



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

Printing date 16.11.2022

Version number 5 (replaces version 4)

Revision: 16.11.2022

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**

Acute Tox. 4 H332 Harmful if inhaled.

Skin Corr. 1B H314 Causes severe skin burns and eye damage.

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.

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

· **2.2 Label elements**

· **Labelling according to Regulation (EC) No 1272/2008**

The product is classified and labelled according to the GB CLP regulation.

· **Hazard pictograms**



GHS05 GHS07 GHS08

· **Signal word** Danger

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

glutaral

2-hydroxyethyl methacrylate

· **Hazard statements**

H332 Harmful if inhaled.

H314 Causes severe skin burns and 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.

H412 Harmful to aquatic life with long lasting effects.

· **Precautionary statements**

P261 Avoid breathing mist/vapours/spray.

P273 Avoid release to the environment.

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

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P302+P352 *IF ON SKIN: Wash with plenty of soap and water.*
P305+P351+P338 *IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.*
P342+P311 *If experiencing respiratory symptoms: Call a POISON CENTER/doctor.*

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

SECTION 3: Composition/information on ingredients

· **3.2 Mixtures**

· **Dangerous components:**

CAS: 868-77-9 EINECS: 212-782-2 Reg.nr.: 01-2119490169-29-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	glutaral Acute Tox. 3, H301; Acute Tox. 2, H330 Resp. Sens. 1, H334 Skin Corr. 1B, H314 Aquatic Acute 1, H400; Aquatic Chronic 2, H411 Skin Sens. 1A, H317; STOT SE 3, H335 EUH071 Specific concentration limit: STOT SE 3; H335: C ≥ 0.5 %	5%
CAS: 128-37-0 EINECS: 204-881-4 Reg.nr.: 01-2119565113-46-xxxx	2,6-di-tert-butyl-p-cresol Aquatic Acute 1, H400; Aquatic Chronic 1, H410	≥0.025-<0.25%

- **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.

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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).
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

· **8.1 Control parameters**

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

111-30-8 glutaral

WEL	Short-term value: 0.2 mg/m ³ , 0.05 ppm Long-term value: 0.2 mg/m ³ , 0.05 ppm Sen
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· **DNELs**

868-77-9 2-hydroxyethyl methacrylate

Oral	general population, long term, systemic	0.83 mg/Kg (not defined)
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Dermal	worker industrial, long term, systemic	1.3 mg/Kg/d (not defined)
	general population, long term, systemic	0.83 mg/Kg/d (not defined)
Inhalative	worker industrial, long term, systemic	4.9 mg/m ³ (not defined)
	general population, long term, systemic	2.9 mg/m ³ (not defined)

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

Oral	general population, long term, systemic	0.25 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	0.5 mg/Kg/d (not defined)
	general population, long term, systemic	0.25 mg/Kg/d (not defined)
Inhalative	worker industrial, long term, systemic	1.76 mg/m ³ (not defined)
	general population, long term, systemic	0.435 mg/m ³ (not defined)

· PNECs

868-77-9 2-hydroxyethyl methacrylate

freshwater	0.482 mg/l (not defined)
marine water	0.482 mg/l (not defined)
sewage treatment plant	10 mg/l (not defined)
sediment, dry weight, freshwater	3.79 mg/Kg (not defined)
sediment, dry weight, marine water	3.79 mg/Kg (not defined)
soil, dry weight	0.476 mg/Kg (not defined)

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

freshwater	0.000199 mg/l (not defined)
marine water	0.00002 mg/l (not defined)
sewage treatment plant	0.017 mg/l (not defined)
sediment, dry weight, freshwater	0.458 mg/Kg (not defined)
sediment, dry weight, marine water	0.046 mg/Kg (not defined)
soil, dry weight	0.054 mg/Kg (not defined)

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

· 8.2 Exposure controls

· Appropriate engineering controls No further data; see item 7.

· Individual protection measures, such as 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).

· Hand protection

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

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- **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/face protection** Tightly sealed safety glasses.
- **Body protection:** Light weight protective clothing

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**

· **General Information**

- | | |
|---|---|
| · Physical state | Fluid |
| · Colour: | Green |
| · Smell: | Aromatic |
| · Odour threshold: | Not determined. |
| · Melting point/freezing point: | Not applicable
Not determined |
| · Boiling point or initial boiling point and boiling range | Not determined |
| · Flammability | Not applicable. |
| · Lower and upper explosion limit | |
| · Lower: | Not determined. |
| · Upper: | Not determined. |
| · Flash point: | 106 °C (868-77-9 2-hydroxyethyl methacrylate) |
| · Decomposition temperature: | Not determined. |
| · SADT | |
| · pH | Not determined. |
| · Viscosity: | |
| · Kinematic viscosity | Not determined. |
| · dynamic: | Not determined. |
| · Solubility | |
| · Water: | Partly soluble |
| · Partition coefficient n-octanol/water (log value) | Not determined. |
| · Steam pressure: | Not determined. |
| · Density and/or relative density | |
| · Density | Not determined |
| · Relative density | Not determined. |
| · Vapour density | Not determined. |

· **9.2 Other information**

No further relevant information available.

· **Appearance:**

· **Form:** Viscous

· **Important information on protection of health and environment, and on safety.**

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

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- **Explosive properties:** Product is not explosive.
- **Change in condition**
- **Evaporation rate** Not determined.

· **Information with regard to physical hazard classes**

- **Explosives** Void
- **Flammable gases** Void
- **Aerosols** Void
- **Oxidising gases** Void
- **Gases under pressure** Void
- **Flammable liquids** Void
- **Flammable solids** Void
- **Self-reactive substances and mixtures** Void
- **Pyrophoric liquids** Void
- **Pyrophoric solids** Void
- **Self-heating substances and mixtures** Void
- **Substances and mixtures, which emit flammable gases in contact with water** Void
- **Oxidising liquids** Void
- **Oxidising solids** Void
- **Organic peroxides** Void
- **Corrosive to metals** Void
- **Desensitised explosives** Void

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 hazard classes as defined in Regulation (EC) No 1272/2008**
 - **Acute toxicity**
Harmful if inhaled.

· **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	5,564 mg/kg (rat)
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Dermal	LD50	>5,000 mg/kg (rabbit)
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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)
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Dermal LD50 >2,000 mg/kg (rat) (OECD 402)

- **Skin corrosion/irritation**
Causes severe skin burns and eye damage.
- **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.
- **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.

· **11.2 Information on other hazards**

- **Endocrine disrupting properties**

None of the ingredients is listed.

SECTION 12: Ecological information

· **12.1 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)

· **12.2 Persistence and degradability**

868-77-9 2-hydroxyethyl methacrylate

Biodegradation 92-100 % /14d (not defined) (OECD 301C)

- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **12.5 Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**
For information on endocrine disrupting properties see section 11.

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· **12.7 Other adverse effects**

· **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.

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.

· **Uncleaned packagings:**

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

SECTION 14: Transport information

· **14.1 UN number or ID number**

· **ADR, IMDG, IATA**

UN3265

· **14.2 UN proper shipping name**

· **IMDG, IATA**

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

· **14.3 Transport hazard class(es)**

· **ADR**



· **Class**

8 (C3) Corrosive substances.

· **Label**

8

· **IMDG, IATA**



· **Class**

8 Corrosive substances.

· **Label**

8

· **14.4 Packing group**

· **ADR, IMDG, IATA**

II

· **14.5 Environmental hazards:**

· **Marine pollutant:**

No

· **14.6 Special precautions for user**

Warning: Corrosive substances.

· **Kemler Number:**

80

· **EMS Number:**

F-A,S-B

· **Segregation groups**

Acids

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· Stowage Category	B
· Stowage Code	SW2 Clear of living quarters.
· 14.7 Maritime transport in bulk according to IMO instruments	Not applicable.
· Transport/Additional information:	-
· ADR	
· 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
· Transport category	2
· Tunnel restriction code	E
· 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

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
No further relevant information available.
- **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.
- H330 Fatal if inhaled.
- H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- H335 May cause respiratory irritation.
- H400 Very toxic to aquatic life.
- H410 Very toxic to aquatic life with long lasting effects.
- H411 Toxic to aquatic life with long lasting effects.
- EUH071 Corrosive to the respiratory tract.

· **Abbreviations and acronyms:**

SADT: Self Accelerating Decomposition Temperature
ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

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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)
DNEL: Derived No-Effect Level (UK REACH)
PNEC: Predicted No-Effect Concentration (UK REACH)
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
Acute Tox. 2: Acute toxicity – Category 2
Acute Tox. 4: Acute toxicity – Category 4
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
Skin Sens. 1A: Skin sensitisation – Category 1A
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1
Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3
* **Data compared to the previous version altered.**

GB