



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **1.1 Product identifier**
 - Trade name: **Gluma Solid Bond P**
- **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** Dental bonding material
- **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**

Flam. Liq. 3 H226 Flammable liquid and vapour.
Skin Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2 H319 Causes serious eye irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.
- **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**
 
GHS02 GHS07
 - **Signal word** Warning
 - **Hazard-determining components of labelling:**

2-hydroxyethyl methacrylate
triethylen glycol dimethacrylate
maleic acid
 - **Hazard statements**

H226 Flammable liquid and vapour.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.
 - **Precautionary statements**

P210 Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
P241 Use explosion-proof electrical/ventilating/lighting/equipment.
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

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P303+P361+P353 *IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.*

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).*

2.3 Other hazards -

Results of PBT and vPvB assessment

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

3.2 Chemical characterisation: Mixtures

- **Description:** Product based on methacrylates

Dangerous components:

CAS: 868-77-9 EINECS: 212-782-2	2-hydroxyethyl methacrylate Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	25-50%
CAS: 64-17-5 EINECS: 200-578-6 Reg.nr.: 2119457610-43-xxxx	ethanol Flam. Liq. 2, H225	10-25%
	Poly(methacrylic-oligo-acrylic acid) Eye Irrit. 2, H319	0-5%
CAS: 109-16-0 EINECS: 203-652-6 Reg.nr.: 01-2119969287-21-0000	triethylen glycol dimethacrylate Skin Sens. 1B, H317	0-5%
CAS: 51978-15-5 EINECS: 257-569-5	maleic-acid-mono-2-methacryloyl-oxyethylester Eye Dam. 1, H318; Acute Tox. 4, H302; Acute Tox. 4, H312; Acute Tox. 4, H332; Skin Irrit. 2, H315	0-5%
CAS: 110-16-7 EINECS: 203-742-5	maleic acid Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	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 and call for doctor for safety reasons.

In case of unconsciousness bring patient into stable side position for transport.

After skin contact Instantly rinse with water.

After eye contact

Rinse opened eye for several minutes under running water. If symptoms persist, 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.

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- **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**
Can form explosive gas-air mixtures.
Formation of toxic gases is possible during heating or in case of fire.
- **5.3 Advice for firefighters**
 - **Protective equipment:** No special measures required.
 - **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:**
Prevent material from reaching sewage system, holes and cellars.
Dilute with much water.
- **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).
Ensure adequate ventilation.
- **6.4 Reference to other sections**
No dangerous materials are released.
See Section 8 for information on personal protection equipment.
-

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** Keep containers tightly sealed.
 - **Information about protection against explosions and fires:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.
- **7.2 Conditions for safe storage, including any incompatibilities**
 - **Storage**
 - **Requirements to be met by storerooms and containers:** Store in cool location.
 - **Information about storage in one common storage facility:** Not required.
 - **Further information about storage conditions:**
Store cool (not above 25 °C).
Store in cool, dry conditions in well sealed containers.
- **7.3 Specific end use(s)** No further relevant information available.

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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:**

64-17-5 ethanol

OELV () 1900 mg/m³, 1000 ppm

· **DNELs**

64-17-5 ethanol

Oral	ge.pop., l.te, syst.	87 mg/Kg (nd)
Dermal	worker profess., l.te., syst.	343 mg/Kg/d (nd)
	ge.pop., acu., local	950 mg/Kg/d (nd)
Inhalative	ge.pop., l.te, syst.	206 mg/Kg/d (nd)
	worker profess., acute, local	1900 mg/m ³ (nd)
	worker profess., l.te., syst.	1900 mg/m ³ (nd)
	ge.pop., acu., local	950 mg/m ³ (nd)
	ge.pop., l.te, syst.	114 mg/m ³ (nd)

109-16-0 triethylen glycol dimethacrylate

Dermal	worker industr., l.te., syst.	13.9 mg/Kg/d (nd)
Inhalative	worker industr., l.te., syst.	48.5 mg/m ³ (nd)

· **PNECs**

64-17-5 ethanol

freshwater	0.96 mg/l (nd)
marine water	0.79 mg/l (nd)
STP	580 mg/l (nd)
sedim., dw, fre.wat.	3.6 mg/Kg (nd)
soil,dw	0.63 mg/Kg (nd)

109-16-0 triethylen glycol dimethacrylate

marine water	0.0164 mg/l (nd)
sedim., dw, fre.wat.	1.85 mg/Kg (nd)
sedim., dw, mar.wat.	0.185 mg/Kg (nd)
soil,dw	0.274 mg/Kg (nd)

· **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.
Avoid contact with the eyes and skin.

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- **Breathing equipment:**
Not necessary with efficient local exhaust. If exposition to vapours is possible, use breathing protective mask (filter A).
Use breathing protection in case of insufficient ventilation.
- **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:**
Protective goggles are recommended.
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**

· **Appearance:**

· **Form:** Fluid

· **Colour:** Yellowish

· **Smell:** Characteristic

· **Odour threshold:** Not determined.

· **pH-value:** Not determined.

· **Change in condition**

· **Melting point/Melting range:** Not determined

· **Boiling point/Boiling range:** 55 °C

· **Flash point:** 35 °C

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

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· Ignition temperature:	425.0 °C
· Decomposition temperature:	Not determined.
· Self-inflammability:	Product is not selfigniting.
· Danger of explosion:	Product is not explosive. However, formation of explosive air/vapour mixtures is possible.
· Critical values for explosion:	
· Lower:	3.5 Vol %
· Upper:	15.0 Vol %
· Steam pressure at 20 °C:	57 hPa
· Density at 20 °C	1.000 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with	
· Water:	Fully miscible
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
· dynamic at 20 °C:	1 mPas
· kinematic:	Not determined.
· Solvent content:	
· Water:	31.9 %
· VOC EU	322.3 g/l
· Solids content:	1.3 %
· 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

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
 - **Acute toxicity** Based on available data, the classification criteria are not met.

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· LD/LC50 values that are relevant for classification:		
868-77-9 2-hydroxyethyl methacrylate		
Oral	LD50	5564 mg/kg (rat)
Dermal	LD50	>3000 mg/kg (can)
64-17-5 ethanol		
Oral	LD50	6200 mg/kg (rat)
Inhalative	LC50/4 h	95.6 mg/l (rat)
Poly(methacrylic-oligo-acrylic acid)		
Oral	LD50	>5000 mg/kg (rat)
109-16-0 triethylen glycol dimethacrylate		
Oral	LD50	> 5000 mg/kg (rat)
Dermal	LD50	> 2000 mg/kg (mouse)
51978-15-5 maleic-acid-mono-2-methacryloyl-oxyethylester		
Oral	LD50	1068 mg/kg (rat)
110-16-7 maleic acid		
Oral	LD50	708 mg/kg (rat)
Dermal	LD50	1560 mg/kg (rab)

- **Primary irritant effect:**
 - **Skin corrosion/irritation**
Causes skin irritation.
 - **Serious eye damage/irritation**
Causes serious eye irritation.
- **Respiratory or skin sensitisation**
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** Based on available data, the classification criteria are not met.
- **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.

SECTION 12: Ecological information

· 12.1 Toxicity

· Aquatic toxicity:	
868-77-9 2-hydroxyethyl methacrylate	
LC50/96h	227 mg/l (fish)
109-16-0 triethylen glycol dimethacrylate	
EC50/72h	> 100 mg/l (algae)

- **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.

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- **Additional ecological information:**
 - **General notes:**
Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.
- **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.
- **Recommended cleaning agent:** Water, if necessary with cleaning agent.

SECTION 14: Transport information

- **14.1 UN-Number**
 - **ADR, IMDG, IATA** 1170
- **14.2 UN proper shipping name**
 - **ADR** 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
 - **IMDG** ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
 - **IATA** ETHANOL, solution
- **14.3 Transport hazard class(es)**
 - **ADR, IMDG, IATA**



 - **Class** 3 Flammable liquids.
 - **Label** 3
- **14.4 Packing group**
 - **ADR, IMDG, IATA** III

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- | | |
|--|---|
| · 14.5 Environmental hazards: | |
| · Marine pollutant: | No |
| · 14.6 Special precautions for user | Warning: Flammable liquids. |
| · Kemler Number: | 30 |
| · EMS Number: | F-E,S-D |
| · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · Transport/Additional information: | - |
| · UN "Model Regulation": | UN1170, ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, III |

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**
 - H225 Highly flammable liquid and vapour.
 - H302 Harmful if swallowed.
 - H312 Harmful in contact with skin.
 - H315 Causes skin irritation.
 - H317 May cause an allergic skin reaction.
 - H318 Causes serious eye damage.
 - H319 Causes serious eye irritation.
 - H332 Harmful if inhaled.
 - H335 May cause respiratory irritation.
- **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)
 - VOCV: Lenkungsabgabe auf flüchtigen organischen Verbindungen, Schweiz (Swiss Ordinance on volatile organic compounds)
 - DNEL: Derived No-Effect Level (REACH)
 - PNEC: Predicted No-Effect Concentration (REACH)
 - LC50: Lethal concentration, 50 percent
 - LD50: Lethal dose, 50 percent
 - PBT: Persistent, Bioaccumulative and Toxic
 - vPvB: very Persistent and very Bioaccumulative

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Flam. Liq. 2: Flammable liquids – Category 2
Flam. Liq. 3: Flammable liquids – Category 3
Acute Tox. 4: Acute toxicity – Category 4
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
Skin Sens. 1: Skin sensitisation – Category 1
Skin Sens. 1B: Skin sensitisation – Category 1B
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
· *** Data compared to the previous version altered.**

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