



**Safety Data Sheet
according to HPR, Schedule 1**

Printing date 11/16/2022

Reviewed on 11/16/2022

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

· **Information department:**

Tel. +1 (800) 431-1785 Fax: +1 (800) 522-1545

e-mail: customer.servicehkna@kulzer-dental.com

· **Emergency telephone number:**

Emergency CONTACT (24-Hour-Number)

ID 105860: (domestic) 1 800 535 5053 or international (001) 352 323 3500

2 Hazard identification

· **Classification of the substance or mixture**

Acute Toxicity (Inhalation) - Category 4

H332 Harmful if inhaled.

Skin Corrosion - Category 1B

H314 Causes severe skin burns and eye damage.

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.

Specific Target Organ Toxicity - Single Exposure - Category 3

H335 May cause respiratory irritation.

· **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:**

glutaral

2-hydroxyethyl methacrylate

· **Hazard statements**

Harmful if inhaled.

Causes severe skin burns and eye damage.

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

May cause an allergic skin reaction.

May cause respiratory irritation.

· **Precautionary statements**

Avoid breathing mist/vapours/spray.

Avoid release to the environment.

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

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If on skin: Wash with plenty of soap and water.

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

If experiencing respiratory symptoms: Call a poison center/doctor.

· **Classification system**

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



Health = 3
Fire = 1
Reactivity = 0

· **HMIS-Ratings (Scale 0-4)**



Health = *3
Fire = 1
Reactivity = 0

· **Other hazards -**

3 Composition/Information on ingredients

· **Chemical characterization: Mixtures**

· **Dangerous components:**

868-77-9	2-hydroxyethyl methacrylate Skin Irritation - Category 2, H315; Eye Irritation - Category 2A, H319; Skin Sensitizer - Category 1, H317	25-50% w/w *
111-30-8	glutaral Acute Toxicity (Oral) - Category 3, H301; Acute Toxicity (Inhalation) - Category 2, H330 Respiratory Sensitizer - Category 1, H334 Skin Corrosion - Category 1B, H314 Skin Sensitizer - Category 1A, H317; Specific Target Organ Toxicity - Single Exposure - Category 3, H335 Flammable Liquids - Category 4, H227 Specific concentration limit: Specific Target Organ Toxicity - Single Exposure - Category 3; H335: C ≥ 0,5 %	5% w/w

* Actual concentration ranges are withheld as a trade secret.

· **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 rinse with water.

If skin irritation continues, consult a doctor.

· **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.

If symptoms persist consult doctor.

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- **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.
- **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

EL Short-term value: C 0,05 ppm

S

EV activated and inactivated

· **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:** Tightly sealed goggles.

· **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

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· Odor threshold:	Not determined.
· pH-value:	Not determined.
· Change in condition	
· Melting point/Melting range:	Not applicable undetermined
· Boiling point/Boiling range:	undetermined
· Flash point:	106 °C (222,8 °F)
· Flammability (solid, gaseous)	Not applicable.
· 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:	Not determined
· 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
- **Additional information:** -

11 Toxicological information

- **Information on toxicological effects**

- **Acute toxicity:**

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

Oral	LD50	>2.000 mg/kg (rat) entnommen vom Wert vom Bayer D634/s , welches vergleichbar und kritischer ist von der Zusammensetzung.
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868-77-9 2-hydroxyethyl methacrylate

Oral	LD50	5.564 mg/kg (rat)
Dermal	LD50	>5.000 mg/kg (rabbit)

111-30-8 glutaral

Oral	LD50	77 mg/kg (rat)
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128-37-0 2,6-di-tert-butyl-p-cresol

Oral	LD50	>6.000 mg/kg (rat) (OECD 401)
Dermal	LD50	>2.000 mg/kg (rat) (OECD 402)

- **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)**

128-37-0	2,6-di-tert-butyl-p-cresol	3
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· **NTP (National Toxicology Program)**

None of the ingredients is listed.

· **Reproductive toxicity** Based on available data, the classification criteria are not met.

12 Ecological information

· **Toxicity**

· **Aquatic toxicity:**

868-77-9 2-hydroxyethyl methacrylate

EC50/72h	345 mg/l (algae) (OECD 201)
EC50/48h (static)	380 mg/l (daphnia) (OECD 202)
LC50/96h	>100 mg/l (fish) (OECD 203)
ErC50 / 72 h	836 mg/l (algae) (OECD 201)
NOEC / 72h	400 mg/l (algae) (OECD 201)
NOEC / 48h	171 mg/l (daphnia) (OECD 202)

128-37-0 2,6-di-tert-butyl-p-cresol

EC50/72h	>0,4 mg/l (algae) (EU C.3)
EC50/21d	0,096 mg/L (daphnia) (OECD 211)
EC50/48h	0,48 mg/l (daphnia) (OECD 202)
LC50/96h	>0,57 mg/l (fish) (OECD 203)
NOEC / 21d	0,069 mg/l (daphnia) (OECD 211)
NOEC / 48h	0,15 mg/l (daphnia) (OECD 202)
NOEC/ 32d	0,053 mg/L (fish) (OECD 210)

· **Persistence and degradability**

868-77-9 2-hydroxyethyl methacrylate

biodegradability	92-100 % /14d (not defined) (OECD 301C)
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· **Behavior in environmental systems:**

- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.

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· **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, ADR, IMDG, IATA**

UN3265

· **UN proper shipping name**

· **IMDG, IATA**

CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S.
(glutaral)

· **Transport hazard class(es)**

· **DOT/TDG (Transport dangerous goods):**



· **Class**

8 Corrosive substances

· **Label**

8

· **ADR**



· **Class**

8 (C3) Corrosive substances

· **Label**

8

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· **IMDG, IATA**



· **Class** 8 Corrosive substances
· **Label** 8

· **Packing group**
· **DOT/TDG, ADR, IMDG, IATA** II

· **Environmental hazards:**
· **Marine pollutant:** No

· **Special precautions for user** Warning: Corrosive substances
· **Hazard identification number (Kemler code):** 80
· **EMS Number:** F-A, S-B
· **Segregation groups** Acids
· **Stowage Category** B
· **Stowage Code** SW2 Clear of living quarters.

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

· **Transport/Additional information:** -

· **ADR**
· **Excepted quantities (EQ)** Code: E2
Maximum net quantity per inner packaging: 30 ml
Maximum net quantity per outer packaging: 500 ml

· **IMDG**
· **Limited quantities (LQ)** 1L
· **Excepted quantities (EQ)** Code: E2
Maximum net quantity per inner packaging: 30 ml
Maximum net quantity per outer packaging: 500 ml

· **UN "Model Regulation":** Void

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**
No further relevant information available.
· **Sara**

· **SARA Section 355 (extremely hazardous substances)**

None of the ingredients is listed.

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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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.

H330 Fatal if inhaled.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H335 May cause respiratory irritation.

· **Date of the latest revision of the safety data sheet 11/16/2022**

· **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)

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.**

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