

## Safety Data Sheet

according to UK REACH Regulation

### Mucopren® Soft

Revision date: 10.03.2026

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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.

###### Uses advised against

Use by untrained dental personnel and/or unapproved areas of application.

##### 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	Telefax: +49 (0)2774/705-66
E-mail:	info@kettenbach.com	
Internet:	www.kettenbach.com	
Responsible Department:	R&D	

#### 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.

\*Safety Information Sheet for Medical Devices\* The particulars given in the Safety Information Sheet only apply to the described product in connection with its appropriate utilization. These particulars are based on the latest state of our knowledge and information. They serve the purpose of describing our product under the aspect of hazards caused by such product and pertaining safety actions. They do not constitute any guarantee of product quality and/or quality features. The particulars given in this Safety Information Sheet are not required according to the Article 31 and Annex II of Regulation (EC) No 1907/2006 (REACH Regulation). This product is classified as a medical device. Medical devices are exempt from the labelling provisions. They merely serve the purpose of providing sufficient information on the voluntary basis with a view to ensure the safe utilization of such substance/mixture/product.

##### 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

Due to the physical form (paste) a classification with H373 is not indicated. Inhalation is not possible. The fillers are not bioavailable and accordingly these substances are not considered in the classification of this product for inhalation hazards according to Article 12, note (b) of CLP Directive 1272/2008.

#### SECTION 3: Composition/information on ingredients

##### 3.2. Mixtures

###### Chemical characterization

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

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#### Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (GB CLP Regulation)			
68909-20-6	silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica (nanoform: Nanoform: 2.5 - 50 nm [D50, number distribution])			10 - <30 (*) %
	272-697-1	014-052-00-7		
	STOT RE 2; H373 EUH066			

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		
68909-20-6	272-697-1	silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	10 - <30 (*) %
	inhalation: Data lacking (gases); dermal: LD50 = >2000 mg/kg; oral: LD50 = >5000 mg/kg		

#### Further Information

(\*) The actual concentration is withheld as a trade secret.

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

##### General information

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

##### 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.

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

No data available

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

No data available

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

##### Suitable extinguishing media

All standard extinguishing agents are suitable.

##### Unsuitable extinguishing media

None known.

#### 5.2. Special hazards arising from the substance or mixture

None.

#### 5.3. Advice for firefighters

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

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#### SECTION 6: Accidental release measures

##### **6.1. Personal precautions, protective equipment and emergency procedures**

###### **General advice**

Use personal protection equipment.

##### **6.2. Environmental precautions**

Do not allow to enter into surface water or drains.

##### **6.3. Methods and material for containment and cleaning up**

###### **For containment**

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents).

###### **Other information**

Allow stiffening. Take up mechanically.

##### **6.4. Reference to other sections**

Safe handling: see section 7

Personal protection equipment: see section 8

Section 12: Ecological Information (non-mandatory)

#### SECTION 7: Handling and storage

##### **7.1. Precautions for safe handling**

###### **Advice on safe handling**

Wear personal protection equipment (refer to section 8).

###### **Advice on protection against fire and explosion**

No special precautionary measures are necessary.

###### **Advice on general occupational hygiene**

Avoid contact with skin, eyes and clothes.

When using do not eat, drink, smoke, sniff.

###### **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**

Keep away from food and drink.

###### **Further information on storage conditions**

Please pay attention to the information on the package!

##### **7.3. Specific end use(s)**

Apart from the uses mentioned in section 1.2, no other specific uses are foreseen.

#### 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**

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#### Appropriate engineering controls

not applicable

#### Individual protection measures, such as personal protective equipment

##### Eye/face protection

Safety glasses.

##### 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.

##### Thermal hazards

None.

##### Environmental exposure controls

Do not allow to enter into surface water or drains.

## 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
Odour threshold:	not determined

#### Test method

Melting point/freezing point:	not applicable
Boiling point or initial boiling point and boiling range:	not applicable
Flammability:	not determined
Lower explosion limits:	not determined DIN EN 1839
Upper explosion limits:	not determined DIN EN 1839
Flash point:	not determined
Auto-ignition temperature:	not determined
Decomposition temperature:	not determined
pH-Value:	neutral
Viscosity / kinematic:	not determined
Water solubility:	insoluble
Solubility in other solvents	
not determined	
Density (at 20 °C):	1.1 - 1.2 g/cm <sup>3</sup>
Bulk density:	not applicable
Particle characteristics:	not determined

### 9.2. Other information

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#### Information with regard to physical hazard classes

Explosive properties  
not Explosive.  
Oxidizing properties  
None.

#### Further Information

The physical data presented above are typical values and should not be construed as a specification.

### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

None by intended use.

#### 10.2. Chemical stability

The product is chemically stable under recommended conditions of storage, use and temperature.

#### 10.3. Possibility of hazardous reactions

No known hazardous reactions.

#### 10.4. Conditions to avoid

Storage outside of the predetermined storage conditions (see packaging)

#### 10.5. Incompatible materials

None by intended use.

#### 10.6. Hazardous decomposition products

Formaldehyde

#### 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

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

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
68909-20-6	silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica				
	oral	LD50 >5000 mg/kg	Rat		
	dermal	LD50 >2000 mg/kg	Rabbit		
	inhalation	Data lacking			

#### Irritation and corrosivity

Skin corrosion/irritation: Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation: Based on available data, the classification criteria are not met.

Irritant effect on the skin: non-irritant.

Irritant effect on the eye: non-irritant.

#### Sensitising effects

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Based on available data, the classification criteria are not met.  
no danger of sensitization.

#### Carcinogenic/mutagenic/toxic effects for reproduction

Germ cell mutagenicity: Based on available data, the classification criteria are not met.  
Carcinogenicity: Based on available data, the classification criteria are not met.  
Reproductive toxicity: 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.

## SECTION 12: Ecological information

### 12.1. Toxicity

Based on available data, the classification criteria are not met.  
product has not been tested.

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h]   [d]	Species	Source	Method
68909-20-6	silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica					
	Acute fish toxicity	LC50 mg/l	>1000	96 h	Danio rerio (zebrafish)	
	Acute algae toxicity	ErC50 mg/l	>10000	72 h	Scenedesmus subspicatus	
	Acute crustacea toxicity	EC50 mg/l	>1000	48 h	Daphnia magna (Big water flea)	

### 12.2. Persistence and degradability

product has not been tested.

### 12.3. Bioaccumulative potential

product has not been tested.

### 12.4. Mobility in soil

product has not been tested.

### 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.

### 12.7. Other adverse effects

None known.

### 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

Do not remove with domestic waste.

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#### List of Wastes Code - residues/unused products

180106 WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (EXCEPT KITCHEN AND RESTAURANT WASTES NOT ARISING FROM IMMEDIATE HEALTH CARE); wastes from natal care, diagnosis, treatment or prevention of disease in humans; chemicals consisting of or containing hazardous substances; hazardous waste

#### List of Wastes Code - used product

150110 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); packaging containing residues of or contaminated by hazardous substances; hazardous waste

#### List of Wastes Code - contaminated packaging

150110 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); packaging containing residues of or contaminated by hazardous substances; hazardous waste

#### Contaminated packaging

Non-contaminated packages may be recycled.

## SECTION 14: Transport information

#### Land transport (ADR/RID)

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

#### Inland waterways transport (ADN)

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

#### Marine transport (IMDG)

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

#### Air transport (ICAO-TI/IATA-DGR)

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

#### 14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

#### 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.

#### Other applicable information

No dangerous good in sense of these transport regulations.

## SECTION 15: Regulatory information

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#### **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**

This data sheet contains changes from the previous version in section(s): 1,2,3,4,5,6,7,8,9,10,11,12,13,14,16.

Date of preparation / Revised on: 10/03/2026

Version number: 4,02

Replaces version number: 4,01 (23/05/2018)

##### **Abbreviations and acronyms**

ATE: Acute toxicity estimate. CAS: Chemical abstracts service. CFR: Code of Federal Regulations. DNEL: Derived No Effect Level EC50: 50% of maximal effective concentration. FDA: Food and Drug Administration. GHS: Globally Harmonised System. IATA: International air transport association. ICAO: Technical instructions for the safe transport of dangerous goods by air. IMDG: International maritime dangerous goods. LC50: Lethal concentration to 50 % of a test population. LD50: Lethal dose to 50% of a test population (median lethal dose). NOAEL: No Observed Adverse Effect Level. PBT: Persistent, bioaccumulative and toxic substance. PEL: Permissible Exposure Limit. PNEC: Predicted No Effect Concentration. REL: Recommended exposure limit. STOT RE: Specific Target Organ Toxicity – Single Exposure. STOT SE: Specific Target Organ Toxicity – Repeated Exposure. TWA: 8-hour Time Weighted Averages (long-term exposure limit). US OSHA: US Occupational Safety and Health Administration. vPvB: Very persistent and very bioaccumulative.

##### **Key literature references and sources for data**

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

##### **Relevant H and EUH statements (number and full text)**

H373 May cause damage to organs through prolonged or repeated exposure.  
EUH066 Repeated exposure may cause skin dryness or cracking.

##### **Further Information**

Training instructions: Use only by personnel trained in dentistry.

Disclaimer: The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions.

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