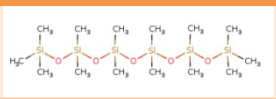
MINISTERIO
PARA LA TRANSICIÓN ECOLÓGICA
Y EL RETO DEMOGRÁFICO

Justification Document for the Selection of a CoRAP Substance

EC/List number	CAS RN	Public Substance name	Chemical structure	Registration type
203-499-5	107-52-8	Tetradecamethylhexasiloxane (L6)		full

Authority: Spain

Date: 19 March 2024

Revision history

Version	*Date*

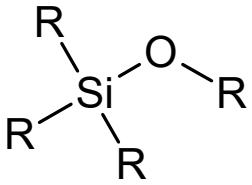
Cover Note

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

1. Background

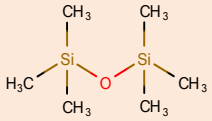
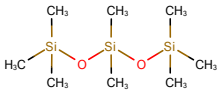
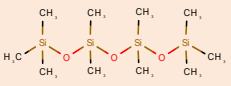
1.1 Analogue substances

ECHA has grouped together structurally similar substances based on the presence of the siloxy moiety shown in the figure below and carried out an Assessment of regulatory needs for the group (GMT-322: Hydrocarbyl siloxanes[1]).

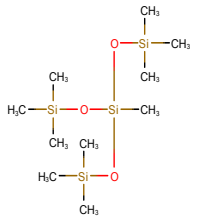
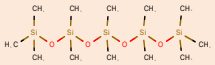
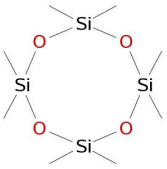
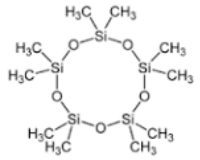
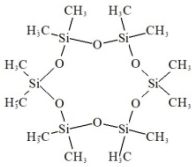


The substances included in the group of hydrocarbyl siloxanes cover linear and branched aliphatic and aromatic siloxanes as well as cyclic siloxanes. In addition polymeric siloxanes notified under previous legislation (NONS) have been included in the group.

The substances within this group that are most similar to tetradecamethylhexasiloxane (L6) based on structural considerations and physico-chemical properties are listed in the below table. Other members of the hydrocarbyl siloxanes may also provide useful information for the assessment of tetradecamethylhexasiloxane (L6).

EC/List number	CAS RN	Public Substance name	Chemical structure
203-492-7	107-46-0	Hexamethyldisiloxane (L2)	
203-497-4	107-51-7	Octamethyltrisiloxane (L3)	
205-491-7	141-62-8	Decamethyltetrasiloxane (L4)	

[1] https://echa.europa.eu/documents/10162/0f1ed1ad-2bb4-2d0d-95c1-971b7d398099

EC/List number	CAS RN	Public Substance name	Chemical structure
241-867-7	17928-28-8	1,1,1,3,5,5,5-heptamethyl-3-[(trimethylsilyl)oxy]trisiloxane (M3T)	
205-492-2	141-63-9	Dodecamethylpentasiloxane (L5)	
209-136-7	556-67-2	Octamethylcyclotetrasiloxane (D4)	
208-764-9	541-02-6	Decamethylcyclopentasiloxane (D5)	
208-762-8	540-97-6	Dodecamethylcyclohexasiloxane (D6)	

1.2 Overview of ongoing or completed other REACH and CLP processes & other EU legislation

EC/ List number	Evaluation			CLH	Restriction	Authorisation
	CCH	TPE	Previously on CoRAP	Annex VI (CLP)	Annex XVII*	Candidate List/ Annex XIV
203-499-5	-	x	-	-	-	-

**Some of the broad restriction entries in the Annex XVII of REACH are not represented in the overview, e.g. when the scope of the restriction is defined by its classification or the substance identification is broad (e.g. entries 3, 28-30 and 40)*

EC/ List number	Other EU legislation	Previous legislation	Stockholm convention	Other
	PPP/ BPR	NONS/ RAR	POP	(e.g. UNEP)
203-499-5	-	-	-	-

2. Classification

You can find information on classification in the ECHA C&L Inventory database, which includes both harmonised classification (when available) and the notified self-classifications. (http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database]. The CLP Regulation and all published ATPs are available on ECHA website: http://echa.europa.eu/web/guest/regulations/clp/legislation .

EC/ List No	CAS RN	Public Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
203-499-5	107-52-8	Tetradecamethylhexasiloxane	-	Not classified	Not classified (1) H315, H319, H335 (1)

(*) the number in brackets indicates the number of notifications received. Each notification can represent a group of notifiers. Therefore the number may differ from the C&L inventory which displays number of notifiers.

3. Tonnage and uses

3.1 Aggregated Tonnage

EC/ List No	Aggregated tonnage (as per ECHA dissemination website*)[2] [3]
203-499-5	≥ 1 to < 10 t/y

** The total tonnage band has been calculated by excluding the intermediate uses,- See also the Manual for Dissemination and Confidentiality under REACH (section 2.6.11): https://echa.europa.eu/documents/10162/22308542/manual_dissemination_en.pdf/7e0b87c2-2681-4380-8389-cd655569d9f0*

3.2 Overview of the Uses

Main types of applications	EC 203-499-5 Key information
Industrial use	Use in heat transfer fluids, automotive care products and as laboratory reactant
Professional use	Use in cosmetics (leave on and wash-off cosmetics) and automotive care products
Consumer Use	Use in cosmetics (leave on and wash-off cosmetics)
Article service life	-
Intermediate use (if TII)	-
Formulation	Formulation of cosmetics and automotive care products

[2] The total aggregated tonnage band may be available on ECHA's webpage at https://echa.europa.eu/information-on-chemicals/registered-substances

[3] Substance Infocard on ECHA's dissemination website accessed on 12 September 2023. NB. REACH registration data on ECHA's webpage has not been updated since 19 May 2023.

4. Justification for inclusion on the CoRAP

4.1 Legal basis

☒ Article 44(2)[4]

☐ Article 45(5)[5]

4.2 Identification of initial grounds of concern

Hazard-based concerns	
Suspected CMR	☐ Carcinogenic ☐ Mutagenic ☐ Reproductive toxicant
Potential ED	☐ Human Health ☐ Environment
Suspected Sensitiser	☐ Respiratory ☐ Skin
Suspected PBT/ vPvB Suspected PMT/ vPvM	☒ Persistent ☒ Bioaccumulative ☐ Mobile ☒ Toxic (as defined in section 4.3 below) ☒ very Persistent ☒ very Bioaccumulative ☐ very Mobile
Other suspected human health hazard(s) (e.g. STOT RE)	☐ (as defined in section 4.3 below)
Other suspected environmental hazard(s)	☐ (as defined in section 4.3 below)
Exposure/ risk-based concerns	
Wide dispersive use	☒
Consumer use	☒
Exposure of workers	☐
Exposure of sensitive populations	☐
Exposure of environment	☒
Cumulative exposure	☐
High RCR	☐
High (aggregated) tonnages	☐
Others (to be specified)	☐

[4] "The Agency shall use the criteria in paragraph 1 […]. Substances shall be included if there are grounds for considering (either on the basis of a dossier evaluation carried out by the Agency or on the basis of any other appropriate source, including information in the registration dossier) that a given substance constitutes a risk to human health or the environment."

[5] "A Member State may notify the Agency at any time of a substance not on the Community rolling action plan, whenever it is in possession of information which suggests that the substance is a priority for evaluation. […]".

4.3 Justification of the concern(s) – to be clarified under Substance evaluation

Existing data supporting the hazard-based concern and other relevant information to justify the inclusion in CoRAP

Persistence:

Hydrolysis half-lives of 12.1 h at pH 4, 5.8 h at pH 5, 6300 h at pH 7 and 36.5 h at pH 9 and 20-25°C were determined for the substance by the registrants using a QSAR estimation method developed specifically for linear and cyclic siloxanes. Information from hydrolysis tests with other linear siloxanes (L3 and L4) support that at pH 7 the hydrolysis of L6 is expected to be slow.

In an OECD TG 310 test, L6 had 0% degradation after 28 days. No simulation studies are available for the substance. L6 meets the screening criteria for P/vP.

In the corresponding substance evaluation conclusion documents[6], Norway concluded that L3, L4 and L5 meet the vPvB criteria.

Therefore, it is expected that L6 might also meet the vP criteria.

Bioaccumulation:

The log Kow of L6 is above 9 based on read-across from an OECD TG 123 study with L5 and KOWWIN QSAR predictions. Hence, it screens B/vB.

The registrants have used read-across from an OECD TG 305 study with L5 to assess the bioaccumulation of L6. Lipid normalized BCFs of approx. 4200 L/kg were determined for L5. Based on an OECD TG 305 study, L5 is B and in the Substance evaluation the eMSCA (Norway) concluded that it is vB, too, as there is some uncertainty in the OECD TG 305 study. Norway estimated the k1 according to the given methods in OECD TG 305 guideline leading to a 5% lipid normalized BCF of 10952 l kg-1 for the low concentration and a lipid normalized BCF of 8588 l kg-1 for the high concentration. Since L6 is a larger molecule than L5, it is expected to have lower bioavailability which may lead to lower bioaccumulation in fish. Further information is needed to conclude on the bioaccumulation potential of L6.

Toxicity:

Regarding ecotoxicity, there are no reliable aquatic toxicity data available for L6.

Based on the ARN document for GMT-322 Hydrocarbyl siloxanes, L6 has potentially the following human health hazards: STOT RE (liver, kidney, thyroid), reproductive toxicity (fertility, and/or development) and potential endocrine disrupting properties. Hence, it may fulfill the criteria for T based on human health hazards.

Summary:

[6] Substance evaluation conclusion documents for L3, L4 and L5 are available at these links: https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807e9149; https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807e9d43; https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807e9fd7

L6 is likely to be P/vP, may potentially be B/vB and T.

Information to be potentially requested

A simulation test may be requested to clarity the persistence, if needed. An OECD TG 305 dietary study may need to be requested to clarify the bioaccumulation potential.

If the substance is concluded to be P/vP and B but not vB, it should be assessed whether further information on toxicity is needed to conclude on potential PBT properties.

Possible follow-up (demonstrating the improvement of risk management measures)

EC/ List number	Harmonised C&L	SVHC	Restriction	Authorisation	Other
203-499-5	☒	☒	☒	☒	☐