

according to Regulation (EG) Nr. 1907/2006

mollosil (Base + Catalyst)

Revision date: 25.04.2022 Product code: 10488 Page 1 of 9

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

mollosil (Base + Catalyst)

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture

Relining material for use in dentistry.

1.3. Details of the supplier of the safety data sheet

Company name: DETAX GmbH
Street: Carl-Zeiss-Straße 4
Place: D-76275 Ettlingen

Telephone: +49 7243/510-0 Telefax: +49 7243/510-100

E-mail: post@detax.com Internet: www.detax.com

Responsible Department: This number is only obtainable during office hours

(Monday - Thursday 8.00 a.m. - 5.00 p.m., Friday 8.00 a.m. - 4.00 p.m.)

Importer: Ivoclar Vivadent Ltd,12 Omega Street, Rosedale,

Auckland 0632, New Zealand.

Customer Services Phone: 0508 486 252 Telephone: +64 9 914 9999

Fax: +64 9 914 9990 Email: Customercare.nz@ivoclar.com

1.4. Emergency telephone number: +1-800-424-9300 (CHEMTREC worldwide)

National Poisons Centre: 0800 764 766 / 24 hours a day, 7 days a week New Zealand wide.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EG) Nr. 1272/2008

Aquatic Chronic 3; H412

Full text of hazard statements: see SECTION 16.

2.2. Label elements

Regulation (EG) Nr. 1272/2008

Hazard statements

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

P273 Avoid release to the environment.

2.3. Other hazards

The mixture contains the following substances fulfilling the PBT criteria according to UK REACH:

 $Dode came thyl cyclohexasiloxane; \ Decame thyl cyclopentasiloxane; \ Octame thyl cyclote trasiloxane.$

The mixture contains the following substances fulfilling the vPvB criteria according to UK REACH:

 $Dode came thyl cyclohexasiloxane; \ Decame thyl cyclopentasiloxane; \ Octame thyl cyclote trasiloxane.$

No information available.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Containes polydimethylsiloxanes with functional groups. + fillers and pigment catalyst: additionally platinum complex compound.



according to Regulation (EG) Nr. 1907/2006

mollosil (Base + Catalyst)

Revision date: 25.04.2022 Product code: 10488 Page 2 of 9

Hazardous components

CAS No	Chemical name						
	EC No	Index No	REACH No				
	Classification (Regulation (EG) Nr. 1272/2008)						
540-97-6	Dodecamethylcyclohexasilox	ane		< 0,2 %			
	208-762-8		01-2119517435-42				
541-02-6 556-67-2	Decamethylcyclopentasiloxane						
	208-764-9		01-2119511367-43				
	Octamethylcyclotetrasiloxane						
	209-136-7	014-018-00-1	01-2119529238-36				
	Flam. Liq. 3, Repr. 2, Aquatic Chronic 1; H226 H361f H410						

Full text of H and EUH statements: see section 16.

Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity			
	Specific Conc.	Limits, M-factors and ATE				
540-97-6	208-762-8	8-762-8 Dodecamethylcyclohexasiloxane				
	dermal: LD50 = 2000 mg/kg; oral: LD50 = 2000 mg/kg					
541-02-6	208-764-9	Decamethylcyclopentasiloxane	< 0,2 %			
	inhalation: LC50 = 8,67 mg/l (vapours); dermal: LD50 = >2000 mg/kg; oral: LD50 = >24100 mg/kg					
556-67-2	209-136-7	Octamethylcyclotetrasiloxane	< 0,05 %			
	l l	50 = 36 mg/l (vapours); dermal: LD50 = >2400 mg/kg; oral: LD50 = 4800 mg/kg c 1; H410: M=10				

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

First aider: Pay attention to self-protection! Remove affected person from the danger area and lay down.

After inhalation

Provide fresh air.

After contact with skin

Wash with plenty of water. Take off contaminated clothing and wash it before reuse.

After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water.

After ingestion

Rinse mouth immediately and drink plenty of water.

Seek immediately medical advice. Do not induce vomiting. In case of spontaneous vomiting take care of an unhindered flow out of the vomit (danger of suffocation).

4.2. Most important symptoms and effects, both acute and delayed

No information available.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

DETAX GmbH



Safety Data Sheet

according to Regulation (EG) Nr. 1907/2006

mollosil (Base + Catalyst)

Revision date: 25.04.2022 Product code: 10488 Page 3 of 9

Suitable extinguishing media

Co-ordinate fire-fighting measures to the fire surroundings.

5.2. Special hazards arising from the substance or mixture

Non-flammable.

5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General advice

Use personal protection equipment.

6.2. Environmental precautions

No special environmental measures are necessary. Clean contaminated articles and floor according to the environmental legislation.

6.3. Methods and material for containment and cleaning up

Other information

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

No special measures are necessary.

Advice on protection against fire and explosion

No special fire protection measures are necessary.

Advice on general occupational hygiene

Take off contaminated clothing. Wash hands before breaks and after work. When using do not eat or drink.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed.

Hints on joint storage

Do not store with acids, lyes, alcohols, metallic powders and metallic oxides (release of hydrogen is favoured).

Further information on storage conditions

Keep only in the original container in a cool, dry and well-ventilated place, away from foodstuffs.

7.3. Specific end use(s)

Silicone material for denture relinings.

For use by trained specialist staff.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.2. Exposure controls

Individual protection measures, such as personal protective equipment



according to Regulation (EG) Nr. 1907/2006

mollosil (Base + Catalyst)

Revision date: 25.04.2022 Product code: 10488 Page 4 of 9

Eye/face protection

Wear eye/face protection.

Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

Skin protection

Wear suitable protective clothing.

Respiratory protection

In case of inadequate ventilation wear respiratory protection.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state: Paste

Colour: base: gingiva coloured ,catalyst: white

Odour: characteristic

Test method

Melting point/freezing point:

Boiling point or initial boiling point and

not determined
not determined

boiling range:

Flammability:

not applicable
not applicable
Lower explosion limits:

not determined

Upper explosion limits:

not determined

Flash point: >100 °C DIN 51755 Auto-ignition temperature: >400 °C DIN 51794

Decomposition temperature: >180 °C pH-Value: not determined Water solubility: The study does not need to be conducted

because the substance is known to be insoluble in water.

Solubility in other solvents

not determined

Partition coefficient n-octanol/water: not determined Vapour pressure: <10 hPa

(at 20 °C)

Density (at 20 °C): 1,03 g/cm³ DIN 51757

Relative vapour density: not determined

9.2. Other information

Information with regard to physical hazard classes

Self-ignition temperature

Solid: not applicable
Gas: not applicable

Oxidizing properties Not oxidizing.

Other safety characteristics

Evaporation rate: not determined Solid content: not determined



according to Regulation (EG) Nr. 1907/2006

mollosil (Base + Catalyst)

Revision date: 25.04.2022 Product code: 10488 Page 5 of 9

Viscosity / dynamic:

290000 mPa·s BROOKFIELD

(at 23 °C)

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

Reacts with: Acids, alkalis, alcohols, powdered metals or metal oxides with release of hydrogen.

10.4. Conditions to avoid

Temperatures > 150°C/ 302 °F.

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

The following applies for the silicone content of the product: At temperature of appr. 150°C/ 302 °F a small amount of formaldehyde can be released by oxidative degradation.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EG) Nr. 1272/2008

Acute toxicity

Based on available data, the classification criteria are not met.

For the product itself no toxicological data are available. In products with a comparable composition, a LD50 (orally, species rat) of > 5000 mg/kg has been found.

ATEmix calculated

ATE (oral) > 2000 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 5 mg/l

CAS No	Chemical name								
	Exposure route	Dose		Species	Source	Method			
540-97-6	Dodecamethylcyclohexa	Dodecamethylcyclohexasiloxane							
	oral	LD50 mg/kg	2000	Rat					
	dermal	LD50 mg/kg	2000	Rat					
541-02-6	Decamethylcyclopentasiloxane								
	oral	LD50 mg/kg	>24100	Rat	GESTIS				
	dermal	LD50 mg/kg	>2000	Rabbit		OECD 402			
	inhalation (4 h) vapour	LC50	8,67 mg/l	Rat		OECD 403			
556-67-2	Octamethylcyclotetrasiloxane								
	oral	LD50 mg/kg	4800	Rat		OECD 401			
	dermal	LD50 mg/kg	>2400	Rabbit		OECD 402			
	inhalation (4 h) vapour	LC50	36 mg/l	Rat	GESTIS	OECD 403			



according to Regulation (EG) Nr. 1907/2006

mollosil (Base + Catalyst)

Revision date: 25.04.2022 Product code: 10488 Page 6 of 9

Irritation and corrosivity

Based on available data, the classification criteria are not met.

Sensitising effects

Based on available data, the classification criteria are not met.

Carcinogenic/mutagenic/toxic effects for reproduction

Based on available data, the classification criteria are not met.

STOT-single exposure

Based on available data, the classification criteria are not met.

STOT-repeated exposure

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

Additional information on tests

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

SECTION 12: Ecological information

12.1. Toxicity

The product is not: Ecotoxic.

12.2. Persistence and degradability

The product has not been tested.

CAS No	Chemical name					
	Method	Value	d	Source		
	Evaluation					
556-67-2	Octamethylcyclotetrasiloxane					
		3,7%	29			
	Not readily biodegradable (according to OECD criteria)					

12.3. Bioaccumulative potential

The product has not been tested.

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment



according to Regulation (EG) Nr. 1907/2006

mollosil (Base + Catalyst)

Revision date: 25.04.2022 Product code: 10488 Page 7 of 9

The mixture contains the following substances fulfilling the PBT criteria according to UK REACH: Dodecamethylcyclohexasiloxane; Decamethylcyclopentasiloxane; Octamethylcyclotetrasiloxane. The mixture contains the following substances fulfilling the vPvB criteria according to UK REACH: Dodecamethylcyclohexasiloxane; Decamethylcyclopentasiloxane; Octamethylcyclotetrasiloxane. Dodecamethylcyclohexasiloxane (D6) fulfills the current criteria set forth under Annex XIII of the EU REACH Regulation for very persistent and very bioaccumulative substances (vPvB) and was included in the candidate list of substances of very high concern (SVHC). According to our knowledge of the state of the art, however, D6 cannot be compared with known persistent, bioaccumulative and toxic (PBT) and/or vPvB substances. The interpretation of the available data by the silicone industry reveals that scientific evidence obtained from field tests essentially points out that D6 does not lead to biomagnification in aquatic and terrestrial food chains. In air, D6 is decomposed by naturally occurring processes in the atmosphere. D-residues which do not decompose in this way in the air are not expected to accumulate from the air in water, the soil or living organisms.

Decamethylcyclopentasiloxane (D5) fulfills the current criteria set forth under Annex XIII of the EU REACH Regulation for vPvB substances and was included in the candidate list of SVHCs. According to our knowledge of the state of the art, however, D5 cannot be compared with known PBT and/or vPvB substances. The interpretation of the available data by the silicone industry reveals that scientific evidence obtained from field tests essentially points out that D5 does not lead to biomagnification in aquatic and terrestrial food chains. In air, D5 is decomposed by naturally occurring processes in the atmosphere. D-residues which do not decompose in this way in the air are not expected to accumulate from the air in water, the soil or living organisms.

Octamethylcyclotetrasiloxane (D4) fulfills the current criteria set forth under Annex XIII of the EU REACH Regulation for PBT and vPvB substances and was included in the candidate list of SVHCs. According to our knowledge of the state of the art, however, D4 cannot be compared with known PBT and/or vPvB substances. The interpretation of the available data by the silicone industry reveals that scientific evidence obtained from field tests essentially points out that D4 does not lead to biomagnification in aquatic and terrestrial food chains. In air, D4 is decomposed by naturally occurring processes in the atmosphere. D-residues which do not decompose in this way in the air are not expected to accumulate from the air in water, the soil or living organisms.

12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

12.7. Other adverse effects

No information available.

Further information

Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Dispose of waste according to applicable legislation.

Contaminated packaging

Wash with plenty of water. Completely emptied packages can be recycled.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN number or ID number:No dangerous good in sense of this transport regulation.14.2. UN proper shipping name:No dangerous good in sense of this transport regulation.14.3. Transport hazard class(es):No dangerous good in sense of this transport regulation.14.4. Packing group:No dangerous good in sense of this transport regulation.

Inland waterways transport (ADN)

14.1. UN number or ID number: No dangerous good in sense of this transport regulation.

Page 8 of 9



Safety Data Sheet

according to Regulation (EG) Nr. 1907/2006

	mollosil (Base + Catalyst)	
ion date: 25.04.2022	Product code: 10488	

14.2. UN proper shipping name:No dangerous good in sense of this transport regulation.14.3. Transport hazard class(es):No dangerous good in sense of this transport regulation.14.4. Packing group:No dangerous good in sense of this transport regulation.

Marine transport (IMDG)

Revision

14.1. UN number or ID number:No dangerous good in sense of this transport regulation.14.2. UN proper shipping name:No dangerous good in sense of this transport regulation.14.3. Transport hazard class(es):No dangerous good in sense of this transport regulation.14.4. Packing group:No dangerous good in sense of this transport regulation.

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number or ID number:No dangerous good in sense of this transport regulation.14.2. UN proper shipping name:No dangerous good in sense of this transport regulation.14.3. Transport hazard class(es):No dangerous good in sense of this transport regulation.14.4. Packing group:No dangerous good in sense of this transport regulation.

14.6. Special precautions for user

No dangerous good in sense of this transport regulation.

14.7. Maritime transport in bulk according to IMO instruments

No dangerous good in sense of this transport regulation.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulatory information

Authorisations (REACH, annex XIV):

Substances of very high concern, SVHC (REACH, article 59):

Dodecamethylcyclohexasiloxane: Decamethylcyclopentasiloxane; Octamethylcyclotetrasiloxane

Restrictions on use (REACH, annex XVII):

Entry 70, Entry 75

Additional information

To follow: 850/2004/EC, 79/117/EEC, 689/2008/EC

The mixture contains substances of very high concern (SVHC candidates):

Dodecamethylcyclohexasiloxane (D6), CAS no. 540-97-6 Decamethylcyclopentasiloxane (D5), CAS no. 541-02-6 Octamethylcyclotetrasiloxane (D4), CAS no. 556-67-2

National regulatory information Approval Code: None allocated

Group Standard: None allocated

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information



according to Regulation (EG) Nr. 1907/2006

mollosil (Base + Catalyst)

Revision date: 25.04.2022 Product code: 10488 Page 9 of 9

Abbreviations and acronyms

ADR: Accord européen sur le transport des marchandises dangereuses par Route

(European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service LC50: Lethal concentration, 50% LD50: Lethal dose, 50% Flam. Liq: Flammable liquids Repr: Reproductive toxicity

Aquatic Chronic: Chronic aquatic hazard

Classification for mixtures and used evaluation method according to Regulation(EG) Nr. 1272/2008

Classification	Classification procedure
Aquatic Chronic 3; H412	Calculation method

Relevant H and EUH statements (number and full text)

H226 Flammable liquid and vapour. H361f Suspected of damaging fertility.

Very toxic to aquatic life with long lasting effects.
 Harmful to aquatic life with long lasting effects.

Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

Identified uses

No	Short title	LCS	SU	PC	PROC	ERC	AC	TF	Specification	
1	Gewerblich	-	-	-	-	-	-	-	2	ĺ

 LCS: Life cycle stages
 SU: Sectors of use

 PC: Product categories
 PROC: Process categories

 ERC: Environmental release categories
 AC: Article categories

TF: Technical functions

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)