



**Safety data sheet
according to 1907/2006/EC, Article 31**

Printing date 25.10.2018

Version number 4

Revision: 25.10.2018

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.

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

· **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**

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**

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**

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P285 In case of inadequate ventilation wear respiratory protection.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P321 Specific treatment (see on this label).

P405 Store locked up.

· **2.3 Other hazards -**

(Contd. on page 2)



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Trade name: Gluma Desensitizer PowerGel

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

(Contd. of page 1)

SECTION 3: Composition/information on ingredients

· **3.2 Chemical characterisation: Mixtures**

· **Dangerous components:**

CAS: 868-77-9 EINECS: 212-782-2 Reg.nr.: 2119490169-29-XXXX	2-hydroxyethyl methacrylate Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	25-50%
CAS: 111-30-8 EINECS: 203-856-5	glutaryl 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 rinse with water.

If skin irritation continues, consult a doctor.

- **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.

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.

· **5.3 Advice for firefighters**

- **Protective equipment:** Put on breathing apparatus.

- **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:** 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).

(Contd. on page 3)



Safety data sheet
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Version number 4

Revision: 25.10.2018

Trade name: Gluma Desensitizer PowerGel

(Contd. of page 2)

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.

· **Information about protection against explosions and fires:** No special measures required.

7.2 Conditions for safe storage, including any incompatibilities

· **Storage**

· **Requirements to be met by storerooms and containers:** No special requirements.

· **Information about storage in one common storage facility:** Not required.

· **Further information about storage conditions:** None.

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

SECTION 8: Exposure controls/personal protection

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

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/m ³ , 0.05 ppm
Sen	

· **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**

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.

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

(Contd. on page 4)



Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 25.10.2018

Version number 4

Revision: 25.10.2018

Trade name: Gluma Desensitizer PowerGel

(Contd. of page 3)

- **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

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/freezing point:** Not applicable
- **Initial boiling point and boiling range:** 100 °C

· **Flash point:** Not applicable

· **Inflammability (solid, gaseous)** Not applicable.

· **Ignition temperature:**

· **Decomposition temperature:** Not determined.

· **Self-inflammability:** Product is not selfigniting.

· **Explosive properties:** 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

(Contd. on page 5)



Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 25.10.2018

Version number 4

Revision: 25.10.2018

Trade name: Gluma Desensitizer PowerGel

(Contd. of page 4)

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

· **LD/LC50 values that are relevant for classification:**

Oral	LD50	>2,000 mg/kg (rat)
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868-77-9 2-hydroxyethyl methacrylate

Oral	LD50	>5,000 mg/kg (rat)
Dermal	LD50	>3,000 mg/kg (rabbit)
Sensitisation	Sensib.	(guinea pig)

- **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 (carcinogenicity, 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.

IRL
(Contd. on page 6)



**Safety data sheet
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Version number 4

Revision: 25.10.2018

Trade name: Gluma Desensitizer PowerGel

(Contd. of page 5)

SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**

868-77-9 2-hydroxyethyl methacrylate

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

· **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**

· **Recommendation**

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

· **European waste catalogue**

18 01 06* | chemicals consisting of or containing dangerous substances

· **Uncleaned packagings:**

· **Recommendation:** Disposal must be made according to official regulations.

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**

· **Class**

Void

· **14.4 Packing group**

· **ADR, IMDG, IATA**

Void

· **14.5 Environmental hazards:**

· **Marine pollutant:**

No

(Contd. on page 7)



Safety data sheet
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Version number 4

Revision: 25.10.2018

Trade name: Gluma Desensitizer PowerGel

(Contd. of page 6)

- | | |
|--|-----------------|
| · 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.
- **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
 - 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.**

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