

## Safety Data Sheet

according to UK REACH Regulation

### Silginat

Revision date: 19.11.2025

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

### 1.1. Product identifier

Silginat

#### Further trade names

Silginat

Silginat Strawberry

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

#### Use of the substance/mixture

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

#### 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 &amp; 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&amp;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

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

none (according to UK REACH Regulation)

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#### 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.

###### 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

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

###### 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

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#### 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 fire protection 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

##### **Exposure limits (EH40)**

CAS No	Substance	ppm	mg/m <sup>3</sup>	fibres/ml	Category	Origin
57-55-6	Propane-1,2-diol, particulates	-	10		TWA (8 h)	WEL
57-55-6	Propane-1,2-diol, total vapour and particulates	150	474		TWA (8 h)	WEL

#### 8.2. Exposure controls

##### **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.

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## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state:	Paste
Colour:	Catalyst: white. Base: pink
Odour:	Silginat: odourless. Silginat strawberry: Strawberry odour.
Odour threshold:	not determined

#### Test method

Melting point/freezing point:	not applicable
Boiling point or initial boiling point and boiling range:	not applicable
Flammability:	No data available
Lower explosion limits:	not applicable
Upper explosion limits:	not applicable
Flash point:	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
pH-Value:	No data available ASTM D 1287:2011
Viscosity / kinematic:	No data available ISO 3219
Water solubility:	insoluble OECD 105
Solubility in other solvents	not applicable
Vapour pressure:	not applicable
Density (at 20 °C):	1,4 - 1,6 g/cm³
Particle characteristics:	No data available

### 9.2. Other information

#### Information with regard to physical hazard classes

Explosive properties	not applicable
Self-ignition temperature	UN Test N.3
Oxidizing properties	not applicable

## 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

strong base  
Oxidising agent, strong

### 10.6. Hazardous decomposition products

Formaldehyde

### Further information

Please pay attention to the Directions for Use.

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## 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: &gt; 2000 mg/kg Rat

#### **ATEmix calculated**

ATE (oral) &gt; 2000 mg/kg; ATE (dermal) &gt; 2000 mg/kg; ATE (inhalation vapour) &gt; 20 mg/l

#### **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**

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.

Not applicable.

#### **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.

Not applicable.

#### **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.

### 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.

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## 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.

## SECTION 14: Transport information

### Land transport (ADR/RID)

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

### Inland waterways transport (ADN)

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

### Marine transport (IMDG)

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

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

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

### 14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

### 14.6. Special precautions for user

N/A

### 14.7. Maritime transport in bulk according to IMO instruments

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No dangerous good in sense of this transport regulation.

#### Other applicable information

Not a hazardous material with respect to these transportation 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

#### 15.2. Chemical safety assessment

For this substance a chemical safety assessment is not required.

### SECTION 16: Other information

#### Changes

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

Date of preparation / Revised on: 19/11/2025

Version number: 3,06

Replaces version number: 3,05 (21/02/2025)

#### 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.

#### 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.)*