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

Printing date 02/10/2025

Reviewed on 02/10/2025

Tel.: +49 (0)800 4372522

#### 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)

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(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.

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Wash thoroughly after handling. Avoid release to the environment.

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

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)



Health = 3Fire = 1 Reactivity = 0

· HMIS-Ratings (Scale 0-4)



Health = \*3 Fire = 1

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

#### 3 Composition/information on ingredients

· Chemical characterization: Mixtures

Description: -

· Dange	· Dangerous components:		
868-77-9	2-hydroxyethyl methacrylate	25-50%	
	Skin Irritation 2, H315; Eye Irritation 2A, H319; Sensitization - Skin 1, H317		
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	5-10%	
	Flammable liquids 4, H227 Specific concentration limit: STOT SE 3; H335: C ≥ 0.5 %		

<sup>·</sup> 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.

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· 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.

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

· 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 section 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/m³
111-30-8	glutaral	0.2 ppm
· PAC-2	:	
	2-hydroxyethyl methacrylate	21 mg/m³
111-30-8	glutaral	1 ppm
· PAC-3		
868-77-9	2-hydroxyethyl methacrylate	1,000 mg/m³
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| 111-30-8 | glutaral | (Contd. of page 3) | 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.
- · 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 section 7.
- · Control parameters
  - · Components with limit values that require monitoring at the workplace:

#### 111-30-8 qlutaral

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

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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.

Tightly sealed goggles.

· Body protection: Light weight protective clothing

Information on basic physical and che General Information	mical properties
· Appearance:	
Form:	Fluid
· Color:	Colorless
· Odor: · Odor threshold:	Aromatic Not determined.
	Not determined.
· pH-value:	Not determined.
· Change in condition	
Melting point/Melting range:	undetermined
· Boiling point/Boiling range:	undetermined
· Flash point:	>95 °C (>203 °F)
· Flammability (solid, gaseous)	Not applicable.
Decomposition temperature:	Not determined.
· Ignition temperature:	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)

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· 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.

No further relevant information available. · Other information

# 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

#### 11 Toxicological information

- Information on toxicological effects
  - Acute toxicity:
    - · LD/LC50 values that are relevant for classification:

LD50 >2,000 mg/kg (rat) Oral

#### 868-77-9 2-hydroxyethyl methacrylate

LD50 5,564 mg/kg (rat) Dermal LD50 >5,000 mg/kg (can)

#### 111-30-8 glutaral

LD50 77 mg/kg (rat) Oral

- 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.

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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.

· 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.
- · 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.

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UN-Number	
· DOT, ADR, IMDG, IATA	UN3265
UN proper shipping name DOT ADR	Corrosive liquid, acidic, organic, n.o.s. (glutaral) 3265 CORROSIVE LIQUID, ACIDIC, ORGAN
· IMDG, IATA	N.O.S. (glutaral) CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O (glutaral)
Transport hazard class(es)	
·DOT	
CORROSVE	
· Class · Label	8 Corrosive substances 8
· ADR	
· Class · Label	8 (C3) Corrosive substances 8
· IMDG, IATA	
· Class · Label	8 Corrosive substances 8
· Packing group · DOT, ADR, IMDG, IATA	II
Environmental hazards: Marine pollutant:	No
Special precautions for user Hazard identification number (I EMS Number:	F-A,S-B
· Segregation groups · Stowage Category	(SGG1) Acids B



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· Stowage Code	(Contd. of page 8 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 m. 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 m Maximum net quantity per outer packaging: 500 ml	
· UN "Model Regulation":	UN 3265 CORROSIVE LIQUID, ACIDIC, ORGANIC N.O.S. (GLUTARAL), 8, II	

# 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.

· 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.

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Cancerogenity 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 02/10/2025 / 3

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 Transportation

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 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 Corrosion TB. Skin Corrosion/irritation — Category TB
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

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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.