

according to Regulation (EC) No 1907/2006

Revision date: 10.08.2018

mollosil plus (Base + Catalyst)

Product code: 10488

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SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

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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**Manufacturer**

Company name:	DETAX GmbH & Co. KG	
Street:	Carl-Zeiss-Strasse	
Place:	D-76275 Ettlingen	
Telephone:	+49 7243/510-0	Telefax: +49 7243/510-100
e-mail:	post@detax.de	
Internet:	www.detax.de	
Responsible Department:	Emergency number: +49 7243/510-0	
	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 / Distributer

Company name:	Ivoclar Vivadent Ltd	
Place:	PO Box 303011, North Harbour, Auckland, 0751	
Telephone:	+64 9 914 9999	Telefax: +64 9 914 9990

1.4. Emergency telephone number:0800 764 766 Poison Hotline (24 hours / 7 days)
NZ: National Poison Centre (New Zealand)**SECTION 2: Hazards identification****2.1. Classification of the substance or mixture****Regulation (EC) No. 1272/2008**

This mixture is not classified as hazardous in accordance with Regulation (EC) No. 1272/2008.

2.2. Label elements**Regulation (EC) No. 1272/2008****Special labelling of certain mixtures**

EUH210 Safety data sheet available on request.

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients**3.2. Mixtures****Chemical characterization**

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

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Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	GHS Classification			
540-97-6	Dodecaemthylcyclohexasiloxane			< 0,5 %
	208-762-8		01-2119517435-42	
541-02-6	Decamethylcyclopentasiloxane			< 0,5 %
	208-764-9		01-2119511367-43	
556-67-2	octamethylcyclotetrasiloxane			< 0,5 %
	209-136-7	014-018-00-1	01-2119529238-36	
	Flam. Liq. 3, Repr. 2, Aquatic Chronic 4; H226 H361f H413			

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

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

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

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Use personal protection equipment.

6.2. Environmental precautions

No special environmental measures are necessary. Clean contaminated objects and areas thoroughly observing environmental regulations.

6.3. Methods and material for containment and cleaning up

Absorb with liquid-binding material (e.g. 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.

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****Protective and hygiene measures**

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

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.

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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
pH-Value:		not determined
Changes in the physical state		
Melting point:		not determined
Initial boiling point and boiling range:		not determined
Flash point:		>100 °C DIN 51755
Flammability		
Solid:		not applicable
Gas:		not applicable
Lower explosion limits:		not determined
Upper explosion limits:		not determined
Ignition temperature:		>400 °C DIN 51794
Auto-ignition temperature		
Solid:		not applicable
Gas:		not applicable
Decomposition temperature:		>180 °C
Oxidizing properties		
Not oxidizing.		
Vapour pressure: (at 20 °C)		<10 hPa
Density (at 20 °C):		1,03 g/cm ³ DIN 51757
Water solubility:		insoluble
Solubility in other solvents		
not determined		
Partition coefficient:		not determined
Viscosity / dynamic: (at 23 °C)		290000 mPa·s BROOKFIELD
Vapour density:		not determined
Evaporation rate:		not determined
9.2. Other information		
Solid content:		not determined

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.

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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 toxicological effects

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.

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

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

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP].

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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

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. Other adverse effects

No information available.

Further information

Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

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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:

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:

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.

Marine transport (IMDG)

14.1. UN 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:

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

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No dangerous good in sense of this transport regulation.

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

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

Classified as Hazardous according to the criteria of the National Occupational Health and Safety Commission (NOHSC) approved criteria for the classifying hazardous substances [NOHSC: 1008] 3rd edition.

Standard for the Uniform Scheduling of Medicines and Poisons.

Carcinogen classification under WHS Regulation 2011, Schedule 10.

Notification status in accordance with section 3 and current national legislation.

HSNO Approval: HSR003719, HSR003225

EPA NZ Classes of hazardous properties:

Classification 3.1D Flammable Liquids: low hazard

Classification 3.1C Flammable Liquids: medium hazard

Classification 6.1D (All): Acutely toxic

Classification 6.1D (O): Acutely toxic

Classification 6.1E (I) Acutely toxic

Classification 6.8B Suspected human reproductive or developmental toxicants

Classification 9.1D (All) Slightly harmful in the aquatic environment or are otherwise designed for biocidal action

SECTION 16: Other information

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%

Relevant H and EUH statements (number and full text)

H226 Flammable liquid and vapour.

H361f Suspected of damaging fertility.

H413 May cause long lasting harmful effects to aquatic life.

EUH210 Safety data sheet available on request.

Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance of

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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

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.)