

page 1/6 CERAMAGE UP

Printing date: June 10, 2020

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

1.1 Product identifier

Trade Name:

CERAMAGE UP

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 date 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.

(Contd. on page2)

Version Number 4



page 2/6 CERAMAGE UP

Printing date: June 10, 2020

(Contd. of page1)

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:

Car. 70000 00 4	UDMA	
Cas: 72869-86-4 EINECS: 276-957-5	Skin Irrit. 2, H315; Skin Sens. 1, H317 Eye Irrit. 2, H319	20-35 %

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:

CO₂, 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.

(Contd. on page3)



page 3/6 CERAMAGE UP

Printing date: June 10, 2020

(Contd. of page2)

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.

(Contd. on page4)

Version Number 4



page 4/6 CERAMAGE UP

Printing date: June 10, 2020

(Contd. of page3)

· 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. Not determined. pΗ 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. Not determined. Vapour pressure Vapour density Not determined. Relative Density: 1.5 (water=1) Solubility: water solubility Insoluble

Partition coefficient: n-octanol/water
Auto-ignition temperature
Decomposition temperature
Viscosity
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.

(Contd. on page5)

Version Number 4



page 5/6 CERAMAGE UP

Printing date: June 10, 2020

(Contd. of page4)

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: Void14.2 UN proper shipping name: Void14.3 Transport hazard class(es): Void

(Contd. on page6)



page 6/6 CERAMAGE UP

Printing date: June 10, 2020

(Contd. of page5)

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:

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



page 1/6
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 date 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.

(Contd. on page2)



page 2/6
CERAMAGE
OPAQUE & PREOPAQUE
Printing date: June 11, 2020

(Contd. on page1)

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

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:

CO₂, Dry chemical, Foam, Dry sand

5.2 Special hazards arising from the substance or mixture:

No further relevant information available.

(Contd. on page3)



page 3/6
CERAMAGE
OPAQUE & PREOPAQUE
Printing date: June 11, 2020

(Contd. on page2)

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.

(Contd. on page4)



page 4/6
CERAMAGE
OPAQUE & PREOPAQUE
Printing date: June 11, 2020

(Contd. on page3)

· 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. Not determined. ΡH 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
Auto-ignition temperature
Decomposition temperature
Viscosity
Not determined.
Not determined.
Not determined.
Not determined.
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.

(Contd. on page5)



page 5/6
CERAMAGE
OPAQUE & PREOPAQUE
Printing date: June 11, 2020

(Contd. on page4)

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
Skip Irrit 2: H315 Causes skip irritation

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.

(Contd. on page6)



page 6/6
CERAMAGE
OPAQUE & PREOPAQUE
Printing date: June 11, 2020

(Contd. on page5)

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:

EINESC: 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



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 date 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)

Version Number 5



page 2/6 CERAMAGE OXYBARRIER Printing date: April 1, 2020

(Contd. of page1)

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. 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, CO₂, 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)

Version Number 5



page 3/6 CERAMAGE OXYBARRIER

Printing date: April 1, 2020

(Contd. of page2)

SECTION 8. Exposure controls/personal protection

8.1 Control parameters:

Exposure limits:

Component		ACGIH (TLV)
Glycerin	TWA: 10 mg/m ³ 8 hr	TWA 10 mg/m ³
	(mist only)	(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. рΗ 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)

Version Number 5



page 4/6 CERAMAGE OXYBARRIER Printing date: April 1, 2020

iting date. April 1, 2020

(Contd. of page3)

Vapour density Not determined.
Relative Density: 1.25 (water=1)

Solubility: water solubility Soluble

Partition coefficient: n-octanol/water
Auto-ignition temperature
Decomposition temperature
Viscosity
Not determined.
Not determined.
Not determined.
Not determined.
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

rat LC50 > 570 mg/m 3 /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. Eve 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.

(Contd. on page5)

Version Number 5



page 5/6 CERAMAGE OXYBARRIER Printing date: April 1, 2020

(Contd. of page4)

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.

(Contd. on page6)

Version Number 5



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

(Contd. of page5)

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

Version Number 5



page 1/6 Dura-Polish

Printing date: April 3, 2020

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

1.1 Product identifier

Trade Name:

Dura-Polish

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 date 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

(Contd. on page2)

Version Number 2



page 2/6 Dura-Polish

Printing date: April 3, 2020

(Contd. on page1)

Al₂O₃ [Cas No. 1344-28-1, EINECS 215-691-6]

70-80 %

Beeswax

Others

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. 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, CO₂, 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:

Use in accordance with instruction. In case of grinding and polishing, wear dust mask and safety glasses, and using dust respirator and local exhaust.

(Contd. on page3)



page 3/6 Dura-Polish

Printing date: April 3, 2020

(Contd. on page2)

7.2 Conditions for safe storage, including any incompatibilities:

Store in a cool and dark area with container tightly closed.

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:

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

SECTION 9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance/Odor/Colour:

Odour threshold

pH

Not determined.

Melting point/freezing point

Boiling Point:

Not determined.

Not determined.

Not determined.

Not determined.

Not determined.

Not determined.

(Contd. on page4)



page 4/6 Dura-Polish

Printing date: April 3, 2020

(Contd. on page3)

Evaporation rate

Flammability (solid, gas)

Upper/lower flammability or explosive limits

Vapour pressure

Vapour density

Relative Density:

Not determined.

Not determined.

Not determined.

Not determined.

Not determined.

Solubility: water solubility Insoluble

Partition coefficient: n-octanol/water
Auto-ignition temperature
Decomposition temperature
Viscosity
Not determined.
Not determined.
Not determined.
Not determined.
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: 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.

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.

Specific target organ toxicity (single exposure):

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

(Contd. on page5)



page 5/6 Dura-Polish

Printing date: April 3, 2020

(Contd. on page4)

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.

SECTION 16. Other information

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

(Contd. on page6)



page 6/6 Dura-Polish

Printing date: April 3, 2020

(Contd. on page5)

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



page 1/6 Dura-Polish DIA

Printing date: April 3, 2020

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

1.1 Product identifier

Trade Name:

Dura-Polish DIA

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 date 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

(Contd. on page2)

Version Number 2



page 2/6 Dura-Polish DIA

Printing date: April 3, 2020

(Contd. on page1)

Synthetic diamond powder 60-70 %

Beeswax

Others

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. 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, CO₂, 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:

Use in accordance with instruction. In case of grinding and polishing, wear dust mask and safety glasses, and using dust respirator and local exhaust.

(Contd. on page3)



page 3/6 Dura-Polish DIA

Printing date: April 3, 2020

(Contd. on page2)

7.2 Conditions for safe storage, including any incompatibilities:

Store in a cool and dark area with container tightly closed.

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:

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

SECTION 9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance/Odor/Colour:

Odour threshold

PH

Not determined.

Melting point/freezing point

Boiling Point:

Not determined.

Not determined.

Not determined.

Not determined.

Not determined.

Not determined.

(Contd. on page4)



page 4/6 Dura-Polish DIA

Printing date: April 3, 2020

(Contd. on page3)

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: Not determined.

Solubility: water solubility Insoluble

Partition coefficient: n-octanol/water
Auto-ignition temperature
Decomposition temperature
Viscosity
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: 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.

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.

Specific target organ toxicity (single exposure):

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

(Contd. on page5)



page 5/6 Dura-Polish DIA

Printing date: April 3, 2020

(Contd. on page4)

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.

SECTION 16. Other information

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

(Contd. on page6)



page 6/6 Dura-Polish DIA

Printing date: April 3, 2020

(Contd. on page5) Abbreviations and acronyms: PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative