

Safety Data Sheet

according to UK REACH Regulation

Mucopren silicone sealant

Revision date: 14.05.2024

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

1.1. Product identifier

Mucopren silicone sealant

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

Further Information

The product is intended for professional use.

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

No risks worthy of mention.

Due to the physical form (paste) a classification with H373 is not indicated. Inhalation is not possible.

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 | | | 15 - < 20 % |
| | 272-697-1 | 014-052-00-7 | 01-2119379499-16 | |
| | 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 | 15 - < 20 % |
| | inhalation: Data lacking (gases); dermal: LD50 = >2000 mg/kg; oral: LD50 = >5000 mg/kg | | |

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. Water fog. Foam. Carbon dioxide (CO₂).

Unsuitable extinguishing media

None known.

5.2. Special hazards arising from the substance or mixture

Not applicable.

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

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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

For containment

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

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.

Further information on storage conditions

No special requirements.

7.3. Specific end use(s)

Not required.

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).

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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: | No data available |
| Flammability: | No data available |
| Lower explosion limits: | No data available |
| Upper explosion limits: | No data available |
| Flash point: | No data available |
| Auto-ignition temperature: | No data available |
| Decomposition temperature: | No data available |
| pH-Value: | neutral |
| Viscosity / kinematic: | No data available |
| Water solubility: | insoluble |
| Dissolution rate: | No data available |
| Partition coefficient n-octanol/water: | No data available |
| Dispersion stability: | No data available |
| Vapour pressure: | No data available |
| Vapour pressure: | No data available |
| Density (at 20 °C): | 1.1 - 1.2 g/cm ³ |
| Relative density: | No data available |
| Bulk density: | not applicable |
| Relative vapour density: | No data available |
| Particle characteristics: | not applicable |

9.2. Other information

Information with regard to physical hazard classes

Explosive properties
not Explosive.

Oxidizing properties
not applicable

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.

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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

strong base
Oxidising agent, strong

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

| 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

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

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

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.

SECTION 12: Ecological information

12.1. Toxicity

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

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| 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) | |

12.5. 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

Do not remove with domestic waste.

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. Completely emptied packings can be re-cycled.

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. |
|--------------------------------------|--|

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- 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 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.

14.5. 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

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

EU regulatory information

Restrictions on use (REACH, annex XVII):
Entry 40, Entry 70

National regulatory information

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

15.2. Chemical safety assessment

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

SECTION 16: Other information

Changes

This data sheet contains changes from the previous version in section(s): 2,16.

Date of preparation / Revised on: 14/05/2024

Version number: 3,04

Replaces version number: 3,03 (22/05/2018)

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.

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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.)