1 Identification

- **Product identifier**
  - **Trade name:** Gluma Desensitizer PowerGel

- **Application of the substance / the mixture** For desensitisation of teeth

- **Details of the supplier of the safety data sheet**
  - **Manufacturer/Supplier:** Kulzer GmbH
  - Leipziger Straße 2, 63450 Hanau (Germany)
  - **Tel.:** +49 (0)800 4372522
  - **Emergency telephone number:**
    - GBK/Infotrac ID 105860: (domestic) 1 800 535 5053 or international (001) 352 323 3500

2 Hazard(s) identification

- **Classification of the substance or mixture**
  - Flammable Liquids - Category 4 H227 Combustible liquid.
  - Acute Toxicity (Oral) - Category 4 H302 Harmful if swallowed.
  - Skin Irritation - Category 2 H315 Causes skin irritation.
  - Serious Eye Damage - Category 1 H318 Causes serious eye damage.
  - Respiratory Sensitizer - Category 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
  - Skin Sensitizer - Category 1 H317 May cause an allergic skin reaction.

- **Label elements**
  - **GHS label elements**
    - The product is classified and labeled according to the Globally Harmonized System (GHS).
  - **Hazard pictograms**
    - GHS05
    - GHS07
    - GHS08

- **Signal word** Danger

- **Hazard-determining components of labeling:**
  - 2-hydroxyethyl methacrylate
  - glutaral

- **Hazard statements**
  - Combustible liquid.
  - Harmful if swallowed.
  - Causes skin irritation.
  - Causes serious eye damage.
  - May cause allergy or asthma symptoms or breathing difficulties if inhaled.
  - May cause an allergic skin reaction.

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

(Contd. on page 2)
3 Composition/information on ingredients

- Chemical characterization: Mixtures
- Dangerous components:

<table>
<thead>
<tr>
<th>Component</th>
<th>% w/w</th>
</tr>
</thead>
<tbody>
<tr>
<td>868-77-9</td>
<td>25-50%</td>
</tr>
<tr>
<td>111-30-8</td>
<td>0-5%</td>
</tr>
</tbody>
</table>

- 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.

(Contd. of page 1)
Trade name: Gluma Desensitizer PowerGel

- After skin contact: Immediately wash with water and soap and rinse thoroughly.
- After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.
- After swallowing: Rinse out mouth and then drink plenty of water. Immediately call a doctor. 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: Formation of toxic gases is possible during heating or in case of fire.
- Advice for firefighters:
  - Protective equipment: Mount respiratory protective device.
- Additional information:

6 Accidental release measures

- Personal precautions, protective equipment and emergency procedures: Wear protective equipment. Keep unprotected persons away.
- Environmental precautions: No special measures required.
- Methods and material for containment and cleaning up:
  - Absorb with liquid binding material (diatomite, universal binders, for small amounts tissues).
  - Dispose contaminated material as waste according to item 13.
  - Send for recovery or disposal in suitable receptacles.
- Reference to other sections:
  - See Section 8 for information on personal protection equipment.
  - See Section 13 for disposal information.

7 Handling and storage

- Handling:
  - Precautions for safe handling: Wear protective equipment. Keep unprotected persons away. Keep receptacles tightly sealed. Ensure good ventilation/exhaustion at the workplace. Please observe the additional instructions in the product’s instructions for use.
  - Information about protection against explosions and fires: No special measures required.
8 Exposure controls/personal protection

· **Additional information about design of technical systems:** No further data; see item 7.

· **Control parameters**

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

<table>
<thead>
<tr>
<th>EL</th>
<th>Short-term value: C 0.05 ppm</th>
</tr>
</thead>
<tbody>
<tr>
<td>S</td>
<td>activated and inactivated</td>
</tr>
</tbody>
</table>

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

· **Exposure controls**

- **Personal protective equipment**

  · **General protective and hygienic measures**
  
  - Keep away from foodstuffs, beverages and feed.
  
  - Immediately remove all soiled and contaminated clothing.
  
  - Wash hands before breaks and at the end of 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.
  
  - Solvent resistant gloves
  
  - 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 through time has to be found out by the manufacturer of the protective gloves and has to be observed.

(Contd. on page 5)
**Trade name:** Gluma Desensitizer PowerGel

- **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:**
  - 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

### 9 Physical and chemical properties

- **Information on basic physical and chemical properties**
  - **General Information**
    - **Appearance:**
      - **Form:** Viscous
      - **Color:** Green
      - **Odor:** Aromatic
      - **Odor threshold:** Not determined.
  - **pH-value at 20 °C (68 °F):** 3.66
  - **Change in condition**
    - **Melting point/Melting range:** Not applicable
    - **Boiling point/Boiling range:** 100 °C (212 °F)
  - **Flash point:** Not applicable
  - **Flammability (solid, gaseous):** Not applicable.
  - **Ignition temperature:**
    - **Decomposition temperature:** Not determined.
  - **Auto igniting:** Product is not selfigniting.
  - **Danger of explosion:** Product does not present an explosion hazard.
  - **Explosion limits:**
    - **Lower:** Not determined.
    - **Upper:** Not determined.
  - **Vapor pressure:** Not determined.
  - **Density at 20 °C (68 °F):** 1.11 g/cm³ (9.263 lbs/gal)
    - **Relative density:** Not determined.
    - **Vapor 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.
Trade name: Gluma Desensitizer PowerGel

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:
      - 868-77-9 2-hydroxyethyl methacrylate:
        - Oral LD50 5564 mg/kg (rat)
        - Dermal LD50 >3000 mg/kg (can)
  - Primary irritant effect:
    - on the skin: Irritant to skin and mucous membranes.
    - on the eye: Strong irritant with the danger of severe eye injury.
  - Sensitization: No sensitizing effects known.
- Additional toxicological information:
  - Carcinogenic categories:
    - IARC (International Agency for Research on Cancer)
      - Butyl-hydroxy-toluol: 3
    - NTP (National Toxicology Program)
      - None of the ingredients is listed.

12 Ecological information
- Toxicity
  - Aquatic toxicity:
    - 868-77-9 2-hydroxyethyl methacrylate
      - LC50/96h 227 mg/l (fish)
  - Persistence and degradability: No further relevant information available.
  - Behavior in environmental systems:
    - Bioaccumulative potential: No further relevant information available.
    - Mobility in soil: No further relevant information available.
Trade name: Gluma Desensitizer PowerGel

Additional ecological information:

- General notes:
  - Avoid transfer into the environment.
  - Do not allow product to reach ground water, water course or sewage system, even in small quantities.
  - Danger to drinking water if even extremely small quantities leak into the ground.

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.

14 Transport information

- UN-Number
  - DOT, TDG, ADN, IMDG, IATA: Void

- UN proper shipping name
  - DOT, TDG, ADN, IMDG, IATA: Void

- Transport hazard class(es)
  - DOT, TDG, ADN, IMDG, IATA
    - Class: Void

- Packing group
  - DOT, TDG, IMDG, IATA: Void

- Environmental hazards:
  - Marine pollutant: No

- Special precautions for user
  - Not applicable.

- Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code
  - Not applicable.

- Transport/Additional information:
  - 

- UN "Model Regulation": Void
15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
  - SARA Section 355 (extremely hazardous substances)

None of the ingredients is listed.

- TSCA (Toxic Substances Control Act) Medical devices are exempted from TSCA.
- GHS label elements
  - The product is classified and labeled according to the Globally Harmonized System (GHS).
- Hazard pictograms
  - GHS05
  - GHS07
  - GHS08

- Signal word Danger
- Hazard-determining components of labeling:
  - 2-hydroxyethyl methacrylate
  - glutaral
- Hazard statements
  - Combustible liquid.
  - Harmful if swallowed.
  - Causes skin irritation.
  - Causes serious eye damage.
  - May cause allergy or asthma symptoms or breathing difficulties if inhaled.
  - May cause an allergic skin reaction.
- Precautionary statements
  - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
  - In case of inadequate ventilation wear respiratory protection.
  - Avoid breathing dust/fume/gas/mist/vapours/spray.
  - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
  - Immediately call a POISON CENTER/doctor.
  - Specific treatment (see on this label).
- 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
  - H227 Combustible liquid.
  - 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.
Trade name: Gluma Desensitizer PowerGel

| H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled. |
| Date of preparation / last revision 06/03/2017 / 2 |
| 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) |
| WHMIS: Workplace Hazardous Materials Information System (Canada) |
| LC50: Lethal concentration, 50 percent |
| LD50: Lethal dose, 50 percent |
| PBT: Persistent, Bioaccumulative and Toxic |
| vPvB: very Persistent and very Bioaccumulative |
| * Data compared to the previous version altered. |