



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

Printing date 11.09.2017

Version number 3

Revision: 11.09.2017

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

· **1.1 Product identifier**

· Trade name: **Gluma Self Etch**

· **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. 2 H225 Highly 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.

STOT SE 3 H336 May cause drowsiness or dizziness.

· **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** Danger

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

4-methacryloxyethyltrimellitic acid anhydride

acetone

2-hydroxyethyl methacrylate

· **Hazard statements**

H225 Highly flammable liquid and vapour.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

H336 May cause drowsiness or dizziness.

· **Precautionary statements**

P210 Keep away from heat/sparks/open flames/hot surfaces. - No smoking.

P241 Use explosion-proof electrical/ventilating/lighting/equipment.

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).

P405 Store locked up.

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- **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: 67-64-1 EINECS: 200-662-2	acetone Flam. Liq. 2, H225; Eye Irrit. 2, H319; STOT SE 3, H336	25-50%
CAS: 70293-55-9	4-methacryloxyethyltrimellitic acid anhydride Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	10-25%
CAS: 868-77-9 EINECS: 212-782-2	2-hydroxyethyl methacrylate Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	< 1%

- **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.
 - **After skin contact** Instantly wash with water and soap and rinse thoroughly.
 - **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.

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:** Do not inhale explosion gases or combustion gases.
 - **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.
- **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).

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- Ensure adequate ventilation.
- Send for recovery or disposal in suitable containers.
- **6.4 Reference to other sections**
- See Section 13 for information on disposal.
- See Section 8 for information on personal protection equipment.
-

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
- Keep containers tightly sealed.
- Ensure good ventilation/exhaustion at the workplace.
- **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:**
- Keep receptacle tightly sealed.
- Protect from the effects of light.
- **7.3 Specific end use(s)** No further relevant information available.

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:**

67-64-1 acetone

WEL Short-term value: 3620 mg/m³, 1500 ppm
Long-term value: 1210 mg/m³, 500 ppm

· **DNELs**

67-64-1 acetone

Oral	ge.pop., l.te, syst.	62 mg/Kg (nd)
Dermal	worker profess., acute, syst.	2420 mg/Kg/d (nd)
	worker profess., l.te., syst.	186 mg/Kg/d (nd)
Inhalative	ge.pop., l.te, syst.	62 mg/Kg/d (nd)
	worker profess., l.te., syst.	1210 mg/m ³ (nd)
	ge.pop., l.te, syst.	200 mg/m ³ (nd)

· **PNECs**

67-64-1 acetone

freshwater	10.6 mg/l (nd)
marine water	1.06 mg/l (rabbit)
STP	19.5 mg/l (nd)
sedim., dw, fre.wat.	30.4 mg/Kg (nd)
sedim., dw, mar.wat.	3.04 mg/Kg (nd)
soil,dw	0.112 mg/Kg (nd)

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· **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**

- Avoid contact with the eyes.
- 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.

· **Breathing equipment:** Not required.

· **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.
- Check protective gloves prior to each use for their proper condition.

· **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:** 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:** -19 °C

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

· **Ignition temperature:** 465 °C

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· 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:	2.6 Vol %
· Upper:	13.0 Vol %
· Steam pressure at 20 °C:	247 hPa
· Density at 20 °C	1 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with	
· Water:	Partly miscible
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
· dynamic:	Not determined.
· kinematic:	Not determined.
· 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:** Protect from heat and direct sunlight.
- **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.

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

67-64-1 acetone		
Oral	LD50	5800 mg/kg (rat)
Dermal	LD50	20000 mg/kg (rabbit)
41137-60-4 diurethandimethacrylate		
Oral	LD50	>5000 mg/kg (rat)
70293-55-9 4-methacryloxyethyltrimellitic acid anhydride		
Oral	LD50	> 2000 mg/kg (mouse)
Dermal	LD50	> 2000 mg/kg (mouse)
868-77-9 2-hydroxyethyl methacrylate		
Oral	LD50	5564 mg/kg (rat)

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Dermal LD50 >3000 mg/kg (can)

- **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**
May cause drowsiness or dizziness.
- **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:**

67-64-1 acetone

EC50/48h 6100 mg/l (daphnia)

LC50/96h 5540 mg/l (fish)

868-77-9 2-hydroxyethyl methacrylate

LC50/96h 227 mg/l (fish)

- **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.
 - **Additional ecological information:**
 - **General notes:** Do not allow product 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.

Disposal must be made according to official regulations.

· **European waste catalogue**

18 01 06* chemicals consisting of or containing hazardous substances

· **Uncleaned packagings:**

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

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· **Recommended cleaning agent:** Water, if necessary with cleaning agent.

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SECTION 14: Transport information

· 14.1 UN-Number · ADR, IMDG, IATA	1090
· 14.2 UN proper shipping name · ADR · IMDG, IATA	1090 ACETONE solution ACETONE, solution
· 14.3 Transport hazard class(es) · ADR	
	
· Class · Label	3 (F1) Flammable liquids. 3
· IMDG, IATA	
	
· Class · Label	3 Flammable liquids. 3
· 14.4 Packing group · ADR, IMDG, IATA	II
· 14.5 Environmental hazards: · Marine pollutant:	No
· 14.6 Special precautions for user · Kemler Number: · EMS Number:	Warning: Flammable liquids. 33 F-E,S-D
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	-
· ADR · Limited quantities (LQ) · Transport category · Tunnel restriction code	1L 2 D/E
· UN "Model Regulation":	UN 1090 ACETONE SOLUTION, 3, II

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SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
 - **Directive 2012/18/EU**
 - **Named dangerous substances - ANNEX I** None of the ingredients is listed.
 - **Seveso category P5c** FLAMMABLE LIQUIDS
 - **Qualifying quantity (tonnes) for the application of lower-tier requirements** 5.000 t
 - **Qualifying quantity (tonnes) for the application of upper-tier requirements** 50.000 t
 - **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.
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.
- H336 May cause drowsiness or dizziness.

· **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)
- 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
- Flam. Liq. 2: Flammable liquids – Category 2
- Skin Irrit. 2: Skin corrosion/irritation – Category 2
- Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
- Skin Sens. 1: Skin sensitisation – Category 1
- STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

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