

SAFETY DATA SHEETS

This SDS packet was issued with item:

072157576

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

072157394 072157501

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

074564027



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

Printing date 11/16/2022

Reviewed on 11/16/2022

1 Identification

· **Product identifier**

· **Trade name:** Gluma Desensitizer

· -

· **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.servicehna@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(s) identification

· **Classification of the substance or mixture**

Acute Toxicity - Inhalation 4

H332 Harmful if inhaled.

Skin Corrosion 1B

H314 Causes severe skin burns and eye damage.

Eye Damage 1

H318 Causes serious eye damage.

Sensitization - Respiratory 1

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

Sensitization - Skin 1

H317 May cause an allergic skin reaction.

Specific Target Organ Toxicity - Single Exposure 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.

Wash thoroughly after handling.

Avoid release to the environment.

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

(Contd. on page 2)

US



**Safety Data Sheet
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Printing date 11/16/2022

Reviewed on 11/16/2022

Trade name: Gluma Desensitizer

(Contd. of page 1)

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 skin irritation or rash occurs: Get medical advice/attention.

Specific treatment (see on this label).

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

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

Description: -

Dangerous components:

868-77-9	2-hydroxyethyl methacrylate Skin Irritation 2, H315; Eye Irritation 2A, H319; Sensitization - Skin 1, H317	25-50%
111-30-8	glutaral Acute Toxicity - Oral 3, H301; Acute Toxicity - Inhalation 2, H330 Sensitization - Respiratory 1, H334 Skin Corrosion 1B, H314 Sensitization - Skin 1A, H317; Specific Target Organ Toxicity - Single Exposure 3, H335 Flammable Liquids 4, H227 Specific concentration limit: STOT SE 3; H335: C ≥ 0.5 %	5-10%

· **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.

(Contd. on page 3)



**Safety Data Sheet
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Printing date 11/16/2022

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Trade name: Gluma Desensitizer

(Contd. of page 2)

- **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** Not required.
- **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 13 for disposal information.
See Section 8 for information on personal protection equipment.

· **Protective Action Criteria for Chemicals**

· PAC-1:		
868-77-9	2-hydroxyethyl methacrylate	1.9 mg/m ³
111-30-8	glutaral	0.2 ppm
· PAC-2:		
868-77-9	2-hydroxyethyl methacrylate	21 mg/m ³
111-30-8	glutaral	1 ppm
· PAC-3:		
868-77-9	2-hydroxyethyl methacrylate	1,000 mg/m ³
111-30-8	glutaral	5 ppm

7 Handling and storage

- **Handling**
 - **Precautions for safe handling**
Keep receptacles tightly sealed.
Wear protective equipment. Keep unprotected persons away.
Ensure good ventilation/exhaustion at the workplace.
 - **Information about protection against explosions and fires:** No special measures required.

(Contd. on page 4)



Safety Data Sheet
acc. to OSHA HCS

Printing date 11/16/2022

Reviewed on 11/16/2022

Trade name: Gluma Desensitizer

(Contd. of page 3)

- **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/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.
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.

(Contd. on page 5)



Safety Data Sheet
acc. to OSHA HCS

Printing date 11/16/2022

Reviewed on 11/16/2022

Trade name: Gluma Desensitizer

Tightly sealed goggles.
· **Body protection:** Light weight protective clothing

(Contd. of page 4)

9 Physical and chemical properties

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

· **General Information**

· **Appearance:**

· **Form:** Fluid
· **Color:** Colorless
· **Odor:** Aromatic
· **Odor threshold:** Not determined.

· **pH-value:** Not determined.

· **Change in condition**

· **Melting point/Melting range:** 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 at 20 °C (68 °F):** 1.16 g/cm³ (9.6802 lbs/gal)

· **Relative density** Not determined.
· **Vapor density** Not determined.
· **Evaporation rate** Not determined.

· **Solubility in / Miscibility with**

· **Water:** Not miscible or difficult to mix

· **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.

(Contd. on page 6)



Safety Data Sheet
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Printing date 11/16/2022

Reviewed on 11/16/2022

Trade name: Gluma Desensitizer

· **Hazardous decomposition products:** none

(Contd. of page 5)

11 Toxicological information

· **Information on toxicological effects**

· **Acute toxicity:**

· **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)
Dermal	LD50	>5,000 mg/kg (can)

111-30-8 glutaral

Oral	LD50	77 mg/kg (rat)
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· **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:**

- Sensitization possible through inhalation.
- Sensitization possible through skin contact.

· **Additional toxicological information:**

Harmful
Irritant

· **Carcinogenic categories**

· IARC (International Agency for Research on Cancer)
None of the ingredients is listed.

· NTP (National Toxicology Program)
None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)
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	
EC50/48h	380 mg/l (daphnia)
LC50/96h	>100 mg/l (fish)
EC50	>3,000 mg/l (bacteria)
NOEC / 21d	24.1 mg/l (daphnia)
ErC50 / 72 h	836 mg/l (algae)
NOEC / 72h	400 mg/l (algae) (OECD 201)

· **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.

(Contd. on page 7)



**Safety Data Sheet
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Printing date 11/16/2022

Reviewed on 11/16/2022

Trade name: Gluma Desensitizer

(Contd. of page 6)

· **Additional ecological information:**

· **General notes:**

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, ADR, IMDG, IATA**

UN3265

· **UN proper shipping name**

· **IMDG, IATA**

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

· **Transport hazard class(es)**

· **DOT**



· **Class**

8 Corrosive substances

· **Label**

8

· **ADR**



· **Class**

8 (C3) Corrosive substances

· **Label**

8

· **IMDG, IATA**



· **Class**

8 Corrosive substances

(Contd. on page 8)



Safety Data Sheet
acc. to OSHA HCS

Printing date 11/16/2022

Reviewed on 11/16/2022

Trade name: **Gluma Desensitizer**

(Contd. of page 7)

· Label	8
· Packing group · DOT, 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) · Excepted quantities (EQ)	1L 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.

· SARA Section 313 (specific toxic chemical listings)

None of the ingredients is listed.

· Hazardous Air Pollutants

None of the ingredients is listed.

· Proposition 65

· Prop 65 - Chemicals known to cause cancer

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

(Contd. on page 9)



**Safety Data Sheet
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Printing date 11/16/2022

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Trade name: Gluma Desensitizer

(Contd. of page 8)

· **Chemicals known to cause reproductive toxicity for males:**
None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**
None of the ingredients is listed.

· **Carcinogenicity categories**

· **EPA (Environmental Protection Agency)**
None of the ingredients is listed.

· **TLV (Threshold Limit Value)**
111-30-8 glutaral A4

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**
None of the ingredients is listed.

· **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.
- H330 Fatal if inhaled.
- H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- H335 May cause respiratory irritation.

· **Date of preparation / last revision** 11/16/2022

· **Abbreviations and acronyms:**

- ADR: Accord relatif au transport international 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
- 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)
- HMS: 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
- NIOSH: National Institute for Occupational Safety
- OSHA: Occupational Safety & Health
- TLV: Threshold Limit Value
- PEL: Permissible Exposure Limit
- REL: Recommended Exposure Limit
- Flammable Liquids 4: Flammable liquids – Category 4
- Acute Toxicity - Oral 3: Acute toxicity – Category 3
- Acute Toxicity - Inhalation 2: Acute toxicity – Category 2
- Acute Toxicity - Inhalation 4: Acute toxicity – Category 4
- Skin Corrosion 1B: Skin corrosion/irritation – Category 1B
- Skin Irritation 2: Skin corrosion/irritation – Category 2
- Eye Damage 1: Serious eye damage/eye irritation – Category 1
- Eye Irritation 2A: Serious eye damage/eye irritation – Category 2A
- Sensitization - Respiratory 1: Respiratory sensitisation – Category 1

(Contd. on page 10)



Safety Data Sheet
acc. to OSHA HCS

Printing date 11/16/2022

Reviewed on 11/16/2022

Trade name: Gluma Desensitizer

(Contd. of page 9)

Sensitization - Skin 1: Skin sensitisation – Category 1

Sensitization - Skin 1A: Skin sensitisation – Category 1A

Specific Target Organ Toxicity - Single Exposure 3: Specific target organ toxicity (single exposure) – Category 3

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

US