



# SAFETY DATA SHEET

## SECTION 1. Identification of the substance or mixture and of the supplier

- 1.1 Product identifier  
Trade Name:  
**CERAMAGE  
(OPAQUE DENTIN/ BODY/ CERVICAL/INCISAL/TRANSLUCENT/CONCENTRATE)**
- 1.2 Relevant identified uses of the substance or mixture and uses advised against  
Relevant identified uses: Dental material  
Uses advised against: No further data
- 1.3 Details of the supplier of the safety data sheet  
Company/Undertaking identification  
Manufacturer's Name: SHOFU DENTAL GmbH  
Address: An der Pönt 70, 40885 Ratingen, Germany  
Phone: +49 (0) 2102-8664-0  
Fax: +49 (0) 2102-8664-64  
E-Mail: info@shofu.de  
Section in Charge: Quality Management & Regulatory Affairs
- 1.4 Emergency Telephone Number  
+49-2102-8664-53 (SHOFU DENTAL GmbH) 24 hours / 7 days

## SECTION 2. Hazards identification

- 2.1 Classification of the substance or mixture  
CLASSIFICATION (EC 1272/2008)
- |               |      |                                     |
|---------------|------|-------------------------------------|
| Skin Irrit. 2 | H315 | Causes skin irritation              |
| Skin Sens. 1  | H317 | May cause an allergic skin reaction |
| Eye Irrit. 2  | H319 | Causes serious eye irritation       |

- 2.2 Label elements  
LABEL IN ACCORDANCE WITH (EC) NO.1272/2008



GHS07

HAZARD-DETERMINING COMPONENTS OF LABELLING  
UDMA

SIGNAL WORD

Warning

HAZARD STATEMENTS

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.

PRECAUTIONARY STATEMENTS

P280	Wear protective gloves/protective clothing/eye protection/face protection.
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P302+P352

IF ON SKIN: Wash with plenty of soap and water.

P305+P351+P338

IF IN EYES: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

P501

Dispose of contents/container in accordance with local/regional/national/international regulation.

## 2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

## SECTION 3. Composition/information on ingredients

3.1 Chemical characterization: Mixtures

3.2 Description: Mixture of substances listed below with nonhazardous additions.

3.3 Dangerous components:

Cas: 72869-86-4 EINECS: 276-957-5	UDMA	5-15 %
	Skin Irrit. 2, H315; Skin Sens. 1, H317 Eye Irrit. 2, H319	

3.4 Additional information: For the wording of the listed risk phrases refer to section 2.

## SECTION 4. First-aid measures

4.1 Description of first aid measures

Eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present. and easy to do. If eye irritation persists, get medical advice/attention.

Skin contact: Wash immediately with soap and plenty of water. If on skin, skin irritation, get medical advice/attention.

Ingestion: Rinse mouth. Get medical advice/attention.

Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. If symptom concerning breath goes out, call a POISON CENTER or doctor.

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

## SECTION 5. Fire-fighting measures

5.1 Extinguishing Media:

CO<sub>2</sub>, Dry chemical, Foam, Dry sand

5.2 Special hazards arising from the substance or mixture:

No further relevant information available.

5.3 Advice for firefighters:

Wear fire protective cloth and self-contained breathing apparatus, if necessary.

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Version Number 5

Revision date: April 1, 2020



# SAFETY DATA SHEET

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## SECTION 6. Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures:  
Avoid eye and skin contact.
- 6.2 Environmental Precautions:  
Send to approved treatment/disposal company or dispose according to local, state and federal regulations.
- 6.3 Methods and material for containment and cleaning up:  
Wipe up and discard in a suitable container.
- 6.4 Reference to other section:  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

## SECTION 7. Handling and storage

- 7.1 Precautions for safe handling:  
Avoid inhalation of grindings and prolonged skin contact with uncured resin.
- 7.2 Conditions for safe storage, including any incompatibilities:  
Store in a cool and dark area.
- 7.3 Specific end use(s):  
No further relevant information available.

## SECTION 8. Exposure controls/personal protection

- 8.1 Control parameters:  
Ingredients with limit values that require monitoring at the workplace:  
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- 8.2 Exposure controls:  
Respiratory Protection: Required (use dust mask while grinding or finishing.)  
Skin Protection: Hand Protection  
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.
  - Material of gloves  
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

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- Penetration time of glove material  
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:  
Butyl rubber, BR  
Nitrile rubber, NBR

Eye Protection: Safety goggles

## SECTION 9. Physical and chemical properties

- 9.1 Information on basic physical and chemical properties
- |  |   |
|--|---|
| Appearance/Odor/Colour:                      | Colored putty-like paste with sweet odor. |
| Odour threshold                              | Not determined.                           |
| pH   | Not determined.                           |
| Melting point/freezing point                 | Not determined.                           |
| Boiling Point:                               | Not determined.                           |
| Flash point:                                 | Not determined.                           |
| Evaporation rate                             | Not determined.                           |
| Flammability (solid, gas)                    | Not applicable.                           |
| Upper/lower flammability or explosive limits | Not determined.                           |
| Vapour pressure                              | Not determined.                           |
| Vapour density                               | Not determined.                           |
| Relative Density:                            | ≈ 1.7 (water=1)                           |
| Solubility: water solubility                 | Insoluble                                 |
| Partition coefficient: n-octanol/water       | Not determined.                           |
| Auto-ignition temperature                    | Not determined.                           |
| Decomposition temperature                    | Not determined.                           |
| Viscosity                                    | Not determined.                           |
| Explosive properties                         | Not applicable.                           |
| Oxidising properties                         | Not applicable.                           |
- 9.2 Other information  
No further relevant information available.

## SECTION 10. Stability and reactivity

- 10.1 Reactivity:  
Polymerization will occur with heat, light.
- 10.2 Chemical stability:  
Stable under normal temperatures and pressures.
- 10.3 Possibility of hazardous reactions:  
No dangerous reactions known.
- 10.4 Condition to Avoid:  
Direct sunlight, high temperature and heating.
- 10.5 Incompatible materials:  
Strong oxidizing materials.

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10.6 Hazardous Decomposition Products:  
None under normal conditions of storage and use.

## SECTION 11. Toxicological information

11.1 Information on toxicological effects:

Acute toxicity:	Based on available data, the classification criteria are not met
Skin corrosion/irritation:	Skin Irrit. 2; H315 Causes skin irritation.
Eye damage/irritation:	Eye Irrit. 2; H319 Causes serious eye irritation.
Sensitization to the respiratory tract:	Based on available data, the classification criteria are not met.
Skin sensitization:	Skin Sens. 1; H317 May cause an allergic skin reaction.
Germ cell mutagenicity/Genotoxicity:	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.
Effects on or via lactation:	Lack of data.
Specific target organ toxicity (single exposure):	Based on available data, the classification criteria are not met.
Specific target organ toxicity (repeated exposure):	Based on available data, the classification criteria are not met.

## SECTION 12. Ecological information

12.1 Toxicity:  
No further relevant information available.

12.2 Persistence and degradability:  
No further relevant information available.

12.3 Bioaccumulative potential:  
No further relevant information available.

12.4 Mobility in soil:  
No further relevant information available.

12.5 Results of PBT and vPvB assessment:  
Not applicable.

12.6 Other adverse effects:  
No further relevant information available.

## SECTION 13. Disposal considerations

13.1 Waste treatment methods:  
Dispose of contents/container to in accordance with local/regional/national/international regulations.

## SECTION 14. Transport information

14.1 UN number:	Void
14.2 UN proper shipping name:	Void
14.3 Transport hazard class(es):	Void

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CERAMAGE

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- 14.4 Packing group: Void
- 14.5 Environmental hazards: No further relevant information available.
- 14.6 Special precautions for user: Not applicable.
- 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code: Not applicable.

## SECTION 15. Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:
- EU REGULATIONS: See Section 2
  - Other regulations, limitations and prohibitive regulations:  
The product is a medical device according to the EC-directive 93/42/EEC.
- 15.2 Chemical safety assessment:  
A Chemical Safety Assessment has not been carried out.

## SECTION 16. Other information

This product is intended for use by dental professionals. (instrument/material)

Relevant phrases:

- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.

Abbreviations and acronyms:

- EINECS: European Inventory of Existing Commercial Chemical Substances
- CAS: Chemical Abstracts Service (division of the American Chemical Society)
- PBT: Persistent, Bioaccumulative and Toxic
- vPvB: very Persistent and very Bioaccumulative



# SAFETY DATA SHEET

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CERAMAGE  
OPAQUE & PREOPAQUE  
Printing date: June 11, 2020

## SECTION 1. Identification of the substance or mixture and of the supplier

- 1.1 Product identifier  
Trade Name:  
**CERAMAGE "OPAQUE & PREOPAQUE"**
- 1.2 Relevant identified uses of the substance or mixture and uses advised against  
Relevant identified uses: Dental material  
Uses advised against: No further data
- 1.3 Details of the supplier of the safety data sheet  
Company/Undertaking identification  
Manufacturer's Name: SHOFU DENTAL GmbH  
Address: An der Pönt 70, 40885 Ratingen, Germany  
Phone: +49 (0) 2102-8664-0  
Fax: +49 (0) 2102-8664-64  
E-Mail: info@shofu.de  
Section in Charge: Quality Management & Regulatory Affairs
- 1.4 Emergency Telephone Number  
+49-2102-8664-53 (SHOFU DENTAL GmbH) 24 hours / 7 days

## SECTION 2. Hazards identification

- 2.1 Classification of the substance or mixture  
CLASSIFICATION (EC 1272/2008)
- |               |      |                                     |
|---------------|------|-------------------------------------|
| Skin Irrit. 2 | H315 | Causes skin irritation              |
| Skin Sens. 1  | H317 | May cause an allergic skin reaction |
| Eye Irrit. 2  | H319 | Causes serious eye irritation       |

- 2.2 Label elements  
LABEL IN ACCORDANCE WITH (EC) NO.1272/2008



GHS07

### HAZARD-DETERMINING COMPONENTS OF LABELLING

UDMA  
2-hydroxyethyl methacrylate

### SIGNAL WORD

Warning

### HAZARD STATEMENTS

H315 Causes skin irritation.  
H317 May cause an allergic skin reaction.  
H319 Causes serious eye irritation.

### PRECAUTIONARY STATEMENTS

P280 Wear protective gloves/protective clothing/eye protection/face protection.

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CERAMAGE  
OPAQUE & PREOPAQUE  
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P302+P352

IF ON SKIN: Wash with plenty of soap and water.

P305+P351+P338

IF IN EYES: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

P501

Dispose of contents/container in accordance with local/regional/national/international regulation.

## 2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

## SECTION 3. Composition/information on ingredients

3.1 Chemical characterization: Mixtures

3.2 Description: Mixture of substances listed below with nonhazardous additions.

3.3 Dangerous components:

Cas: 72869-86-4 EINECS: 276-957-5	UDMA	25-35 %
	Skin Irrit. 2, H315; Skin Sens. 1, H317 Eye Irrit. 2, H319	
Cas: 868-77-9 EINECS: 212-782-2	2-hydroxyethyl methacrylate	4-7 %
	Skin Irrit. 2, H315; Skin Sens. 1, H317 Eye Irrit. 2, H319	

3.4 Additional information: For the wording of the listed risk phrases refer to section 2.

## SECTION 4. First-aid measures

4.1 Description of first aid measures

Eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present. and easy to do. If eye irritation persists, get medical advice/attention.

Skin contact: Wash immediately with soap and plenty of water. If on skin, skin irritation, get medical advice/attention.

Ingestion: Rinse mouth. Get medical advice/attention.

Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. If symptom concerning breath goes out, call a POISON CENTER or doctor.

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

## SECTION 5. Fire-fighting measures

5.1 Extinguishing Media:

CO<sub>2</sub>, Dry chemical, Foam, Dry sand

5.2 Special hazards arising from the substance or mixture:

No further relevant information available.

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CERAMAGE  
OPAQUE & PREOPAQUE  
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## 5.3 Advice for firefighters:

Wear fire protective cloth and self-contained breathing apparatus, if necessary.

## SECTION 6. Accidental release measures

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

Avoid eye and skin contact.

### 6.2 Environmental Precautions:

Send to approved treatment/disposal company or dispose according to local, state and federal regulations.

### 6.3 Methods and material for containment and cleaning up:

Absorb with suitable absorbent (e.g. paper towel, cloth, dry sand, saw dust and vermiculite) and discard in a suitable container.

### 6.4 Reference to other section:

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

## SECTION 7. Handling and storage

### 7.1 Precautions for safe handling:

Avoid inhalation of grindings and prolonged skin contact with uncured resin.

### 7.2 Conditions for safe storage, including any incompatibilities:

Store in a cool and dark area.

### 7.3 Specific end use(s):

No further relevant information available.

## SECTION 8. Exposure controls/personal protection

### 8.1 Control parameters:

Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

### 8.2 Exposure controls:

Respiratory Protection:

Required (use dust mask while grinding or finishing.)

Skin Protection: Hand Protection

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

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CERAMAGE  
OPAQUE & PREOPAQUE  
Printing date: June 11, 2020

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- Material of gloves  
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
- Penetration time of glove material  
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:  
Butyl rubber, BR  
Nitrile rubber, NBR

Eye Protection: Safety goggles

## SECTION 9. Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Appearance/Odor/Colour:	Creamy paste multiple shades yellowish white to yellowish brown with sweet odor from acrylate.
Odour threshold	Not determined.
pH	Not determined.
Melting point/freezing point	Not determined.
Boiling Point:	Not determined.
Flash point:	Not determined.
Evaporation rate	Not determined.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	Not determined.
Vapour pressure	Not determined.
Vapour density	Not determined.
Relative Density:	1.69 (OPAQUE), 1.57 (PREOPAQUE) (water=1)
Solubility: water solubility	Insoluble
Partition coefficient: n-octanol/water	Not determined.
Auto-ignition temperature	Not determined.
Decomposition temperature	Not determined.
Viscosity	Not determined.
Explosive properties	Not applicable.
Oxidising properties	Not applicable.

### 9.2 Other information

No further relevant information available.

## SECTION 10. Stability and reactivity

### 10.1 Reactivity:

Polymerization will occur with heat, light.

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CERAMAGE  
OPAQUE & PREOPAQUE  
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- 10.2 Chemical stability:  
Stable under normal temperatures and pressures.
- 10.3 Possibility of hazardous reactions:  
No dangerous reactions known.
- 10.4 Condition to Avoid:  
Direct sunlight, high temperature and heating.
- 10.5 Incompatible materials:  
Strong oxidizing materials.
- 10.6 Hazardous Decomposition Products:  
None under normal conditions of storage and use.

## SECTION 11. Toxicological information

- 11.1 Information on toxicological effects:
- Acute toxicity: 2-Hydroxy Ethyl Methacrylate;  
Oral rat LD50 5050 mg/kg  
Dermal rabbit LD50 > 3000 mg/kg
- Skin corrosion/irritation: Skin Irrit. 2; H315 Causes skin irritation.
- Eye damage/irritation: Eye Irrit. 2; H319 Causes serious eye irritation.
- Sensitization to the respiratory tract:  
Based on available data, the classification criteria are not met.
- Skin sensitization: Skin Sens. 1; H317 May cause an allergic skin reaction.
- Germ cell mutagenicity/Genotoxicity:  
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.
- Effects on or via lactation: Lack of data.
- Specific target organ toxicity (single exposure):  
Based on available data, the classification criteria are not met.
- Specific target organ toxicity (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:  
No further relevant information available.
- 12.2 Persistence and degradability:  
No further relevant information available.
- 12.3 Bioaccumulative potential:  
No further relevant information available.
- 12.4 Mobility in soil:  
No further relevant information available.
- 12.5 Results of PBT and vPvB assessment:  
Not applicable.
- 12.6 Other adverse effects:  
No further relevant information available.

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CERAMAGE  
OPAQUE & PREOPAQUE  
Printing date: June 11, 2020

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## SECTION 13. Disposal considerations

### 13.1 Waste treatment methods:

Dispose of contents/container to in accordance with local/regional/national/international regulations.

## SECTION 14. Transport information

- |   |  |
|---|--|
| 14.1 UN number:   | Void                                       |
| 14.2 UN proper shipping name:   | Void                                       |
| 14.3 Transport hazard class(es):  | Void                                       |
| 14.4 Packing group:   | Void                                       |
| 14.5 Environmental hazards:   | No further relevant information available. |
| 14.6 Special precautions for user:  | Not applicable.                            |
| 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code: | Not applicable.                            |

## SECTION 15. Regulatory information

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

- EU REGULATIONS: See Section 2
- Other regulations, limitations and prohibitive regulations:  
The product is a medical device according to the EC-directive 93/42/EEC.

### 15.2 Chemical safety assessment:

A Chemical Safety Assessment has not been carried out.

## SECTION 16. Other information

This product is intended for use by dental professionals. (instrument/material)

### Relevant phrases:

- H315 Causes skin irritation.  
H317 May cause an allergic skin reaction.  
H319 Causes serious eye irritation.

### Abbreviations and acronyms:

EINECS: European Inventory of Existing Commercial Chemical Substances  
CAS: Chemical Abstracts Service (division of the American Chemical Society)  
LD50: Lethal dose, 50 percent  
PBT: Persistent, Bioaccumulative and Toxic  
vPvB: very Persistent and very Bioaccumulative



# SAFETY DATA SHEET

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CERAMAGE  
FLOWABLE COMPOSITE RESIN  
Printing date: June 10, 2020

## SECTION 1. Identification of the substance or mixture and of the supplier

- 1.1 Product identifier  
Trade Name:  
**CERAMAGE "FLOWABLE COMPOSITE RESIN"**
- 1.2 Relevant identified uses of the substance or mixture and uses advised against  
Relevant identified uses: Dental material  
Uses advised against: No further data
- 1.3 Details of the supplier of the safety data sheet  
Company/Undertaking identification  
Manufacturer's Name: SHOFU DENTAL GmbH  
Address: An der Pönt 70, 40885 Ratingen, Germany  
Phone: +49 (0) 2102-8664-0  
Fax: +49 (0) 2102-8664-64  
E-Mail: info@shofu.de  
Section in Charge: Quality Management & Regulatory Affairs
- 1.4 Emergency Telephone Number  
+49-2102-8664-53 (SHOFU DENTAL GmbH) 24 hours / 7 days

## SECTION 2. Hazards identification

- 2.1 Classification of the substance or mixture  
CLASSIFICATION (EC 1272/2008)
- |               |      |                                     |
|---------------|------|-------------------------------------|
| Skin Irrit. 2 | H315 | Causes skin irritation              |
| Skin Sens. 1  | H317 | May cause an allergic skin reaction |
| Eye Irrit. 2  | H319 | Causes serious eye irritation       |

- 2.2 Label elements  
LABEL IN ACCORDANCE WITH (EC) NO.1272/2008



GHS07

HAZARD-DETERMINING COMPONENTS OF LABELLING

UDMA

SIGNAL WORD

Warning

HAZARD STATEMENTS

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.

PRECAUTIONARY STATEMENTS

P280	Wear protective gloves/protective clothing/eye protection/face protection.
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P302+P352

IF ON SKIN: Wash with plenty of soap and water.

P305+P351+P338

IF IN EYES: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

P501

Dispose of contents/container in accordance with local/regional/national/international regulation.

## 2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

## SECTION 3. Composition/information on ingredients

3.1 Chemical characterization: Mixtures

3.2 Description: Mixture of substances listed below with nonhazardous additions.

3.3 Dangerous components:

Cas: 72869-86-4 EINECS: 276-957-5	UDMA	10-30 %
	Skin Irrit. 2, H315; Skin Sens. 1, H317 Eye Irrit. 2, H319	

3.4 Additional information: For the wording of the listed risk phrases refer to section 2.

## SECTION 4. First-aid measures

4.1 Description of first aid measures

Eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present. and easy to do. If eye irritation persists, get medical advice/attention.

Skin contact: Wash immediately with soap and plenty of water. If on skin, skin irritation, get medical advice/attention.

Ingestion: Rinse mouth. Get medical advice/attention.

Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. If symptom concerning breath goes out, call a POISON CENTER or doctor.

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

## SECTION 5. Fire-fighting measures

5.1 Extinguishing Media:

CO<sub>2</sub>, Dry chemical, Foam, Dry sand

5.2 Special hazards arising from the substance or mixture:

No further relevant information available.

5.3 Advice for firefighters:

Wear fire protective cloth and self-contained breathing apparatus, if necessary.

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CERAMAGE  
FLOWABLE COMPOSITE RESIN  
Printing date: June 10, 2020

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## SECTION 6. Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures:  
Avoid eye and skin contact.
- 6.2 Environmental Precautions:  
Send to approved treatment/disposal company or dispose according to local, state and federal regulations.
- 6.3 Methods and material for containment and cleaning up:  
Wipe up and discard in a suitable container.
- 6.4 Reference to other section:  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

## SECTION 7. Handling and storage

- 7.1 Precautions for safe handling:  
Avoid inhalation of grindings and prolonged skin contact with uncured resin.
- 7.2 Conditions for safe storage, including any incompatibilities:  
Store in a cool and dark area.
- 7.3 Specific end use(s):  
No further relevant information available.

## SECTION 8. Exposure controls/personal protection

- 8.1 Control parameters:  
Ingredients with limit values that require monitoring at the workplace:  
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- 8.2 Exposure controls:  
Respiratory Protection:  
Required (use dust mask while grinding or finishing.)
- Skin Protection:  
Hand Protection  
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.
- Material of gloves  
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

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CERAMAGE  
FLOWABLE COMPOSITE RESIN  
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- Penetration time of glove material  
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:  
Butyl rubber, BR  
Nitrile rubber, NBR

Eye Protection: Safety goggles

## SECTION 9. Physical and chemical properties

- 9.1 Information on basic physical and chemical properties
- |  |  |
|--|--|
| Appearance/Odor/Colour:                      | Colored low viscosity paste with sweet odor. |
| Odour threshold                              | Not determined.                              |
| pH   | Not determined.                              |
| Melting point/freezing point                 | Not determined.                              |
| Boiling Point:                               | Not determined.                              |
| Flash point:                                 | Not determined.                              |
| Evaporation rate                             | Not determined.                              |
| Flammability (solid, gas)                    | Not applicable.                              |
| Upper/lower flammability or explosive limits | Not determined.                              |
| Vapour pressure                              | Not determined.                              |
| Vapour density                               | Not determined.                              |
| Relative Density:                            | 1.54 (water=1)                               |
| Solubility: water solubility                 | Insoluble                                    |
| Partition coefficient: n-octanol/water       | Not determined.                              |
| Auto-ignition temperature                    | Not determined.                              |
| Decomposition temperature                    | Not determined.                              |
| Viscosity                                    | Not determined.                              |
| Explosive properties                         | Not applicable.                              |
| Oxidising properties                         | Not applicable.                              |
- 9.2 Other information  
No further relevant information available.

## SECTION 10. Stability and reactivity

- 10.1 Reactivity:  
Polymerization will occur with heat, light.
- 10.2 Chemical stability:  
Stable under normal temperatures and pressures.
- 10.3 Possibility of hazardous reactions:  
No dangerous reactions known.
- 10.4 Condition to Avoid:  
Direct sunlight, high temperature and heating.
- 10.5 Incompatible materials:  
Strong oxidizing materials.

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# SAFETY DATA SHEET

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CERAMAGE  
FLOWABLE COMPOSITE RESIN  
Printing date: June 10, 2020

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## 10.6 Hazardous Decomposition Products:

None under normal conditions of storage and use.

## SECTION 11. Toxicological information

### 11.1 Information on toxicological effects:

Acute toxicity:	Based on available data, the classification criteria are not met
Skin corrosion/irritation:	Skin Irrit. 2; H315 Causes skin irritation.
Eye damage/irritation:	Eye Irrit. 2; H319 Causes serious eye irritation.
Sensitization to the respiratory tract:	Based on available data, the classification criteria are not met.
Skin sensitization:	Skin Sens. 1; H317 May cause an allergic skin reaction.
Germ cell mutagenicity/Genotoxicity:	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.
Effects on or via lactation:	Lack of data.
Specific target organ toxicity (single exposure):	Based on available data, the classification criteria are not met.
Specific target organ toxicity (repeated exposure):	Based on available data, the classification criteria are not met.

## SECTION 12. Ecological information

### 12.1 Toxicity:

No further relevant information available.

### 12.2 Persistence and degradability:

No further relevant information available.

### 12.3 Bioaccumulative potential:

No further relevant information available.

### 12.4 Mobility in soil:

No further relevant information available.

### 12.5 Results of PBT and vPvB assessment:

Not applicable.

### 12.6 Other adverse effects:

No further relevant information available.

## SECTION 13. Disposal considerations

### 13.1 Waste treatment methods:

Dispose of contents/container to in accordance with local/regional/national/international regulations.

## SECTION 14. Transport information

14.1 UN number:	Void
14.2 UN proper shipping name:	Void
14.3 Transport hazard class(es):	Void

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# SAFETY DATA SHEET

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CERAMAGE  
FLOWABLE COMPOSITE RESIN  
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- 14.4 Packing group: Void
- 14.5 Environmental hazards: No further relevant information available.
- 14.6 Special precautions for user: Not applicable.
- 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code: Not applicable.

## SECTION 15. Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:
- EU REGULATIONS: See Section 2
  - Other regulations, limitations and prohibitive regulations:  
The product is a medical device according to the EC-directive 93/42/EEC.
- 15.2 Chemical safety assessment:  
A Chemical Safety Assessment has not been carried out.

## SECTION 16. Other information

This product is intended for use by dental professionals. (instrument/material)

### Relevant phrases:

- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.

### Abbreviations and acronyms:

- EINECS: European Inventory of Existing Commercial Chemical Substances
- CAS: Chemical Abstracts Service (division of the American Chemical Society)
- PBT: Persistent, Bioaccumulative and Toxic
- vPvB: very Persistent and very Bioaccumulative



# SAFETY DATA SHEET

page 1/6  
CERAMAGE  
MODELLING LIQUID  
Printing date: June 11, 2020

## SECTION 1. Identification of the substance or mixture and of the supplier

- 1.1 Product identifier  
Trade Name:  
**CERAMAGE "MODELLING LIQUID"**
- 1.2 Relevant identified uses of the substance or mixture and uses advised against  
Relevant identified uses: Dental material  
Uses advised against: No further data
- 1.3 Details of the supplier of the safety data sheet  
Company/Undertaking identification  
Manufacturer's Name: SHOFU DENTAL GmbH  
Address: An der Pönt 70, 40885 Ratingen, Germany  
Phone: +49 (0) 2102-8664-0  
Fax: +49 (0) 2102-8664-64  
E-Mail: info@shofu.de  
Section in Charge: Quality Management & Regulatory Affairs
- 1.4 Emergency Telephone Number  
+49-2102-8664-53 (SHOFU DENTAL GmbH) 24 hours / 7 days

## SECTION 2. Hazards identification

- 2.1 Classification of the substance or mixture  
CLASSIFICATION (EC 1272/2008)
- |               |      |                                     |
|---------------|------|-------------------------------------|
| Acute Tox. 4  | H302 | Harmful if swallowed                |
|               | H312 | Harmful in contact with skin        |
| Skin Irrit. 2 | H315 | Causes skin irritation              |
| Skin Sens. 1  | H317 | May cause an allergic skin reaction |
| Eye Irrit. 2  | H319 | Causes serious eye irritation       |

- 2.2 Label elements  
LABEL IN ACCORDANCE WITH (EC) NO.1272/2008



GHS07

### HAZARD-DETERMINING COMPONENTS OF LABELLING

UDMA  
Dimethyl Aminoethyl Methacrylate

### SIGNAL WORD

Warning

### HAZARD STATEMENTS

H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.

(Contd. on page2)



# SAFETY DATA SHEET

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CERAMAGE  
MODELLING LIQUID  
Printing date: June 11, 2020

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H319 Causes serious eye irritation.

## PRECAUTIONARY STATEMENTS

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P302+P352

IF ON SKIN: Wash with plenty of soap and water.

P305+P351+P338

IF IN EYES: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

P501

Dispose of contents/container in accordance with local/regional/national/international regulation.

## 2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

## SECTION 3. Composition/information on ingredients

3.1 Chemical characterization: Mixtures

3.2 Description: Mixture of substances listed below with nonhazardous additions.

3.3 Dangerous components:

Cas: 72869-86-4 EINECS: 276-957-5	UDMA	25-35 %
	Skin Irrit. 2, H315; Skin Sens. 1, H317 Eye Irrit. 2, H319	
Cas: 2867-47-2 EINECS: 220-688-8	Dimethyl Aminoethyl Methacrylate	1-5 %
	Acute Tox. 4, H302 H312; Skin Irrit. 2, H315 Skin Sens. 1, H317; Eye Irrit. 2, H319	

3.4 Additional information: For the wording of the listed risk phrases refer to section 2.

## SECTION 4. First-aid measures

4.1 Description of first aid measures

Eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present. and easy to do. If eye irritation persists, get medical advice/attention.

Skin contact: Wash immediately with soap and plenty of water. If on skin, skin irritation, get medical advice/attention.

Ingestion: Rinse mouth. Get medical advice/attention.

Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. If symptom concerning breath goes out, call a POISON CENTER or doctor.

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

(Contd. on page3)



# SAFETY DATA SHEET

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CERAMAGE  
MODELLING LIQUID  
Printing date: June 11, 2020

(Contd. on page2)

## SECTION 5. Fire-fighting measures

- 5.1 Extinguishing Media:  
CO<sub>2</sub>, Dry chemical, Foam, Dry sand
- 5.2 Special hazards arising from the substance or mixture:  
No further relevant information available.
- 5.3 Advice for firefighters:  
Wear fire protective cloth and self-contained breathing apparatus, if necessary.

## SECTION 6. Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures:  
Avoid eye and skin contact.
- 6.2 Environmental Precautions:  
Send to approved treatment/disposal company or dispose according to local, state and federal regulations.
- 6.3 Methods and material for containment and cleaning up:  
Wipe up and discard in a suitable container.
- 6.4 Reference to other section:  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

## SECTION 7. Handling and storage

- 7.1 Precautions for safe handling:  
Avoid inhalation of grindings and prolonged skin contact with uncured resin.
- 7.2 Conditions for safe storage, including any incompatibilities:  
Store in a cool and dark area.
- 7.3 Specific end use(s):  
No further relevant information available.

## SECTION 8. Exposure controls/personal protection

- 8.1 Control parameters:  
Ingredients with limit values that require monitoring at the workplace:  
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- 8.2 Exposure controls:  
Respiratory Protection:  
Required (use dust mask while grinding or finishing.)  
Skin Protection:  
Hand Protection  
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.  
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/the chemical mixture.  
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

(Contd. on page4)



# SAFETY DATA SHEET

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CERAMAGE  
MODELLING LIQUID  
Printing date: June 11, 2020

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- Material of gloves  
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
- Penetration time of glove material  
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:  
Butyl rubber, BR  
Nitrile rubber, NBR

Eye Protection: Safety goggles

## SECTION 9. Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Appearance/Odor/Colour:	Colored viscous liquid with sweet odor.
Odour threshold	Not determined.
pH	Not determined.
Melting point/freezing point	Not determined.
Boiling Point:	Not determined.
Flash point:	126 °C
Evaporation rate	Not determined.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	Not determined.
Vapour pressure	Not determined.
Vapour density	Not determined.
Relative Density:	1.08 (water=1)
Solubility: water solubility	Insoluble
Partition coefficient: n-octanol/water	Not determined.
Auto-ignition temperature	Not determined.
Decomposition temperature	Not determined.
Viscosity	Not determined.
Explosive properties	Not applicable.
Oxidising properties	Not applicable.

### 9.2 Other information

No further relevant information available.

## SECTION 10. Stability and reactivity

### 10.1 Reactivity:

Polymerization will occur with heat, light.

### 10.2 Chemical stability:

Stable under normal temperatures and pressures.

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# SAFETY DATA SHEET

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CERAMAGE  
MODELLING LIQUID  
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10.3 Possibility of hazardous reactions:

No dangerous reactions known.

10.4 Condition to Avoid:

Direct sunlight, high temperature and heating.

10.5 Incompatible materials:

Strong oxidizing materials.

10.6 Hazardous Decomposition Products:

None under normal conditions of storage and use.

## SECTION 11. Toxicological information

11.1 Information on toxicological effects:

Acute toxicity:

Acute Tox. 4: H302 Harmful if swallowed.

H312 Harmful in contact with skin.

Dimethyl Aminoethyl Methacrylate;

Oral rat LD50 2659 mg/kg

Inhalation rat LC50 2.28-3.24 mg/L

(355-504 ppm)(4H)(Vapor)

Skin corrosion/irritation:

Skin Irrit. 2; H315 Causes skin irritation.

Eye damage/irritation:

Eye Irrit. 2; H319 Causes serious eye irritation.

Sensitization to the respiratory tract:

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

Skin sensitization:

Skin Sens. 1; H317 May cause an allergic skin reaction.

Germ cell mutagenicity/Genotoxicity:

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.

Effects on or via lactation: Lack of data.

Specific target organ toxicity (single exposure):

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

Specific target organ toxicity (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:

No further relevant information available.

12.2 Persistence and degradability:

No further relevant information available.

12.3 Bioaccumulative potential:

No further relevant information available.

12.4 Mobility in soil:

No further relevant information available.

12.5 Results of PBT and vPvB assessment:

Not applicable.

(Contd. on page6)



# SAFETY DATA SHEET

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CERAMAGE  
MODELLING LIQUID  
Printing date: June 11, 2020

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12.6 Other adverse effects:  
No further relevant information available.

## SECTION 13. Disposal considerations

13.1 Waste treatment methods:  
Dispose of contents/container to in accordance with local/regional/national/international regulations.

## SECTION 14. Transport information

14.1 UN number: Void  
14.2 UN proper shipping name: Void  
14.3 Transport hazard class(es): Void  
14.4 Packing group: Void  
14.5 Environmental hazards: No further relevant information available.  
14.6 Special precautions for user: Not applicable.  
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:  
Not applicable.

## SECTION 15. Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:  
• EU REGULATIONS: See Section 2  
• Other regulations, limitations and prohibitive regulations:  
The product is a medical device according to the EC-directive 93/42/EEC.  
15.2 Chemical safety assessment:  
A Chemical Safety Assessment has not been carried out.

## SECTION 16. Other information

This product is intended for use by dental professionals. (instrument/material)

Relevant phrases:

H302 Harmful if swallowed.  
H312 Harmful in contact with skin.  
H315 Causes skin irritation.  
H317 May cause an allergic skin reaction.  
H319 Causes serious eye irritation.

Abbreviations and acronyms:

EINESC: European Inventory of Existing Commercial Chemical Substances  
CAS: Chemical Abstracts Service (division of the American Chemical Society)  
LC50: Lethal concentration, 50 percent  
LD50: Lethal dose, 50 percent  
PBT: Persistent, Bioaccumulative and Toxic  
vPvB: very Persistent and very Bioaccumulative





# SAFETY DATA SHEET

page 1/6  
CERAMAGE  
OXYBARRIER  
Printing date: April 1, 2020

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

- 1.1 Product identifier  
Trade Name:  
**CERAMAGE "OXYBARRIER"**
- 1.2 Relevant identified uses of the substance or mixture and uses advised against  
Relevant identified uses: Dental material  
Uses advised against: No further data
- 1.3 Details of the supplier of the safety data sheet  
Company/Undertaking identification  
Manufacturer's Name: SHOFU DENTAL GmbH  
Address: An der Pönt 70, 40885 Ratingen, Germany  
Phone: +49 (0) 2102-8664-0  
Fax: +49 (0) 2102-8664-64  
E-Mail: info@shofu.de  
Section in Charge: Quality Management & Regulatory Affairs
- 1.4 Emergency Telephone Number  
+49-2102-8664-53 (SHOFU DENTAL GmbH) 24 hours / 7 days

## SECTION 2. Hazards identification

- 2.1 Classification of the substance or mixture  
CLASSIFICATION (EC 1272/2008)  
Not applicable.
- 2.2 Label elements  
LABEL IN ACCORDANCE WITH (EC) NO.1272/2008  
Void  
HAZARD-DETERMINING COMPONENTS OF LABELLING  
SIGNAL WORD  
Void  
HAZARD STATEMENTS  
Void  
PRECAUTIONARY STATEMENTS  
Void
- 2.3 Other hazards  
Results of PBT and vPvB assessment  
PBT: Not applicable.  
vPvB: Not applicable.

## SECTION 3. Composition/information on ingredients

- 3.1 Chemical characterization: Mixtures
- 3.2 Description: Mixture of substances listed below with nonhazardous additions.
- 3.3 Dangerous components: Void  
Glycerin [Cas No. 56-81-5, EINECS 200-289-5] 70-80 %  
Polyethylene Glycol [Cas No. 25322-68-3, EINECS 500-038-2]

(Contd. on page2)



# SAFETY DATA SHEET

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CERAMAGE  
OXYBARRIER  
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3.4 Additional information: For the wording of the listed risk phrases refer to section 2.

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## SECTION 4. First-aid measures

### 4.1 Description of first aid measures

Eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present. and easy to do. If eye irritation persists, get medical advice/attention.

Skin contact: Wash immediately with soap and plenty of water. If on skin, skin irritation, get medical advice/attention.

Ingestion: Rinse mouth. If you feel un-well, get medical advice/attention.

Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. If symptom concerning breath goes out, call a POISON CENTER or doctor.

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

No further relevant information available.

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

No further relevant information available.

## SECTION 5. Fire-fighting measures

### 5.1 Extinguishing Media:

Water, CO<sub>2</sub>, Dry chemical, Foam, Dry sand

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

No further relevant information available.

### 5.3 Advice for firefighters:

Wear fire protective cloth and self-contained breathing apparatus, if necessary.

## SECTION 6. Accidental release measures

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

Not required.

### 6.2 Environmental Precautions:

Send to approved treatment/disposal company or dispose according to local, state and federal regulations.

### 6.3 Methods and material for containment and cleaning up:

Wipe up and discard in a suitable container.

### 6.4 Reference to other section:

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

## SECTION 7. Handling and storage

### 7.1 Precautions for safe handling:

Only adequately trained personal should handle this product. For use in dentistry only.

### 7.2 Conditions for safe storage, including any incompatibilities:

Keep away from direct sunlight or heat.

### 7.3 Specific end use(s):

No further relevant information available.

(Contd. on page3)



# SAFETY DATA SHEET

(Contd. of page2)

## SECTION 8. Exposure controls/personal protection

### 8.1 Control parameters:

Exposure limits:

Component		ACGIH (TLV)
Glycerin	TWA: 10 mg/m <sup>3</sup> 8 hr (mist only)	TWA 10 mg/m <sup>3</sup> (Glycerin mist)

### 8.2 Exposure controls:

Respiratory Protection:

Not required.

Skin Protection:

Hand Protection

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

· Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:

Butyl rubber, BR  
Nitrile rubber, NBR

Eye Protection: Safety goggles

## SECTION 9. Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Appearance/Odor/Colour:	Blue colored paste
Odour threshold	Not determined.
pH	Not determined.
Melting point/freezing point	Not determined.
Boiling Point:	Not determined.
Flash point:	Not determined.
Evaporation rate	Not determined.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	Not determined.
Vapour pressure	Not determined.

(Contd. on page4)



# SAFETY DATA SHEET

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CERAMAGE  
OXYBARRIER  
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Vapour density	Not determined.
Relative Density:	1.25 (water=1)
Solubility: water solubility	Soluble
Partition coefficient: n-octanol/water	Not determined.
Auto-ignition temperature	Not determined.
Decomposition temperature	Not determined.
Viscosity	Not determined.
Explosive properties	Not applicable.
Oxidising properties	Not applicable.
9.2 Other information	
No further relevant information available.	

## SECTION 10. Stability and reactivity

- 10.1 Reactivity:  
No further relevant information available.
- 10.2 Chemical stability:  
Stable under normal temperatures and pressures.
- 10.3 Possibility of hazardous reactions:  
No dangerous reactions known.
- 10.4 Condition to Avoid:  
Avoid exposure to direct sun light on the container.
- 10.5 Hazardous Decomposition Products:  
None under normal conditions of storage and use.

## SECTION 11. Toxicological information

- 11.1 Information on toxicological effects:
- |                 |                      |                   |      |                             |
|-----------------|----------------------|-------------------|------|-----------------------------|
| Acute toxicity: | Glycerin;            | Oral rat          | LD50 | 12600 mg/kg                 |
|                 |                      | Dermal rabbit     | LD50 | > 10 g/kg                   |
|                 |                      | Inhalation<br>rat | LC50 | > 570 mg/m <sup>3</sup> /1H |
|                 | Polyethylene Glycol; | Oral rat          | LD50 | 22 g/kg                     |
|                 |                      | Dermal rabbit     | LD50 | > 20g/kg                    |
- Skin corrosion/irritation: Based on available data, the classification criteria are not met.
- Eye damage/irritation: Based on available data, the classification criteria are not met.
- Sensitization to the respiratory tract:  
Based on available data, the classification criteria are not met.
- Skin sensitization: Based on available data, the classification criteria are not met.
- Germ cell mutagenicity/Genotoxicity:  
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.
- Effects on or via lactation: Lack of data.

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# SAFETY DATA SHEET

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CERAMAGE  
OXYBARRIER  
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- Specific target organ toxicity (single exposure):  
Based on available data, the classification criteria are not met.
- Specific target organ toxicity (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:  
No further relevant information available.
- 12.2 Persistence and degradability:  
No further relevant information available.
- 12.3 Bioaccumulative potential:  
No further relevant information available.
- 12.4 Mobility in soil:  
No further relevant information available.
- 12.5 Results of PBT and vPvB assessment:  
Not applicable.
- 12.6 Other adverse effects:  
No further relevant information available.

## SECTION 13. Disposal considerations

- 13.1 Waste treatment methods:  
Dispose of contents/container to in accordance with local/regional/national/international regulations.

## SECTION 14. Transport information

- 14.1 UN number: Void
- 14.2 UN proper shipping name: Void
- 14.3 Transport hazard class(es): Void
- 14.4 Packing group: Void
- 14.5 Environmental hazards: No further relevant information available.
- 14.6 Special precautions for user: Not applicable.
- 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:  
Not applicable.

## SECTION 15. Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:
- EU REGULATIONS: See Section 2
  - Other regulations, limitations and prohibitive regulations:  
The product is a medical device according to the EC-directive 93/42/EEC.
- 15.2 Chemical safety assessment:  
A Chemical Safety Assessment has not been carried out.

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# SAFETY DATA SHEET

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CERAMAGE  
OXYBARRIER  
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## SECTION 16. Other information

This product is intended for use by dental professionals. (instrument/material)

### Abbreviations and acronyms:

- EINESC: European Inventory of Existing Commercial Chemical Substances
- CAS: Chemical Abstracts Service (division of the American Chemical Society)
- LC50: Lethal concentration, 50 percent
- LD50: Lethal dose, 50 percent
- PBT: Persistent, Bioaccumulative and Toxic
- vPvB: very Persistent and very Bioaccumulative



# SAFETY DATA SHEET

page 1/6  
CERAMAGE  
SEP

Printing date: April 1, 2020

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

- 1.1 Product identifier  
Trade Name:  
**CERAMAGE "SEP"**
- 1.2 Relevant identified uses of the substance or mixture and uses advised against  
Relevant identified uses: Dental material  
Uses advised against: No further data
- 1.3 Details of the supplier of the safety data sheet  
Company/Undertaking identification  
Manufacturer's Name: SHOFU DENTAL GmbH  
Address: An der Pönt 70, 40885 Ratingen, Germany  
Phone: +49 (0) 2102-8664-0  
Fax: +49 (0) 2102-8664-64  
E-Mail: info@shofu.de  
Section in Charge: Quality Management & Regulatory Affairs
- 1.4 Emergency Telephone Number  
+49-2102-8664-53 (SHOFU DENTAL GmbH) 24 hours / 7 days

## SECTION 2. Hazards identification

- 2.1 Classification of the substance or mixture  
CLASSIFICATION (EC 1272/2008)
- |              |      |                                    |
|--------------|------|------------------------------------|
| Flam.liq. 2  | H225 | Highly flammable liquid and vapour |
| Eye Irrit. 2 | H319 | Causes serious eye irritation      |

- 2.2 Label elements  
LABEL IN ACCORDANCE WITH (EC) NO.1272/2008



GHS02



GHS07

### HAZARD-DETERMINING COMPONENTS OF LABELLING

Ethanol

### SIGNAL WORD

Danger

### HAZARD STATEMENTS

H225	Highly flammable liquid and vapour.
H319	Causes serious eye irritation.

### PRECAUTIONARY STATEMENTS

P210	Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
P233	Keep container tightly closed.
P242	Use only non-sparking tools.

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- P280 Wear protective gloves/protective clothing/eye protection/face protection.
- P303+P361+P353  
IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
- P264 Wash hands thoroughly after handling.
- P305+P351+P338  
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P337+P313  
If eye irritation persists: Get medical advice/attention.
- P403+P325  
Store in a well-ventilated place. Keep cool.
- P501 Dispose of contents/container in accordance with local/regional/national/international regulation.

## 2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

## SECTION 3. Composition/information on ingredients

3.1 Chemical characterization: Mixtures

3.2 Description: Mixture of substances listed below with nonhazardous additions.

3.3 Dangerous components:

Cas: 64-17-5	Ethanol	55-60 %
EINECS: 200-578-6	Flam. Liq. 2 H225, Eye Irrit. 2 H319	

3.4 Additional information: For the wording of the listed risk phrases refer to section 2.

## SECTION 4. First-aid measures

4.1 Description of first aid measures

Eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present. and easy to do. If eye irritation persists, get medical advice/attention.

Skin contact: Wash immediately with soap and plenty of water. If on skin, skin irritation, get medical advice/attention.

Ingestion: Rinse mouth. Get medical advice/attention.

Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. If symptom concerning breath goes out, call a POISON CENTER or doctor.

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

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## SECTION 5. Fire-fighting measures

- 5.1 Extinguishing Media:  
CO<sub>2</sub>, Dry chemical, Foam, Dry sand
- 5.2 Special hazards arising from the substance or mixture:  
Easily flammable liquid in room temp.  
In case of fire, irritation gasses and fumes may emit.
- 5.3 Advice for firefighters:  
Wear fire protective cloth and self-contained breathing apparatus, if necessary.

## SECTION 6. Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures:  
Avoid contact with eyes and skin.
- 6.2 Environmental Precautions:  
Send to approved treatment/disposal company or dispose according to local, state and federal regulations.
- 6.3 Methods and material for containment and cleaning up:  
Wipe up and discard in a suitable container.
- 6.4 Reference to other section:  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

## SECTION 7. Handling and storage

- 7.1 Precautions for safe handling:  
Handle in a well ventilated place.  
Keep away from naked flames, sparks and sources of heat. No smoking.
- 7.2 Conditions for safe storage, including any incompatibilities:  
Keep container tightly closed. Store in a cool, dark and fireproof area.  
Separated from strong oxidants.
- 7.3 Specific end use(s):  
No further relevant information available

## SECTION 8. Exposure controls/personal protection

- 8.1 Control parameters:  
Exposure limits:

Component		ACGIH (TLV)	NIOSH REL	OSHA PEL
Ethanol	TWA: 1000 ppm TWA; 1920 mg/m <sup>3</sup> TWA WEL-STEL: 3000 ppm STEL; 5760 mg/m <sup>3</sup> STEL	TWA 1000 ppm	TWA 1000 ppm (1900 mg/m <sup>3</sup> )	TWA 1000 ppm (1900 mg/m <sup>3</sup> )

- 8.2 Exposure controls:  
Respiratory Protection:  
Not required.

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**Skin Protection:**      **Hand Protection**  
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.  
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/the chemical mixture.  
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

- **Material of gloves**  
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
- **Penetration time of glove material**  
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:**  
Butyl rubber, BR  
Nitrile rubber, NBR

**Eye Protection:**      **Safety goggles**

## SECTION 9. Physical and chemical properties

9.1	Information on basic physical and chemical properties	
	Appearance/Odor/Colour:	Slightly milky white liquid with alcohol odor
	Odour threshold	Not determined.
	pH	Not determined.
	Melting point/freezing point	Not determined.
	Boiling Point:	Not determined.
	Flash point:	15.8 °C (closed)
	Evaporation rate	Not determined.
	Flammability (solid, gas)	Not applicable.
	Upper/lower flammability or explosive limits	Not determined.
	Vapour pressure	Not determined.
	Vapour density	Not determined.
	Relative Density:	0.93 (water=1)
	Solubility: water solubility	Soluble
	Partition coefficient: n-octanol/water	Not determined.
	Auto-ignition temperature	Not determined.
	Decomposition temperature	Not determined.
	Viscosity	Not determined.
	Explosive properties	Not applicable.
	Oxidising properties	Not applicable.

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- 9.2 Other information  
No further relevant information available.

## SECTION 10. Stability and reactivity

- 10.1 Reactivity:  
No further relevant information available.
- 10.2 Chemical stability:  
Stable under normal temperatures and pressures.
- 10.3 Possibility of hazardous reactions:  
No dangerous reactions known.
- 10.4 Condition to Avoid:  
Avoid direct sunlight, excess heat, flame and other source of ignition.
- 10.5 Incompatible materials:  
Strong oxidizing materials.
- 10.6 Hazardous Decomposition Products:  
None under normal conditions of storage and use.

## SECTION 11. Toxicological information

- 11.1 Information on toxicological effects:
- |                 |                                   |
|-----------------|-----------------------------------|
| Acute toxicity: | Ethanol;                          |
|                 | Oral mouse LD50 3450 mg/kg        |
|                 | Inhalation rat LC50 20000 ppm/10H |
- Skin corrosion/irritation: Based on available data, the classification criteria are not met.
- Eye damage/irritation: Eye Irrit. 2; H319 Causes serious eye irritation.
- Sensitization to the respiratory tract:  
Based on available data, the classification criteria are not met.
- Skin sensitization: Based on available data, the classification criteria are not met.
- Germ cell mutagenicity/Genotoxicity:  
Based on available data, the classification criteria are not met.
- Carcinogenicity: Ethyl alcohol:  
ACGIH-A4; Not classifiable as a human carcinogen.  
[DFG 2004] MAK; Carcinogen category: 5
- Reproductive toxicity: Based on available data, the classification criteria are not met.
- Effects on or via lactation: Lack of data.
- Specific target organ toxicity (single exposure):  
Based on available data, the classification criteria are not met.
- Specific target organ toxicity (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:  
No further relevant information available.
- 12.2 Persistence and degradability:  
No further relevant information available.

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- 12.3 Bioaccumulative potential:  
No further relevant information available.
- 12.4 Mobility in soil:  
No further relevant information available.
- 12.5 Results of PBT and vPvB assessment:  
Not applicable.
- 12.6 Other adverse effects:  
No further relevant information available.

## SECTION 13. Disposal considerations

- 13.1 Waste treatment methods:  
Dispose of contents/container to in accordance with local/regional/national/international regulations.

## SECTION 14. Transport information

- 14.1 UN number: 1170
- 14.2 UN proper shipping name: ETHANOL, solution
- 14.3 Transport hazard class(es): 3 Flammable liquids.
- 14.4 Packing group: II
- 14.5 Environmental hazards: No further relevant information available.
- 14.6 Special precautions for user: Warning: Flammable liquids.
- 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:  
Not applicable.

## SECTION 15. Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:
- EU REGULATIONS: See Section 2
  - Other regulations, limitations and prohibitive regulations:  
The product is a medical device according to the EC-directive 93/42/EEC.
- 15.2 Chemical safety assessment:  
A Chemical Safety Assessment has not been carried out.

## SECTION 16. Other information

This product is intended for use by dental professionals. (instrument/material)

Relevant phrases:

- H225 Highly flammable liquid and vapour.  
H319 Causes serious eye irritation.

Abbreviations and acronyms:

- EINECS: European Inventory of Existing Commercial Chemical Substances  
CAS: Chemical Abstracts Service (division of the American Chemical Society)  
LC50: Lethal concentration, 50 percent  
LD50: Lethal dose, 50 percent  
PBT: Persistent, Bioaccumulative and Toxic  
vPvB: very Persistent and very Bioaccumulative



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## SECTION 1. Identification of the substance or mixture and of the supplier

- 1.1 Product identifier  
Trade Name:  
**CERAMAGE "SPACER"**
- 1.2 Relevant identified uses of the substance or mixture and uses advised against  
Relevant identified uses: Spacer to allow space for dental cement  
Uses advised against: No further data
- 1.3 Details of the supplier of the safety data sheet  
Company/Undertaking identification  
Manufacturer's Name: SHOFU DENTAL GmbH  
Address: An der Pönt 70, 40885 Ratingen, Germany  
Phone: +49 (0) 2102-8664-0  
Fax: +49 (0) 2102-8664-64  
E-Mail: info@shofu.de  
Section in Charge: Quality Management & Regulatory Affairs
- 1.4 Emergency Telephone Number  
+49-2102-8664-53 (SHOFU DENTAL GmbH) 24 hours / 7 days

## SECTION 2. Hazards identification

- 2.1 Classification of the substance or mixture  
CLASSIFICATION (EC 1272/2008)  
Skin Sens. 1      H317      May cause an allergic skin reaction

- 2.2 Label elements  
LABEL IN ACCORDANCE WITH (EC) NO.1272/2008



GHS07

### HAZARD-DETERMINING COMPONENTS OF LABELLING

Rubber, natural

### SIGNAL WORD

Warning

### HAZARD STATEMENTS

H317      May cause an allergic skin reaction.

### PRECAUTIONARY STATEMENTS

P280      Wear protective gloves/protective clothing/eye protection/face protection.

P302+P352

IF ON SKIN: Wash with plenty of soap and water.

P501      Dispose of contents/container in accordance with local/regional/national/international regulation.

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## 2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

## SECTION 3. Composition/information on ingredients

3.1 Chemical characterization: Mixtures

3.2 Description: Mixture of substances listed below with nonhazardous additions.

3.3 Dangerous components:

Cas: 9006-04-6	Rubber, natural	55-65 %
EINECS: 232-689-0	Skin Sens. 1 H317	

Others: Water 35-40 %

3.4 Additional information: For the wording of the listed risk phrases refer to section 2.

## SECTION 4. First-aid measures

4.1 Description of first aid measures

Eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present. and easy to do. If eye irritation persists, get medical advice/attention.

Skin contact: Wash immediately with soap and plenty of water. If on skin, skin irritation, get medical advice/attention.

Ingestion: Rinse mouth. Get medical advice/attention.

Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. If symptom concerning breath goes out, call a POISON CENTER or doctor.

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

## SECTION 5. Fire-fighting measures

5.1 Extinguishing Media:

CO<sub>2</sub>, Dry chemical, Foam, Dry sand

5.2 Special hazards arising from the substance or mixture:

No further relevant information available.

5.3 Advice for firefighters:

Wear fire protective cloth and self-contained breathing apparatus, if necessary.

## SECTION 6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures:

Avoid eye and skin contact.

6.2 Environmental Precautions:

Send to approved treatment/disposal company or dispose according to local, state and federal regulations.

6.3 Methods and material for containment and cleaning up:

Absorb with suitable absorbent (e.g. paper towel, cloth, dry sand, saw dust and vermiculite) and discard in a suitable container.

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## 6.4 Reference to other section:

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

## SECTION 7. Handling and storage

### 7.1 Precautions for safe handling:

Handle in a well ventilated area. Avoid contact with skin and eyes.

### 7.2 Conditions for safe storage, including any incompatibilities:

Store in a cool and dry conditions with lid tightly closed.

### 7.3 Specific end use(s):

No further relevant information available.

## SECTION 8. Exposure controls/personal protection

### 8.1 Control parameters:

Exposure limits:

Component	ACGIH (TLV)
Rubber, natural (As a pure protein)	TWA: 0.001 mg/m <sup>3</sup>

### 8.2 Exposure controls:

Respiratory Protection:

Dust mask

Skin Protection:

Hand Protection

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

- Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

- Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

- For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:

Butyl rubber, BR

Nitrile rubber, NBR

Eye Protection:

Safety goggles

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## SECTION 9. Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Appearance/Odor/Colour:	Milky viscous liquid with unique odor.
Odour threshold	Not determined.
pH	Not determined.
Melting point/freezing point	Not determined.
Boiling Point:	≈ 100 °C
Flash point:	Not determined.
Evaporation rate	Not determined.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	Not determined.
Vapour pressure	Not determined.
Vapour density	Not determined.
Relative Density:	≈ 1 (water=1)
Solubility: water solubility	Soluble
Partition coefficient: n-octanol/water	Not determined.
Auto-ignition temperature	Not determined.
Decomposition temperature	Not determined.
Viscosity	Not determined.
Explosive properties	Not applicable.
Oxidising properties	Not applicable.

### 9.2 Other information

No further relevant information available.

## SECTION 10. Stability and reactivity

### 10.1 Reactivity:

No further relevant information available.

### 10.2 Chemical stability:

Stable under normal temperatures and pressures.

### 10.3 Possibility of hazardous reactions:

No dangerous reactions known.

### 10.4 Condition to Avoid:

Direct sunlight, high temperature and heating.

### 10.5 Incompatible materials:

Strong oxidizing materials.

### 10.6 Hazardous Decomposition Products:

None under normal conditions of storage and use.

## SECTION 11. Toxicological information

### 11.1 Information on toxicological effects:

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

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Sensitization to the respiratory tract:	Based on available data, the classification criteria are not met.
Skin sensitization:	Skin Sens. 1; H317 May cause an allergic skin reaction.
Germ cell mutagenicity/Genotoxicity:	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.
Effects on or via lactation:	Lack of data.
Specific target organ toxicity (single exposure):	Based on available data, the classification criteria are not met.
Specific target organ toxicity (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:  
No further relevant information available.
- 12.2 Persistence and degradability:  
No further relevant information available.
- 12.3 Bioaccumulative potential:  
No further relevant information available.
- 12.4 Mobility in soil:  
No further relevant information available.
- 12.5 Results of PBT and vPvB assessment:  
Not applicable.
- 12.6 Other adverse effects:  
No further relevant information available.

## SECTION 13. Disposal considerations

- 13.1 Waste treatment methods:  
Dispose of contents/container to in accordance with local/regional/national/international regulations.

## SECTION 14. Transport information

- 14.1 UN number: Void
- 14.2 UN proper shipping name: Void
- 14.3 Transport hazard class(es): Void
- 14.4 Packing group: Void
- 14.5 Environmental hazards: No further relevant information available.
- 14.6 Special precautions for user: Not applicable.
- 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:  
Not applicable.

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## SECTION 15. Regulatory information

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

- EU REGULATIONS: See Section 2

15.2 Chemical safety assessment:

A Chemical Safety Assessment has not been carried out.

## SECTION 16. Other information

16.1 Indication of changes:

Address change in section 1.

16.2 Abbreviations and acronyms:

EINESC: European Inventory of Existing Commercial Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

16.3 Key literature references and sources for data:

No further relevant information available.

16.4 Classification for mixtures and used evaluation method according to regulation (EC) 1207/2008 [CLP]:

See SECTION 2.1 (classification).

16.5 Relevant R-, H- and EUH-phrases (number and full text):

H317 May cause an allergic skin reaction.

16.6 Training advice:

No further relevant information available.

16.7 Further information:

This product is intended for use by dental professionals. (instrument/material)

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