

Safety Data Sheet

according to UK REACH Regulation

Mucopren Soft

Revision date: 22.05.2018

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

1.1. Product identifier

Mucopren Soft

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

Use of the substance/mixture

Permanently soft, polyvinyl siloxane liner. Medical device for use in dentistry, observe instructions for use.

1.3. Details of the supplier of the safety data sheet

Company name: Kettenbach GmbH & Co. KG
 Street: Im Heerfeld 7
 Place: D-35713 Eschenburg
 Telephone: + 49(0) 2774/705-0
 E-mail: info@kettenbach.com
 Internet: www.kettenbach.com
 Responsible Department: R&D
 Telefax: +49 (0)2774/705-66

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

GB CLP Regulation

This mixture is not classified as hazardous in accordance with GB CLP Regulation.

2.2. Label elements

Additional advice on labelling

There is no requirement for the product to be specially labelled according to EC directives or the corresponding national laws.

2.3. Other hazards

No risks worthy of mention.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Preparation of silicone polymers and fillers with platinum-catalyst (ppm-range).

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (GB CLP Regulation)			
68478-92-2	Platinum, 1,3-diethenyl-1,1,3,3-tetramethyldisiloxane complexes			< 2 %
	270-844-4		01-2120224513-67	
	Repr. 2, Aquatic Chronic 3; H361d H412			

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		
68478-92-2	270-844-4	Platinum, 1,3-diethenyl-1,1,3,3-tetramethyldisiloxane complexes	< 2 %
	inhalation: Data lacking (gases); dermal: Data lacking; oral: LD50 = >5000 mg/kg		

SECTION 4: First aid measures

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4.1. Description of first aid measures

After inhalation

not applicable

After contact with skin

In general the product is not skin irritative.

After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water. In case of troubles or persistent symptoms, consult an ophthalmologist.

After ingestion

Seek medical attention if problems persist.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Water fog. Foam. Carbon dioxide (CO₂).

5.3. Advice for firefighters

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

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General advice

Not required.

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

Other information

Take up mechanically.

6.4. Reference to other sections

No release of hazardous substances.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

No special precautionary measures are necessary.

Advice on protection against fire and explosion

No special precautionary measures are necessary.

Advice on general occupational hygiene

The usual precautions when handling chemicals have to be obtained.
Avoid contact with skin, eyes and clothes.

Further information on handling

No special precautionary measures are necessary.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

No special requirements.

Hints on joint storage

Not required.

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Further information on storage conditions

No special requirements.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Additional advice on limit values

To date, no national critical limit values exist.

8.2. Exposure controls

Appropriate engineering controls

not applicable

Individual protection measures, such as personal protective equipment

Eye/face protection

Not required.

Hand protection

Single-use gloves.

Suitable material: PE (polyethylene).

Unsuitable material: NR (Natural rubber (Caoutchouc), Natural latex).

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

Not required.

Respiratory protection

With correct and proper use, and under normal conditions, breathing protection is not required.

Environmental exposure controls

Not required.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	Paste
Colour:	Base: pink transparent. Catalyst: colourless transparent.
Odour:	odourless
Melting point/freezing point:	not applicable
Boiling point or initial boiling point and boiling range:	not applicable
pH-Value:	neutral
Water solubility:	insoluble
Density (at 20 °C):	1,1 - 1,2 g/cm ³

9.2. Other information

Information with regard to physical hazard classes

Explosive properties

not Explosive.

SECTION 10: Stability and reactivity

10.4. Conditions to avoid

None by intended use.

10.5. Incompatible materials

None by intended use.

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10.6. Hazardous decomposition products

None by intended use.

Further information

Please pay attention to the Directions for Use.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in GB CLP Regulation

Acute toxicity

Acute toxicity, oral LD50: > 2000 mg/kg Rat

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; ATE (inhalation gas) > 20000 ppm

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
68478-92-2	Platinum, 1,3-diethenyl-1,1,3,3-tetramethyldisiloxane complexes				
	oral	LD50 >5000 mg/kg	Rat		
	dermal	Data lacking			
	inhalation	Data lacking			

Irritation and corrosivity

Irritant effect on the skin: non-irritant.

Irritant effect on the eye: non-irritant.

Sensitising effects

no danger of sensitization.

SECTION 12: Ecological information

12.1. Toxicity

product has not been tested.

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] [d]	Species	Source	Method
68478-92-2	Platinum, 1,3-diethenyl-1,1,3,3-tetramethyldisiloxane complexes					
	Aquatic toxicity	Data lacking				

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to UK REACH.

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.

Further information

Do not allow to enter into surface water or drains.

1 (slightly hazardous to water)

Doesn't get into the sewage water as long as the process is carried out according to regulations.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Remove according to the regulations.

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Additional information:

List of Wastes Code - residues/unused products

070217 WASTES FROM ORGANIC CHEMICAL PROCESSES; wastes from the MFSU of plastics, synthetic rubber and man-made fibres; waste containing silicones other than those mentioned in 07 02 16

List of Wastes Code - used product

200399 MUNICIPAL WASTES (HOUSEHOLD WASTE AND SIMILAR COMMERCIAL, INDUSTRIAL AND INSTITUTIONAL WASTES) INCLUDING SEPARATELY COLLECTED FRACTIONS; other municipal wastes; municipal wastes not otherwise specified

Contaminated packaging

Completely emptied packings can be re-cycled.

SECTION 14: Transport information

Other applicable information

No dangerous good in sense of these transport regulations.

SECTION 15: Regulatory information

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

National regulatory information

Water hazard class (D): 1 - slightly hazardous to water

SECTION 16: Other information

Changes

Update 2018-05-17

Relevant H and EUH statements (number and full text)

H361d Suspected of damaging the unborn child.

H412 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.

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