SAFETY DATA SHEET

Printing date: April 3, 2020

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

1.1 Product identifier

Trade Name:

HC Primer

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)

Flam.liq. 2	H225	Highly flammable liquid and vapour
Skin Irrt. 2	H315	Causes skin irritation
Skin Sens. 1	H317	May cause an allergic skin reaction
Eye Irrit. 2	H319	Causes serious eye irritation
STOT SE 3	H335	May cause respiratory irritation
	H336	May cause drowsiness or dizziness

2.2 Label elements

LABEL IN ACCORDANCE WITH (EC) NO.1272/2008

GHS02 GHS07

HAZARD-DETERMINING COMPONENTS OF LABELLING

Acetone

Methyl Methacrylate

SIGNAL WORD

Danger

HAZARD STATEMENTS.

H225	Highly flammable liquid and vapour.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.

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H335 May cause respiratory irritation.
H336 May cause drowsiness or dizziness

PRECAUTIONARY STATEMENTS

P202 Do not handle until all safety precautions have been read and understood.
P210 Keep away from heat/sparks/open flames/hot surfaces. – No smoking.
P233 Keep container tightly closed.
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P264 Wash hands thoroughly after handling.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.

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: 67-64-1 EINECS: 200-662-2	Acetone Flam. Liq. 2 H225, Eye Irrit. 2 H319 STOT SE 3 H336	10-20 %
Cas: 80-62-6 EINECS: 201-297-1	Methyl Methacrylate Flam. Liq. 2 H225, Skin Irrit. 2 H315 Skin Sens 1 H317, STOT SE 3 H335	10-20 %

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.

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(Contd. on page2)

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_2, Dry chemical, Foam, Dry sand

5.2 Special hazards arising from the substance or mixture:

Easily flammable liquid in room temp.

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 open flames, sparks and sources of heat. No smoking.

7.2 Conditions for safe storage, including any incompatibilities:

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

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		EU	ACGIH (TLV)
Acetone	TWA; 500 ppm, 1210 mg/m^3 STEL; 1500 ppm, 3620 mg/m^3	TWA; 500 ppm 8 hr TWA; 1210 mg/m^3 8 hr	500 ppm TWA 750 ppm STEL

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Component	NIOSH	OSHA-Final PELs
Acetone	250 ppm TWA (590mg/m^3 TWA) 2500 ppm IDLH	1000 ppm TWA 2400 mg/m^3 TWA

Component		ACGIH
Methyl Methacrylate	STEL: 100 ppm 15 min, 416 mg/m^3 15 min TWA; 50 ppm 8 hr, 208 mg/m^3 8 hr	50 ppm TWA 100 ppm STEL

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:	Colorless liquid with sweet odor
Odour threshold	Not determined.
pH	Not determined.
Melting point/freezing point	Not determined.
Boiling Point:	Not determined.

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Flash point:	-3.5 ºC (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:	0.95 (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:

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:	Acetone;			
	Oral	rat	LD50	5800 mg/kg
	Dermal	rabbit	LD50	> 15800 mg/kg
		rat	LD50	> 7400 mg/kg
	Inhalation	rat	LC50	76 mg/l, 4h
	Methyl Methacrylate;			
	Oral	rat	LD50	7872 mg/kg
	Dermal	rabbit	LD50	> 5000 mg/kg
	Inhalation	rat	LC50	7093 ppm/4H(Vapor)
Skin corrosion/irritation:	Skin Irrt. 2; H315 Causes skin irritation.			
Eye damage/irritation:	Eye Irrit. 2; H319 Causes serious eye irritation.			

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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: Methyl Methacrylate;
Classified by IARC as group 3, ACGIH as group A4
EPA class E
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):
STOT SE 3; H335 May cause respiratory irritation. H336 May cause drowsiness or dizziness.
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:
Acetone;
Fish toxicity: Fathead minnow; LC50/96H >100mg/L
Methyl Methacrylate;
For Daphnia magna acute toxicity EC50/48hr 69mg/L.
12.2 Persistence and degradability:
Methyl Methacrylate;
Readily biodegradable. Degradability by BOD is 94.3%.
12.3 Bioaccumulative potential:
Methyl Methacrylate;
Bioaccumulation is not expected to be significant. Log Kow = 1.38.
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: 1090
14.2 UN proper shipping name: Aceton, solution

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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.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H336 May cause drowsiness or dizziness

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