



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

Printing date 29.06.2021

Version number 4

Revision: 29.06.2021

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

· **1.1 Product identifier**

· Trade name: **GLUMA Bond universal**

· **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.

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 CLP regulation.

· **Hazard pictograms**



GHS02 GHS07

· **Signal word** Danger

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

7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate

acetone

4-methacryloxyethyltrimellitic acid anhydride

· **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.

H412 Harmful to aquatic life with long lasting effects.

· **Precautionary statements**

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P261 Avoid breathing mist/vapours/spray.

P273 Avoid release to the environment.

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P280 Wear protective gloves/protective clothing/eye protection/face protection.
P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or 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.

· **Additional information:**

Contains isocyanates. May produce an allergic reaction.

· **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:** -

· **Dangerous components:**

CAS: 67-64-1 EINECS: 200-662-2 Reg.nr.: 01-2119471330-49-xxxx	acetone Flam. Liq. 2, H225 Eye Irrit. 2, H319; STOT SE 3, H336	25-50%
CAS: 72869-86-4 EINECS: 276-957-5 Reg.nr.: 01-2120751202-68-xxxx	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diaza-hexadecane-1,16-diyl bismethacrylate Aquatic Chronic 2, H411 Skin Sens. 1B, H317	≥10-<25%
CAS: 70293-55-9	4-methacryloxyethyltrimellitic acid anhydride Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	10-25%

· **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 and call for doctor for safety reasons.

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

· **After skin contact** If skin irritation continues, consult a doctor.

· **After eye contact**

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

· **After swallowing**

In case of persistent symptoms consult doctor.

Rinse out mouth and then drink plenty of water.

· **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.

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- **For safety reasons unsuitable extinguishing agents** Water with a full water jet.
- **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.
- **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.
Send for recovery or disposal in suitable containers.
- **6.4 Reference to other sections**
See Section 7 for information on safe handling
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** 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:**
Keep receptacle tightly sealed.
Protect from the effects of light.
Store in cool, dry conditions in well sealed containers.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**
 - **Additional information about design of technical systems:** No further data; see item 7.

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

67-64-1 acetone

WEL	Short-term value: 3620 mg/m ³ , 1500 ppm Long-term value: 1210 mg/m ³ , 500 ppm
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· **DNELs**

67-64-1 acetone

Oral	ge.pop., l.te, syst.	62 mg/Kg (nd)
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Dermal	worker industr., l.te., syst.	186 mg/Kg/d (nd)
	ge.pop., l.te, syst.	62 mg/Kg/d (nd)
Inhalative	worker industr., l.te., syst.	1210 mg/m ³ (nd)
	worker industr., l.te., local	2420 mg/m ³ (nd)
	ge.pop., l.te, syst.	200 mg/m ³ (nd)
72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate		
Oral	ge.pop., l.te, syst.	0.3 mg/Kg (nd)
Dermal	worker industr., l.te., syst.	1.3 mg/Kg/d (nd)
	ge.pop., l.te, syst.	0.7 mg/Kg/d (nd)
Inhalative	worker industr., l.te., syst.	3.3 mg/m ³ (nd)
	ge.pop., l.te, syst.	0.6 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)

72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate

freshwater	0.01 mg/l (nd)
marine water	0.001 mg/l (nd)
STP	3.61 mg/l (nd)
sedim., dw, fre.wat.	4.56 mg/Kg (nd)
sedim., dw, mar.wat.	0.46 mg/Kg (nd)
soil,dw	0.91 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

- 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: Use breathing protection against the effects of fumes/dust/aerosol.

· 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.
- 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 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**

· **Appearance:**

- **Form:** Liquid
- **Colour:** Clear
- **Smell:** Characteristic
- **Odour threshold:** Not determined.

· **pH-value:** Not determined.

· **Change in condition**

- **Melting point/freezing point:** Not determined
- **Initial boiling point and boiling range:** Not determined

· **Flash point:** -19 °C

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

· **Decomposition temperature:** Not determined.

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

· **Explosive properties:** Product is not explosive. However, formation of explosive air/vapour mixtures is possible.

· **Critical values for explosion:**

- **Lower:** Not determined.
- **Upper:** Not determined.

· **Steam pressure:** Not determined.

- **Density at 20 °C** 0.99 g/cm³
- **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.

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· **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
 - **Additional information:** -

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	>15800 mg/kg (rabbit)
Inhalative	LC50/4 h	76 mg/l (rat)

72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate

Oral	LD50	>5000 mg/kg (rat) (OECD 401)
Dermal	LD50	>2000 mg/kg (rat) (OECD 402)

70293-55-9 4-methacryloxyethyltrimellitic acid anhydride

Oral	LD50	>2000 mg/kg (mouse)
Dermal	LD50	>2000 mg/kg (mouse)

- **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.
- **Additional toxicological information:**
 - **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.

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SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**

67-64-1 acetone

EC50/48h	8800 mg/l (daphnia)
LC50/96h	6210 mg/l (fish) (OECD 203)

72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate

EC50/48h	>1.2 mg/l (daphnia) (OECD 202)
LC50/96h	10.1 mg/l (fish) (OECD 203)
ErC50 / 72 h	>0.68 mg/l (algae) (OECD 201)
NOEC / 72h	0.21 mg/l (algae) (OECD 201)

· **12.2 Persistence and degradability**

67-64-1 acetone

Biodegradation	90.9 % /28d (nd) (OECD 301D)
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72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate

Biodegradation	22 % /28d (nd) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)
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· **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.
Danger to drinking water if even small quantities leak into soil.

· **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**

Disposal must be made according to official regulations.
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**

· **ADR, IMDG, IATA** UN1090

· **14.2 UN proper shipping name**

· **ADR** 1090 ACETONE, mixture
· **IMDG, IATA** ACETONE, mixture

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· **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**

1 L
2
D/E

· **UN "Model Regulation":**

UN1090, ACETONE, mixture, 3, II

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**

H225 Highly flammable liquid and vapour.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.

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H319 Causes serious eye irritation.

H336 May cause drowsiness or dizziness.

H411 Toxic to aquatic life with long lasting effects.

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

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

Skin Sens. 1B: Skin sensitisation – Category 1B

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

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.**