

## Safety Data Sheet

according to Regulation (EC) No 1907/2006

### silasoft® Normal

Print date: 08.04.2016

Product code: 10270

Page 1 of 7

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

### 1.1. Product identifier

silasoft® Normal

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

#### Use of the substance/mixture

Impression material for use in dental technology.

### 1.3. Details of the supplier of the safety data sheet

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.)

### 1.4. Emergency telephone 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 - 4.00 p.m.)

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

This mixture is not classified as hazardous according to Regulation (EC) No. 1272/2008.

### 2.2. Label elements

#### Special labelling of certain mixtures

EUH210 Safety data sheet available on request.

#### Additional advice on labelling

According to Regulation (EC) 1272/2008, art.1 No. 5 (d) this product as a medical product must not be labelled!

### 2.3. Other hazards

No information available.

## SECTION 3: Composition/information on ingredients

### 3.2. Mixtures

#### Chemical characterization

Contains polydimethylsiloxane with functional groups. + fillers and pigment

## Safety Data Sheet

according to Regulation (EC) No 1907/2006

### silasoft® Normal

Print date: 08.04.2016

Product code: 10270

Page 2 of 7

#### Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification according to Regulation (EC) No. 1272/2008 [CLP]			
68855-54-9	kieselguhr			20 - < 25 %
	272-489-0			
	STOT RE 2; H373			
14464-46-1	cristobalite			1 - < 5 %
	238-455-4			
	STOT RE 1; H372			

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

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

##### After inhalation

Provide fresh air. Medical treatment necessary.

##### After contact with skin

Wash with plenty of water. Immediately remove any contaminated clothing, shoes or stockings. Medical treatment necessary.

##### After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water. In case of eye irritation consult an ophthalmologist.

##### After ingestion

Rinse mouth thoroughly with water. Let water be drunken in little sips (dilution effect). Do not induce vomiting. If you feel unwell, seek medical advice.

#### 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. Vapours can form explosive mixtures with air.

#### 5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus.

#### Additional information

Use water spray jet to protect personnel and to cool endangered containers. Suppress gases/vapours/mists with water spray jet.

### SECTION 6: Accidental release measures

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

Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes and clothes. Use personal protection equipment.

according to Regulation (EC) No 1907/2006

**silasoft® Normal**

Print date: 08.04.2016

Product code: 10270

Page 3 of 7

**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**

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

**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. Keep locked up. Store in a place accessible by authorized persons only. Provide adequate ventilation as well as local exhaustion at critical locations.

**Advice on storage compatibility**

No special measures are necessary.

**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)**

Component B of a silicone based dental impression material.  
For use by trained specialist staff.

**SECTION 8: Exposure controls/personal protection****8.1. Control parameters****8.2. Exposure controls****Appropriate engineering controls**

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

**Protective and hygiene measures**

Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme. Wash hands and face before breaks and after work and take a shower if necessary. 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.

according to Regulation (EC) No 1907/2006

### silasoft® Normal

Print date: 08.04.2016

Product code: 10270

Page 4 of 7

Suitable are gloves of the following material: NBR (Nitrile rubber)

#### Skin protection

Wear suitable protective clothing.

#### Respiratory protection

In case of inadequate ventilation wear respiratory protection.

## SECTION 9: Physical and chemical properties

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

Physical state:	Paste	
Colour:	pink - opaque	
Odour:	odourless	
		<b>Test method</b>
pH-Value:		not determined
<b>Changes in the physical state</b>		
Melting point:		not determined
Initial boiling point and boiling range:		not determined
Flash point:		>100 °C DIN 51755
<b>Flammability</b>		
Solid:		not applicable
Gas:		not applicable
Lower explosion limits:		not determined
Upper explosion limits:		not determined
Ignition temperature:		>200 °C DIN 51794
<b>Auto-ignition temperature</b>		
Solid:		not applicable
Gas:		not applicable
Decomposition temperature:		>250 °C
<b>Oxidizing properties</b>		
Not oxidizing.		
Vapour pressure:		<1 hPa
(at 20 °C)		
Density (at 20 °C):		1,17 g/cm <sup>3</sup> DIN 51757
Water solubility:		practically insoluble
<b>Solubility in other solvents</b>		
not determined		
Partition coefficient:		not determined
Viscosity / dynamic:		14000 mPa·s BROOKFIELD
(at 23 °C)		
Vapour density:		not determined
Evaporation rate:		not determined
<b>9.2. Other information</b>		
Solid content:		not determined

## SECTION 10: Stability and reactivity

## Safety Data Sheet

according to Regulation (EC) No 1907/2006

### silasoft® Normal

Print date: 08.04.2016

Product code: 10270

Page 5 of 7

#### **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**

No known hazardous reactions.

#### **10.4. Conditions to avoid**

Temperatures > 150°C/ 302 °F.

#### **10.5. Incompatible materials**

No information available.

#### **10.6. Hazardous decomposition products**

At a temperature of approx. 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.

##### **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.

##### **STOT-single exposure**

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

##### **Severe effects after repeated or prolonged exposure**

Based on available data, the classification criteria are not met.  
Due to physical form (paste) classification with H372 is not appropriate. An inhalation of the product is not possible. Due to physical form (paste) classification with H373 is not appropriate. An inhalation of the product is not possible.  
EC regulation 1272/2008 annex 1, section 1.1.1.5: "For the purpose of classification of health hazards (part 3), the route of exposure, information on mechanisms and metabolism studies are useful for determining the relevance of effects in humans. If this information raises doubts as to their relevance in humans, in spite of the indisputable data legitimacy and quality, a lower classification may be justified. When there is scientific evidence that the mechanism or mode of action is not relevant to humans, the substance or mixture should not be classified."

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

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**

The product is not: Ecotoxic.

#### **12.2. Persistence and degradability**

The product has not been tested.

#### **12.3. Bioaccumulative potential**

## Safety Data Sheet

according to Regulation (EC) No 1907/2006

### silasoft® Normal

Print date: 08.04.2016

Product code: 10270

Page 6 of 7

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**

Not identified as PBT/ vPvB substances

#### **12.6. Other adverse effects**

No information available.

#### **Further information**

Avoid release to the environment.

### SECTION 13: Disposal considerations

#### **13.1. Waste treatment methods**

##### **Advice on disposal**

Do not allow to enter into surface water or drains. Dispose of waste according to applicable legislation.

##### **Contaminated packaging**

This material and its container must be disposed of as hazardous waste. Handle contaminated packages in the same way as the substance itself.

### 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)**

##### **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**

No dangerous good in sense of this transport regulation.

#### **14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**

No dangerous good in sense of this transport regulation.

## Safety Data Sheet

according to Regulation (EC) No 1907/2006

**silasoft® Normal**

Print date: 08.04.2016

Product code: 10270

Page 7 of 7

### SECTION 15: Regulatory information

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

##### EU regulatory information

##### Additional information

To follow: 850/2004/EC, 79/117/EEC, 689/2008/EC

##### National regulatory information

Employment restrictions: Observe employment restrictions for young people. Observe employment restrictions for child bearing mothers and nursing.

Water contaminating class (D): - - not water contaminating

#### 15.2. Chemical safety assessment

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

### 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-phrases (Number and full text)

H372 Causes damage to organs (lung) through prolonged or repeated exposure if inhaled.  
H373 May cause damage to organs through prolonged or repeated exposure.  
EUH210 Safety data sheet available on request.

#### Further Information

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

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