

**Safety Data Sheet
acc. to OSHA HCS**

Printing date 01/20/2016

Reviewed on 01/19/2016

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:**

Heraeus Kulzer GmbH
Grüner Weg 11, D-63450 Hanau

Tel.: 0800 4372522

· **Information department:**

Tel. +1 (800) 431-1785 Fax: +1 (800) 522-1545
e-mail: customer.servicehka@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**

Flam. Liq. 4 H227 Combustible liquid.
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.

· **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 flames and hot surfaces. – No smoking.
[In case of inadequate ventilation] wear respiratory protection.
Avoid breathing dust/fume/gas/mist/vapors/spray

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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).

· **Classification system**

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



· **HMIS-Ratings (Scale 0-4)**



· **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**

· **Dangerous components:**

868-77-9	2-hydroxyethyl methacrylate Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	25-50%
111-30-8	glutaral Acute Tox. 3, H301; Acute Tox. 3, H331; Resp. Sens. 1, H334; Skin Corr. 1B, H314; Skin Sens. 1, H317; Flam. Liq. 4, H227	0-5%

- **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. 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.

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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.
- **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.

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· **Control parameters**

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

111-30-8 glutaral

REL Short-term value: C 0.8 mg/m³, C 0.2 ppm

TLV Short-term value: C 0.2 mg/m³, 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.
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.
recommended

· **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:**

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

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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.

· **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

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· **Additional information:** -

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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	>5000 mg/kg (rat)
Dermal	LD50	>3000 mg/kg (rabbit)
Sensitization	Sensib.	sensitizing (guinea pig)

· **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
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· **NTP (National Toxicology Program)**

None of the ingredients is listed.

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

None of the ingredients is listed.

12 Ecological information

· **Toxicity**

· **Aquatic toxicity:**

868-77-9 2-hydroxyethyl methacrylate

EC50/48h (static)	380 mg/l (daphnia) (OECD 202 Teil 1)
EC50/72h	836 mg/l (algae) (OECD 201)
LC50/96h	>100 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.

· **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.

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

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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	Void
· UN proper shipping name	
· DOT, ADR, ADN, IMDG, IATA	Void
· Transport hazard class(es)	
· DOT, ADR, ADN, IMDG, IATA	
· Class	Void
· Packing group	
· DOT, ADR, 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.

· **Carcinogeny categories**

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

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

· **GHS label elements**

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

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· **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 flames and hot surfaces. – No smoking.
[In case of inadequate ventilation] wear respiratory protection.
Avoid breathing dust/fume/gas/mist/vapors/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.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.*

· **Date of preparation / last revision** 01/20/2016 / 1

· **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
DOT: US Department of Transportation
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
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)*

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HMIS: Hazardous Materials Identification System (USA)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
OSHA: Occupational Safety & Health
TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit
Flam. Liq. 4: Flammable liquids, Hazard Category 4
Acute Tox. 3: Acute toxicity, Hazard Category 3
Acute Tox. 4: Acute toxicity, Hazard Category 4
Skin Corr. 1B: Skin corrosion/irritation, Hazard Category 1B
Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2
Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1
Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2
Resp. Sens. 1: Sensitisation - Respirat., Hazard Category 1
Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

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

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