

Material Safety Data Sheet
acc. to OSHA HCS

Printing date 07/04/2014

Reviewed on 07/04/2014

1 Identification

· Product identifier

· **Trade name:** **Gluma Desensitizer PowerGel**

· **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.

· **Application of the substance / the preparation** For desensitisation of teeth

· Details of the supplier of the safety data sheet

· **Manufacturer/Supplier:**

Heraeus Kulzer GmbH
Grüner Weg 11, D-63450 Hanau

Tel.: 0800 4372522

· **Information department:**

Marc Henn
Tel. +1 (574) 2995444 / Fax: +1 (574) 2912542
e-mail: marc.henn@kulzer-dental.com

· **Emergency telephone number:**

Emergency CONTACT (24-Hour-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

· **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**

Xn; Harmful

R20/22: Harmful by inhalation and if swallowed.

Xi; Irritant

R37/38-41-42/43: Irritating to respiratory system and skin. Risk of serious damage to eyes.
May cause sensitization by inhalation and skin contact.

· **Information concerning particular hazards for human and environment:**

The product has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

· **Classification system:**

The classification was made according to the latest editions of the EU-lists, and expanded upon from company and literature data.

· Label elements

· **Labelling according to EU guidelines:**

The product has been classified and marked in accordance with EU Directives / Ordinance on Hazardous Materials

· **Code letter and hazard designation of product:**



Xn Harmful

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

2-hydroxyethyl methacrylate
glutaral

· **Risk phrases:**

20/22 Harmful by inhalation and if swallowed.
37/38 Irritating to respiratory system and skin.
41 Risk of serious damage to eyes.
42/43 May cause sensitization by inhalation and skin contact.

· **Safety phrases:**

9 Keep container in a well-ventilated place.

(Contd. on page 2)

USA

Material Safety Data Sheet
acc. to OSHA HCS

Printing date 07/04/2014

Reviewed on 07/04/2014

Trade name: Gluma Desensitizer PowerGel

(Contd. of page 1)

- 23 Do not breathe vapour.
- 24 Avoid contact with skin.
- 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- 37/39 Wear suitable gloves and eye/face protection.
- 45 In case of accident or if you feel unwell, seek medical advice immediately.

· **Classification system**

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



· **HMIS-Ratings (Scale 0-4)**



3 Composition/information on ingredients

· **Chemical characterization: Mixtures**

· **Dangerous components:**

868-77-9	2-hydroxyethyl methacrylate	Xi R36/38-43	25-50%
111-30-8	glutaral	T R23/25; C R34; Xi R42/43; N R50	2-8%

· **Additional information** For the wording of the listed risk 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. Then consult a doctor.
- **After swallowing**
Rinse out mouth and then drink plenty of water.
Immediately call a 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.

(Contd. on page 3)

USA

Material Safety Data Sheet
acc. to OSHA HCS

Printing date 07/04/2014

Reviewed on 07/04/2014

Trade name: Gluma Desensitizer PowerGel

(Contd. of page 2)

· **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.
- **Conditions for safe storage, including any incompatibilities**
 - **Storage**
 - **Requirements to be met by storerooms and receptacles:** No special requirements.
 - **Information about storage in one common storage facility:** Not required.
 - **Further information about storage conditions:** None.
- **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 item 7.
- **Control parameters**

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

111-30-8 glutaral

REL	Short-term value: C 0.8 mg/m ³ , C 0.2 ppm
TLV	Short-term value: C 0.2 mg/m ³ , C 0.05 ppm
SEN	

· **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.
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).

(Contd. on page 4)

USA

Material Safety Data Sheet
acc. to OSHA HCS

Printing date 07/04/2014

Reviewed on 07/04/2014

Trade name: Gluma Desensitizer PowerGel

(Contd. of page 3)

· **Protection of hands:**

Protective gloves are recommended, if skin contact cannot be avoided.

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

Solvent resistant gloves

· **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

· **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

· **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

· **Auto igniting:** Product is not selfigniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Density at 20 °C (68 °F):** 1.11 g/cm³ (9.263 lbs/gal)

· **Solubility in / Miscibility with**

· **Water:** Partly soluble

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

10 Stability and reactivity

· **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

(Contd. on page 5)

Material Safety Data Sheet
acc. to OSHA HCS

Printing date 07/04/2014

Reviewed on 07/04/2014

Trade name: Gluma Desensitizer PowerGel

(Contd. of page 4)

· **Additional information:** -

11 Toxicological information

- **Information on toxicological effects**
 - **Acute toxicity:**
 - **Primary irritant effect:**
 - **on the skin:** Irritant to skin and mucous membranes.
 - **on the eye:** Strong irritant with the danger of severe eye injury.
 - **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:** No further relevant information available.
- **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.
- **Additional ecological information:**
 - **General notes:** Avoid transfer into the environment.
- **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, ADR, ADN, IMDG, IATA
- **UN proper shipping name**
 - DOT, ADR, ADN, IMDG, IATA
- **Transport hazard class(es)**
 - DOT, ADR, ADN, IMDG, IATA
 - Class
- **Packing group**
 - DOT, ADR, IMDG, IATA

(Contd. on page 6)

USA

Material Safety Data Sheet
acc. to OSHA HCS

Printing date 07/04/2014

Reviewed on 07/04/2014

Trade name: Gluma Desensitizer PowerGel

(Contd. of page 5)

- | | |
|--|-----------------|
| · 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: | - |

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.

- **Carcinogenicity categories**

- **TLV (Threshold Limit Value established by ACGIH)**

111-30-8	glutaral	A4
	Butyl-hydroxy-toluol	A4

- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

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**

R23/25 Toxic by inhalation and if swallowed.

R34 Causes burns.

R36/38 Irritating to eyes and skin.

R42/43 May cause sensitization by inhalation and skin contact.

R43 May cause sensitization by skin contact.

R50 Very toxic to aquatic organisms.

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

USA