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

1.1 Product identifier
- Trade name: **Gluma Ceramic Primer**

1.2 Relevant identified uses of the substance or mixture and uses advised against
- Application of the substance / the mixture: Auxiliary for manufacture of dental prosthesis
- No further relevant information available.

1.3 Details of the supplier of the safety data sheet
- Manufacturer/Supplier: Kulzer GmbH
  Leipziger Straße 2, 63450 Hanau (Germany)
  Tel.: +49 (0)800 4372522
- Informing department: E-Mail: msds@kulzer-dental.com

1.4 Emergency telephone number:
- Emergency CONTACT (24-Hour-Number): +49 (0)6132-84463

**SECTION 2: Hazards identification**

2.1 Classification of the substance or mixture
- Classification according to Regulation (EC) No 1272/2008
  - Flam. Liq. 2 H225 Highly flammable liquid and vapour.
  - Eye Irrit. 2 H319 Causes serious eye irritation.
  - STOT SE 3 H336 May cause drowsiness or dizziness.

2.2 Label elements
- Labelling according to Regulation (EC) No 1272/2008
  - The product is classified and labelled according to the CLP regulation.
  - **Hazard pictograms**
    - GHS02
    - GHS07
  - **Signal word** Danger
  - **Hazard-determining components of labelling:** propan-2-ol
  - **Hazard statements**
    - H225 Highly flammable liquid and vapour.
    - H319 Causes serious eye irritation.
    - H336 May cause drowsiness or dizziness.
  - **Precautionary statements**
    - P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
    - P261 Avoid breathing mist/vapours/spray.
    - P280 Wear protective gloves/protective clothing/eye protection/face protection.
    - P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
    - 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.

2.3 Other hazards
- **Results of PBT and vPvB assessment**
  - **PBT:** Not applicable.
Trade name: Gluma Ceramic Primer

SECTION 3: Composition/information on ingredients

- 3.2 Chemical characterisation: Mixtures

  - Description:
  
  - Dangerous components:

| EINECS: 200-661-7 | | 75-90% |

| CAS: 67-64-1 | acetone | Flam. Liq. 2, H225 | Eye Irrit. 2, H319; STOT SE 3, H336 |
| EINECS: 200-662-2 | | ≥5-<10% |
| Reg.nr.: 01-219471330-49-xxxx |

- Additional information: For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

- 4.1 Description of first aid measures

  - After inhalation: Supply fresh air; consult doctor in case of symptoms.
  
  - After skin contact: Instantly wash with water and soap and rinse thoroughly.
  
  - After eye contact: Rinse opened eye for several minutes under running water. If symptoms persist, consult doctor.
  
  - After swallowing: If in case of persistent symptoms consult doctor.
  
  - Rinse out mouth and then drink plenty of water.

- 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: Firefighting measures

- 5.1 Extinguishing media

  - Suitable extinguishing agents
  
  CO2, extinguishing powder or water jet. Fight larger fires with water jet or alcohol-resistant foam.

- 5.2 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.

- 5.3 Advice for firefighters

  - Protective equipment: No special measures required.

  - Additional information:

SECTION 6: Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures

  Wear protective equipment. Keep unprotected persons away.

- 6.2 Environmental precautions:

  Dilute with much water.

  Prevent material from reaching sewage system, holes and cellars.

- 6.3 Methods and material for containment and cleaning up:

  Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).

  Ensure adequate ventilation.
Trade name: Gluma Ceramic Primer

6.4 Reference to other sections
No dangerous materials are released.
See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for information on disposal.

SECTION 7: Handling and storage

7.1 Precautions for safe handling
Keep containers 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.

Information about protection against explosions and fires:
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.

7.2 Conditions for safe storage, including any incompatibilities

Storage
Requirements to be met by storerooms and containers: Store in 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 containers.

7.3 Specific end use(s)
No further relevant information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters
Additional information about design of technical systems: No further data; see item 7.

Components with critical values that require monitoring at the workplace:

<table>
<thead>
<tr>
<th>Component</th>
<th>Oral ge.pop., i.te, syst.</th>
<th>Dermal worker industr., i.te., syst.</th>
<th>Inhalative worker industr., i.te., syst.</th>
</tr>
</thead>
<tbody>
<tr>
<td>67-63-0 propan-2-ol</td>
<td>26 mg/Kg (nd)</td>
<td>888 mg/Kg/d (nd)</td>
<td>319 mg/Kg/d (nd)</td>
</tr>
<tr>
<td>WEL</td>
<td>Short-term value: 1250 mg/m³, 500 ppm</td>
<td>Long-term value: 999 mg/m³, 400 ppm</td>
<td></td>
</tr>
<tr>
<td>67-64-1 acetone</td>
<td>89 mg/m³ (nd)</td>
<td>500 mg/m³ (nd)</td>
<td>89 mg/m³ (nd)</td>
</tr>
<tr>
<td>WEL</td>
<td>Short-term value: 3620 mg/m³, 1500 ppm</td>
<td>Long-term value: 1210 mg/m³, 500 ppm</td>
<td></td>
</tr>
</tbody>
</table>

DNELs

<table>
<thead>
<tr>
<th>Component</th>
<th>Oral ge.pop., i.te, syst.</th>
<th>Dermal worker industr., i.te., syst.</th>
<th>Inhalative worker industr., i.te., syst.</th>
</tr>
</thead>
<tbody>
<tr>
<td>67-63-0 propan-2-ol</td>
<td>62 mg/Kg (nd)</td>
<td>186 mg/Kg/d (nd)</td>
<td>62 mg/Kg/d (nd)</td>
</tr>
<tr>
<td>67-64-1 acetone</td>
<td>1210 mg/m³ (nd)</td>
<td>1210 mg/m³ (nd)</td>
<td>1210 mg/m³ (nd)</td>
</tr>
</tbody>
</table>
Trade name: Gluma Ceramic Primer

| Worker indust., l.te., local ge.,pop., l.te, syst. | 2420 mg/m³ (nd) | 200 mg/m³ (nd) |

- **PNECs**

<table>
<thead>
<tr>
<th>67-63-0 propan-2-ol</th>
</tr>
</thead>
<tbody>
<tr>
<td>freshwater</td>
</tr>
<tr>
<td>marine water</td>
</tr>
<tr>
<td>STP</td>
</tr>
<tr>
<td>sedim., dw, fre.wat.</td>
</tr>
<tr>
<td>sedim., dw, mar.wat.</td>
</tr>
<tr>
<td>soil,dw</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>67-64-1 acetone</th>
</tr>
</thead>
<tbody>
<tr>
<td>freshwater</td>
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<tr>
<td>marine water</td>
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<tr>
<td>STP</td>
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<td>sedim., dw, fre.wat.</td>
</tr>
<tr>
<td>sedim., dw, mar.wat.</td>
</tr>
<tr>
<td>soil,dw</td>
</tr>
</tbody>
</table>

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

- **8.2 Exposure controls**
  - **Personal protective equipment**
    - **General protective and hygienic measures**
      Avoid contact with the eyes.
      Keep away from foodstuffs, beverages and food.
      Instantly remove any soiled and impregnated garments.
      Wash hands during breaks and at the end of the 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.
      **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 trough 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.
SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- General information
  - Appearance: Fluid
  - Form: Fluid
  - Colour: Colourless
  - Smell: Alcohol-like
  - Odour threshold: Not determined.
  - pH-value: Not determined.
- Change in condition
  - Melting point/freezing point: Not determined
  - Initial boiling point and boiling range: 55 °C
- Flash point: 5 °C
- Inflammability (solid, gaseous) Not applicable.
- Ignition temperature: > 400 °C
- Decomposition temperature: Not determined.
- Self-inflammability: Product is not selfigniting.
- Explosive properties: Product is not explosive. However, formation of explosive air/vapour mixtures is possible.
- Critical values for explosion:
  - Lower: 2.0 Vol %
  - Upper: 12.0 Vol %
- Steam pressure at 20 °C: 48 hPa
- Density at 20 °C: 0.8 g/cm³
  - Relative density: Not determined.
  - Vapour 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.

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
- Conditions to be avoided: No decomposition if used and stored according to specifications.
- Possibility of hazardous reactions No dangerous reactions known

---

Trade name: Gluma Ceramic Primer

Tightly sealed safety glasses.
Body protection: Light weight protective clothing
**SECTION 11: Toxicological information**

### 11.1 Information on toxicological effects

- **Acute toxicity** Based on available data, the classification criteria are not met.

#### LD/LC50 values that are relevant for classification:

<table>
<thead>
<tr>
<th>Compounds</th>
<th>Oral LD50</th>
<th>Dermal LD50</th>
<th>Inhalative LC0</th>
</tr>
</thead>
<tbody>
<tr>
<td>67-63-0 propan-2-ol</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>67-64-1 acetone</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **Primary irritant effect:**
  - Skin corrosion/irritation Based on available data, the classification criteria are not met.
  - Serious eye damage/irritation Causes serious eye irritation.
  - Respiratory or skin sensitisation Based on available data, the classification criteria are not met.

- **Additional toxicological information:**
  - CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
    - Germ cell mutagenicity 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.
  - STOT-single exposure May cause drowsiness or dizziness.
  - STOT-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

- **Aquatic toxicity:**
  - 67-63-0 propan-2-ol
    - LC50/96h 9640 mg/l (fish) (OECD 203)
    - LC50/24h >10000 mg/L (daphnia) (OECD 202)
  - 67-64-1 acetone
    - EC50/48h 8800 mg/l (daphnia)
    - LC50/96h 6210 mg/l (fish) (OECD 203)

### 12.2 Persistence and degradability

- 67-63-0 propan-2-ol
  - Biodegradation 53% /5d (nd) (EU C.5)
Trade name: Gluma Ceramic Primer

67-64-1 acetone

Biodegradation 90.9 % /28d (nd) (OECD 301D)

- 12.3 Bioaccumulative potential No further relevant information available.
- 12.4 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 bodies or sewage system.

- 12.5 Results of PBT and vPvB assessment
  - PBT: Not applicable.
  - vPvB: Not applicable.

- 12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

- 13.1 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 cleaning agent: Water, if necessary with cleaning agent.

SECTION 14: Transport information

- 14.1 UN-Number
  - ADR, IMDG, IATA UN1993

- 14.2 UN proper shipping name
  - ADR 1993 FLAMMABLE LIQUID, N.O.S., special provision 640D (ISOPROPANOL (ISOPROPYL ALCOHOL), ACETONE)
  - IMDG, IATA FLAMMABLE LIQUID, N.O.S. (ISOPROPANOL (ISOPROPYL ALCOHOL), ACETONE)

- 14.3 Transport hazard class(es)
  - ADR 3 (F1) Flammable liquids.

  - Class 3
  - Label
---

**Trade name:** Gluma Ceramic Primer

---

### IMDG, IATA

- **Class:** 3 Flammable liquids.
- **Label:** 3

### 14.4 Packing group

- **ADR, IMDG, IATA:** II

### 14.5 Environmental hazards:

- **Marine pollutant:** No

### 14.6 Special precautions for user

- **Kemler Number:** 33
- **EMS Number:** F-E,S-E

### 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

- **Not applicable.**

### Transport/Additional information:

- **ADR**
  - **Limited quantities (LQ):** 1L
  - **Excepted quantities (EQ):** Code: E2
    - Maximum net quantity per inner packaging: 30 ml
    - Maximum net quantity per outer packaging: 500 ml
- **Transport category:** 2
- **Tunnel restriction code:** D/E

- **IMDG**
  - **Limited quantities (LQ):** 1L
  - **Excepted quantities (EQ):** Code: E2
    - Maximum net quantity per inner packaging: 30 ml
    - Maximum net quantity per outer packaging: 500 ml

- **UN "Model Regulation":** UN1993, FLAMMABLE LIQUID, N.O.S., special provision 640D (ISOPROPANOL (ISOPROPYL ALCOHOL), ACETONE), 3, II

---

### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
  - **Directive 2012/18/EU**
  - **Named dangerous substances - ANNEX I** None of the ingredients is listed.

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

(Contd. on page 9)
SECTION 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.
  H319 Causes serious eye irritation.
  H336 May cause drowsiness or dizziness.

· Abbreviations and acronyms:
  ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
  IMDG: International Maritime Code for Dangerous Goods
  IATA: International Air Transport Association
  GHS: Globally Harmonised System of Classification and Labelling of Chemicals
  EINECS: European Inventory of Existing Commercial Chemical Substances
  ELINCS: European List of Notified Chemical Substances
  CAS: Chemical Abstracts Service (division of the American Chemical Society)
  DNEL: Derived No-Effect Level (REACH)
  PNEC: Predicted No-Effect Concentration (REACH)
  LC50: Lethal concentration, 50 percent
  LD50: Lethal dose, 50 percent
  PBT: Persistent, Bioaccumulative and Toxic
  vPvB: very Persistent and very Bioaccumulative
  Flam. Liq. 2: Flammable liquids – Category 2
  Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
  STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

· * Data compared to the previous version altered.