB[1]	☐ 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)

vPvB

Octamethyltrisiloxane has a high measured bioconcentration factor in fish (BCF = 7730 L/kg) and is not readily biodegradable. 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.

Octamethyltrisiloxane 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, if uses of those substances are restricted, the supply volume of octamethyltrisiloxane could increase.

[1] 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

4.4 Other completed/ongoing regulatory processes that may affect suitability for substance evaluation

☐ Compliance check, Final decision	☐ Dangerous substances Directive 67/548/EEC
☒ 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 ; Biocidal Product Regulation (Regulation (EU) 528/2012)
☐ Annex XIV (Authorisation)	☐ Other (provide further details below)
☐ Annex XVII (Restriction)	

Terrestrial and developmental toxicity testing proposed by registrant for octamethyltrisiloxane.

D4 and D5 have been agreed to meet the PBT/vPvB criteria, which may affect the supply of octamethyltrisiloxane if this is used as a substitute in the future.

4.5 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 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.

4.6 Potential follow-up and link to risk management

☐ Harmonised C&L	☐ Restriction	☐ Authorisation	☐ Other (provide further details)

To be determined following substance evaluation.