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

· 1.1 Product identifier
  · Trade name: Gluma Desensitizer PowerGel

· 1.2 Relevant identified uses of the substance or mixture and uses advised against
  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
    Acute Tox. 4 H302 Harmful if swallowed.
    Skin Irrit. 2 H315 Causes skin irritation.
    Eye Dam. 1 H318 Causes serious eye damage.
    Resp. Sens. 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
    Skin Sens. 1 H317 May cause an allergic skin reaction.
    STOT SE 3 H335 May cause respiratory irritation.

· 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
    GHS05  GHS07  GHS08

  · Signal word Danger
  · Hazard-determining components of labelling:
    2-hydroxyethyl methacrylate
    glutaral
  · Hazard statements
    H302 Harmful if swallowed.
    H315 Causes skin irritation.
    H318 Causes serious eye damage.
    H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
    H317 May cause an allergic skin reaction.
    H335 May cause respiratory irritation.
  · Precautionary statements
    P285 In case of inadequate ventilation wear respiratory protection.

(Contd. on page 2)
Trade name: **Gluma Desensitizer PowerGel**

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 Immediately call a POISON CENTER/doctor.
P321 Specific treatment (see on this label).
P405 Store locked up.

2.3 Other hazards -
- Results of PBT and vPvB assessment
  - PBT: Not applicable.
  - vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

3.2 Chemical characterisation: Mixtures

Dangerous components:

| CAS: 868-77-9 | 2-hydroxyethyl methacrylate | Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317 | 25-50% |
| CAS: 111-30-8 | glutaral | Acute Tox. 3, H301; Acute Tox. 3, H331; Resp. Sens. 1, H334; Skin Corr. 1B, H314; Aquatic Acute 1, H400; Skin Sens. 1, H317 | 0-5% |

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. Then consult doctor.
- After swallowing Rinse out mouth and then drink plenty of water. Instantly call for doctor. In case of persistent symptoms consult 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: 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
Formation of toxic gases is possible during heating or in case of fire.
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: No special measures required.

6.3 Methods and material for containment and cleaning up:
Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues). Dispose of contaminated material as waste according to item 13. Send for recovery or disposal in suitable containers.

6.4 Reference to other sections
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
Wear protective equipment. Keep unprotected persons away. Keep containers tightly sealed. Ensure good ventilation/exhaustion at the workplace. Please observe the additional instructions in the product's instructions for use.

7.2 Conditions for safe storage, including any incompatibilities

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

SECTION 8: Exposure controls/personal protection

8.1 Control parameters
Components with critical values that require monitoring at the workplace:

111-30-8 glutaral

OEL () Short-term value: 0.2 mg/m³, 0.05 ppm
Sen

8.2 Exposure controls

Personal protective equipment
General protective and hygienic measures
Keep away from foodstuffs, beverages and food. Instantly remove any soiled and impregnated garments.

(Contd. on page 4)
Wash hands during breaks and at the end of the work.
Do not inhale gases / fumes / aerosols.
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
  If skin contact cannot be avoided, protective gloves are recommended to avoid possible sensitization.

  - **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.

  - **Eye protection:**
    Before use, put on the protective goggles and cover the patient’s eyes to protect against splashes of material.

- **Body protection:** Light weight protective clothing

**SECTION 9: Physical and chemical properties**

- **9.1 Information on basic physical and chemical properties**

  - General Information
    - **Appearance:**
      - Form: Viscous
      - Colour: Green
      - Smell: Aromatic
      - Odour threshold: Not determined.

  - **pH-value at 20 °C:** 3.66

  - Change in condition
    - Melting point/Melting range: Not applicable
    - Boiling point/Boiling range: 100 °C

  - Flash point: Not applicable
### Trade name: Gluma Desensitizer PowerGel

- **Inflammability (solid, gaseous)**: Not applicable.
- **Decomposition temperature**: Not determined.
- **Self-inflammability**: Product is not selfigniting.
- **Danger of explosion**: Product is not explosive.
  - **Critical values for explosion**:
    - **Lower**: Not determined.
    - **Upper**: Not determined.
- **Steam pressure**: Not determined.
- **Density at 20 °C**: 1.11 g/cm³
  - **Relative density**: Not determined.
- **Vapour density**: Not determined.
- **Evaporation rate**: Not determined.
- **Solubility in / Miscibility with**
  - **Water**: Partly soluble
- **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.
- **10.3 Possibility of hazardous reactions**
  No dangerous reactions known
- **10.4 Conditions to avoid**
  No further relevant information available.
- **10.5 Incompatible materials**: No further relevant information available.
- **10.6 Hazardous decomposition products**: None
  - **Additional information**: -

### SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
  - **Acute toxicity**
    Harmful if swallowed.
- **LD/LC50 values that are relevant for classification:**

  | 868-77-9 2-hydroxyethyl methacrylate | Oral LD50 5564 mg/kg (rat) | Dermal LD50 >3000 mg/kg (can) |

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Trade name: Gluma Desensitizer PowerGel

· **Primary irritant effect:**
  · Skin corrosion/irritation
    Causes skin irritation.
  · Serious eye damage/irritation
    Causes serious eye damage.
· **Respiratory or skin sensitisation**
  May cause allergy or asthma symptoms or breathing difficulties if inhaled.
  May cause an allergic skin reaction.
· **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 respiratory irritation.
· **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

<table>
<thead>
<tr>
<th>Aquatic toxicity:</th>
</tr>
</thead>
<tbody>
<tr>
<td>868-77-9 2-hydroxyethyl methacrylate</td>
</tr>
<tr>
<td>LC50/96h 227 mg/l (fish)</td>
</tr>
</tbody>
</table>

· **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.
· **Additional ecological information:**
  · General notes:
    Avoid transfer into the environment.
    Do not allow product to reach ground water, water bodies or sewage system, even in small quantities.
    Danger to drinking water if even extremely small quantities leak into soil.

#### 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

<table>
<thead>
<tr>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Must not be disposed of together with household garbage. Do not allow product to reach sewage system.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>European waste catalogue</th>
</tr>
</thead>
<tbody>
<tr>
<td>18 01 06* chemicals consisting of or containing dangerous substances</td>
</tr>
</tbody>
</table>
Trade name: Gluma Desensitizer PowerGel

**SECTION 14: Transport information**

- **14.1 UN-Number**
  - ADR, ADN, IMDG, IATA: Void
- **14.2 UN proper shipping name**
  - ADR, ADN, IMDG, IATA: Void
- **14.3 Transport hazard class(es)**
  - ADR, ADN, IMDG, IATA: Void
- **14.4 Packing group**
  - ADR, IMDG, IATA: Void
- **14.5 Environmental hazards**
  - Marine pollutant: No
- **14.6 Special precautions for user**
  - Not applicable.
- **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**
  - Not applicable.
- **Transport/Additional information**
  - UN "Model Regulation"**: Void

**SECTION 15: Regulatory information**

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
  - REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3
- **15.2 Chemical safety assessment**
  - A Chemical Safety Assessment has not been carried out.

**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**
  - H301 Toxic if swallowed.
  - H314 Causes severe skin burns and eye damage.
  - H315 Causes skin irritation.
  - H317 May cause an allergic skin reaction.
  - H319 Causes serious eye irritation.
  - H331 Toxic if inhaled.
  - H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
  - H400 Very toxic to aquatic life.

(Contd. on page 8)
Trade name: Gluma Desensitizer PowerGel

Abbreviations and acronyms:
ADR: Accord européen sur le transport 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)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Acute Tox. 3: Acute toxicity – Category 3
Acute Tox. 4: Acute toxicity – Category 4
Skin Corr. 1B: Skin corrosion/irritation – Category 1B
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
Resp. Sens. 1: Respiratory sensitisation – Category 1
Skin Sens. 1: Skin sensitisation – Category 1
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

* Data compared to the previous version altered.