



Safety Data Sheet
according to HPR, Schedule 1

Printing date 07/02/2024

Reviewed on 07/02/2024

1 Identification

· **Product identifier**

· Trade name: **Gluma Ceramic Primer**

· -

· **Application of the substance / the mixture** Auxiliary for manufacture of dental prothesis

· **Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier:**

Kulzer GmbH

Leipziger Straße 2, 63450 Hanau (Germany)

Tel.: +49 (0)800 4372522

· **Information department:**

Tel. +1 (800) 431-1785 Fax: +1 (800) 522-1545

e-mail: customer.servicehkna@kulzer-dental.com

· **Emergency telephone number:**

Emergency CONTACT (24-Hour-Number)

ID 105860: (domestic) 1 800 535 5053 or international (001) 352 323 3500

2 Hazard identification

· **Classification of the substance or mixture**

Flammable Liquids - Category 2

H225 Highly flammable liquid and vapour.

Eye Irritation - Category 2A

H319 Causes serious eye irritation.

Skin Sensitizer - Category 1

H317 May cause an allergic skin reaction.

Specific Target Organ Toxicity - Single Exposure - Category 3

H336 May cause drowsiness or dizziness.

· **Label elements**

· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**



GHS02 GHS07

· **Signal word** Danger

· **Hazard-determining components of labeling:**

propan-2-ol

acetone

methyl methacrylate

· **Hazard statements**

Highly flammable liquid and vapour.

Causes serious eye irritation.

May cause an allergic skin reaction.

May cause drowsiness or dizziness.

· **Precautionary statements**

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Avoid breathing mist/vapours/spray.

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

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

If eye irritation persists: Get medical advice/attention.

· **Classification system**

· **NFPA ratings for USA (scale 0-4)**



· **HMIS-Ratings (Scale 0-4)**



· **Other hazards -**

3 Composition/Information on ingredients

· **Chemical characterization: Mixtures**

· **Description: -**

· **Dangerous components:**

67-63-0	propan-2-ol Flammable Liquids - Category 2, H225 Eye Irritation - Category 2A, H319; Specific Target Organ Toxicity - Single Exposure - Category 3, H336	75-90% w/w *
67-64-1	acetone Flammable Liquids - Category 2, H225 Eye Irritation - Category 2A, H319; Specific Target Organ Toxicity - Single Exposure - Category 3, H336	≥5-<10% w/w *
80-62-6	methyl methacrylate Flammable Liquids - Category 2, H225 Skin Irritation - Category 2, H315; Skin Sensitizer - Category 1, H317; Specific Target Organ Toxicity - Single Exposure - Category 3, H335	≥0,1-<0,2% w/w *

* Actual concentration ranges are withheld as a trade secret.

· **Additional information** For the wording of the listed hazard phrases refer to section 16.

4 First-aid measures

· **Description of first aid measures**

· **After inhalation** Supply fresh air; consult doctor in case of complaints.

· **After skin contact** Immediately wash with water and soap and rinse thoroughly.

· **After eye contact**

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

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- **After swallowing**
*Rinse out mouth and then drink plenty of water.
If symptoms persist consult doctor.*
- **Information for doctor**
 - **Most important symptoms and effects, both acute and delayed**
No further relevant information available.
 - **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire-fighting measures

- **Extinguishing media**
 - **Suitable extinguishing agents**
CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture**
*Can form explosive gas-air mixtures.
Formation of toxic gases is possible during heating or in case of fire.*
- **Advice for firefighters**
 - **Protective equipment:** *No special measures required.*
- **Additional information -**

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
- **Environmental precautions:**
*Dilute with plenty of water.
Prevent seepage into sewage system, workpits and cellars.*
- **Methods and material for containment and cleaning up:**
*Absorb with liquid binding material (diatomite, universal binders, for small amounts tissues).
Ensure adequate ventilation.*
- **Reference to other sections**
*No dangerous substances are released.
See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.*
-

7 Handling and storage

- **Handling**
 - **Precautions for safe handling**
*Keep receptacles tightly sealed.
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
Please observe the additional instructions in the product's instructions for use.*

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- **Information about protection against explosions and fires:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.
- **Conditions for safe storage, including any incompatibilities**
 - **Storage**
 - **Requirements to be met by storerooms and receptacles:** Store in a cool location.
 - **Information about storage in one common storage facility:** Not required.
 - **Further information about storage conditions:**
Store in cool, dry conditions in well sealed receptacles.
 - **Specific end use(s)** No further relevant information available.

8 Exposure controls/ Personal protection

- **Additional information about design of technical systems:** No further data; see section 7.
- **Control parameters**

- **Components with limit values that require monitoring at the workplace:**

67-63-0 propan-2-ol

EL	STEL: 400 ppm TWA: 200 ppm
EV	STEL: 400 ppm TWA: 200 ppm

67-64-1 acetone

EL	STEL: 500 ppm TWA: 250 ppm
EV	STEL: 750 ppm TWA: 500 ppm

- **Additional information:** The lists that were valid during the creation were used as basis.

- **Exposure controls**
 - **Personal protective equipment**
 - **General protective and hygienic measures**
Avoid contact with the eyes.
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
 - **Breathing equipment:**
Not necessary with efficient local exhaust. If exposition to vapours is possible, use breathing protective mask (filter A).
 - **Protection of hands:**
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
Check protective gloves prior to each use for their proper condition.
recommended

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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:**
Protective goggles are recommended.
Tightly sealed goggles.
- **Body protection:** Light weight protective clothing

9 Physical and chemical properties

· Information on basic physical and chemical properties	
· General Information	
· Appearance:	
· Form:	Fluid
· Color:	Colorless
· Odor:	Alcohol-like
· Odor threshold:	Not determined.
· pH-value:	Not determined.
· Change in condition	
· Melting point/Melting range:	undetermined
· Boiling point/Boiling range:	55 °C (131 °F)
· Flash point:	5 °C (41 °F)
· Flammability (solid, gaseous)	Not applicable.
· Auto igniting:	> 400 °C (> 752 °F)
· Decomposition temperature:	Not determined.
· Ignition temperature:	Product is not selfigniting.
· Danger of explosion:	Product is not explosive. However, formation of explosive air/vapor mixtures are possible.
· Explosion limits:	
· Lower:	2,0 Vol %
· Upper:	12,0 Vol %
· Vapor pressure at 20 °C (68 °F):	48 hPa (36 mm Hg)
· Density at 20 °C (68 °F):	0,8 g/cm ³ (6,676 lbs/gal)
· Relative density	Not determined.

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· Vapor density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with	
· Water:	Fully miscible
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
· dynamic:	Not determined.
· kinematic:	Not determined.
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Possibility of hazardous reactions** No dangerous reactions known
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** none
- **Additional information:** -

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**

· **LD/LC50 values that are relevant for classification:**

67-63-0 propan-2-ol

Oral	LD50	5.840 mg/kg (rat) (OECD 401)
Dermal	LD50	>12.800 mg/kg (rabbit) (OECD 402)
Inhalative	LC0	≥10.000 ppm /6h (rat) (OECD 403)

67-64-1 acetone

Oral	LD50	5.800 mg/kg (rat)
Dermal	LD50	>15.800 mg/kg (rabbit) weight of evidence
Inhalative	LC50/4 h	76 mg/l (rat) weight of evidence

- **Primary irritant effect:**
- **on the eye:** Irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:** Irritant
- **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

67-63-0	propan-2-ol	3
80-62-6	methyl methacrylate	3

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· **NTP (National Toxicology Program)**

None of the ingredients is listed.

· **Reproductive toxicity** Based on available data, the classification criteria are not met.

12 Ecological information

· **Toxicity**

· **Aquatic toxicity:**

67-63-0 propan-2-ol

LC50/96h 9.640 mg/l (fish) (OECD 203)

LC50/24h >10.000 mg/L (daphnia) (OECD 202)

67-64-1 acetone

EC50/48h 8.800 mg/l (daphnia)

LC50/96h 6.210 mg/l (fish) (OECD 203)

· **Persistence and degradability**

67-63-0 propan-2-ol

biodegradability 53 % /5d (not defined) (EU C.5)

67-64-1 acetone

biodegradability 90,9 % /28d (not defined) (OECD 301D)

· **Behavior in environmental systems:**

· **Bioaccumulative potential** No further relevant information available.

· **Mobility in soil** No further relevant information available.

· **Additional ecological information:**

· **General notes:**

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **Other adverse effects** No further relevant information available.

13 Disposal considerations

· **Waste treatment methods**

· **Recommendation**

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

· **Uncleaned packagings:**

· **Recommendation:** Disposal must be made according to official regulations.

· **Recommended cleansing agent:** Water, if necessary with cleansing agents.

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14 Transport information

· UN-Number · DOT/TDG, ADR, IMDG, IATA	UN1993
· UN proper shipping name · DOT/TDG · ADR · IMDG, IATA	Flammable liquids, n.o.s. (Isopropanol, Acetone) 1993 Flammable liquids, n.o.s., special provision 640D (Isopropanol, Acetone) FLAMMABLE LIQUID, N.O.S. (ISOPROPANOL (ISOPROPYL ALCOHOL), ACETONE)
· Transport hazard class(es) · DOT/TDG (Transport dangerous goods):	
	
· Class · Label	3 Flammable liquids 3
· ADR	
	
· Class · Label	3 (F1) Flammable liquids 3
· IMDG, IATA	
	
· Class · Label	3 Flammable liquids 3
· Packing group · DOT/TDG, ADR, IMDG, IATA	II
· Environmental hazards: · Marine pollutant:	No
· Special precautions for user · Hazard identification number (Kemler code): · EMS Number: · Stowage Category	Warning: Flammable liquids 33 F-E,S-E B
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.

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· Transport/Additional information: -	
· ADR · Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· IMDG · Limited quantities (LQ) · Excepted quantities (EQ)	1L Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· UN "Model Regulation":	UN 1993 FLAMMABLE LIQUID, N.O.S., SPECIAL PROVISION 640D (ISOPROPANOL (ISOPROPYL ALCOHOL), ACETONE), 3, II

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**
No further relevant information available.

· **Sara**

· **SARA Section 355 (extremely hazardous substances)**

7647-01-0 | hydrogen chloride

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **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.

· **Date of the latest revision of the safety data sheet** 07/02/2024

· **Abbreviations and acronyms:**

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

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

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

LC50: Lethal concentration, 50 percent

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LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative

*** Data compared to the previous version altered.**

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