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Safety data sheet according to 1907/2006/EC. Article 31

Printing date 08.01.2025

Version number 4 (replaces version 3)

Revision: 09.12.2024

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 H225 Highly flammable liquid and vapour. Flam. Liq. 2 Skin Irrit. 2 H315 Causes skin irritation. Eve 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 GB 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-dioxa-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. (Contd. on page 2)



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· Precautionary statements

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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.

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:

Product contains: Reportable explosives precursors. Making available, introduction, possession and use according to Regulation (EU) 2019/1148, Article 9.

· 2.3 Other hazards -

• Results of PBT and vPvB assessment

• PBT: Not applicable.

vPvB: Not applicable.

· 3.2 Mixtures · Description: -				
Dangerous components:				
CAS: 67-64-1 EINECS: 200-662-2 Index number: 606-001-00-8 Reg.nr.: 01-2119471330-49-xxxx	acetone Flam. Liq. 2, H225 Eye Irrit. 2, H319; STOT SE 3, H336 EUH066	25-50%		
CAS: 72869-86-4 EINECS: 276-957-5 Index number: 607-134-00-4 Reg.nr.: 01-2120751202-68-xxxx	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12- diazahexadecane-1,16-diyl bismethacrylate Aquatic Chronic 2, H411 Skin Sens. 1B, H317 EUH204	<i>≥</i> 10-<25%		
CAS: 70293-55-9	4-methacryloxyethyltrimellitic acid anhydride Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	10-25%		

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

Rinse out mouth and then drink plenty of water.

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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. **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.

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• 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection · 8.1 Control parameters · Components with critical values that require monitoring at the workplace: 67-64-1 acetone Short-term value: 3620 mg/m³, 1500 ppm WEL (Great Britain) Long-term value: 1210 mg/m³, 500 ppm IOELV (European Union) Long-term value: 1210 mg/m³, 500 ppm · DNELs 67-64-1 acetone Oral general population, long term, systemic 62 mg/Kg (not defined) Dermal worker industrial, long term, systemic 186 mg/Kg/d (not defined) general population, long term, systemic 62 mg/Kg/d (not defined) worker industrial, long term, systemic Inhalative 1,210 mg/m3 (not defined) worker industrial, long term, local 2,420 mg/m3 (not defined) general population, long term, systemic 200 mg/m3 (not defined) 72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate 0.3 mg/Kg (not defined) general population, long term, systemic Oral Dermal worker industrial, long term, systemic 1.3 mg/Kg/d (not defined) general population, long term, systemic 0.7 mg/Kg/d (not defined) Inhalative worker industrial, long term, systemic 3.3 mg/m3 (not defined) general population, long term, systemic 0.6 mg/m3 (not defined) · PNECs 67-64-1 acetone freshwater 10.6 mg/l (not defined) marine water 1.06 mg/l (rabbit) 19.5 mg/l (not defined) sewage treatment plant sediment, dry weight, freshwater 30.4 mg/Kg (not defined) sediment, dry weight, marine water 3.04 mg/Kg (not defined) 0.112 mg/Kg (not defined) soil, dry weight 72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate 0.01 mg/l (not defined) freshwater marine water 0.001 mg/l (not defined) sewage treatment plant 3.61 mg/l (not defined) sediment, dry weight, freshwater 4.56 mg/Kg (not defined) sediment, dry weight, marine water 0.46 mg/Kg (not defined) soil, dry weight 0.91 mg/Kg (not defined) (Contd. on page 5)



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(Contd. of page 4) • Additional information: The lists that were valid during the compilation were used as basis. · 8.2 Exposure controls Appropriate engineering controls No further data; see section 7. Individual protection measures, such as 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. Hand protection 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 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 trough 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/face 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** Physical state Fluid · Colour: Clear Smell: Characteristic Not determined. Odour threshold: • Melting point/freezing point: Not determined Boiling point or initial boiling point and 55 °C boiling range · Flammability Not applicable. (Contd. on page 6) GB



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• Lower and upper explosion limit	
· Lower:	Not determined.
· Upper:	Not determined.
Flash point:	1.5 °C
• Decomposition temperature:	Not determined.
·SADT	Net determined
· pH	Not determined.
Viscosity:	
Kinematic viscosity	Not determined.
Kinematic viscosity	
· dynamic:	Not determined.
· Solubility	
· Water:	Partly miscible
 Partition coefficient n-octanol/water (log 	
value)	Not determined.
Steam pressure:	Not determined.
· Vapour pressure:	
• Density and/or relative density	
· Density at 20 °C	0.99 g/cm³
· Relative density	Not determined.
· Vapour density	Not determined.
• 9.2 Other information No f	urther relevant information available.
· Appearance:	
Form:	Fluid
 Important information on protection of health 	
and environment, and on safety.	
Self-inflammability:	Product is not selfigniting.
• Explosive properties:	Product is not explosive. However, formation
	explosive air/vapour mixtures is possible.
· Change in condition	
· Evaporation rate	Not determined.
-	Not determined.
Information with regard to physical hazard	
classes	
· Explosives	Void
· Flammable gases	Void
Aerosols	Void
· Aerosols · Oxidising gases	Void Void
· Aerosols · Oxidising gases · Gases under pressure	
· Aerosols · Oxidising gases · Gases under pressure	Void Void
· Aerosols · Oxidising gases · Gases under pressure · Flammable liquids	Void Void Highly flammable liquid and vapour.
· Aerosols · Oxidising gases · Gases under pressure · Flammable liquids · Flammable solids	Void Void Highly flammable liquid and vapour. Void
 Aerosols Oxidising gases Gases under pressure Flammable liquids Flammable solids Self-reactive substances and mixtures 	Void Void Highly flammable liquid and vapour. Void Void
 Aerosols Oxidising gases Gases under pressure Flammable liquids Flammable solids Self-reactive substances and mixtures Pyrophoric liquids 	Void Void Highly flammable liquid and vapour. Void Void Void
 Aerosols Oxidising gases Gases under pressure Flammable liquids Flammable solids Self-reactive substances and mixtures Pyrophoric liquids Pyrophoric solids 	Void Void Highly flammable liquid and vapour. Void Void Void Void
 Aerosols Oxidising gases Gases under pressure Flammable liquids Flammable solids Self-reactive substances and mixtures Pyrophoric liquids Pyrophoric solids Self-heating substances and mixtures 	Void Void Highly flammable liquid and vapour. Void Void Void
 Aerosols Oxidising gases Gases under pressure Flammable liquids Flammable solids Self-reactive substances and mixtures Pyrophoric liquids Pyrophoric solids Self-heating substances and mixtures Substances and mixtures, which emit 	Void Void Highly flammable liquid and vapour. Void Void Void Void Void
 Aerosols Oxidising gases Gases under pressure Flammable liquids Flammable solids Self-reactive substances and mixtures Pyrophoric liquids Pyrophoric solids Self-heating substances and mixtures Substances and mixtures, which emit flammable gases in contact with water 	Void Void Highly flammable liquid and vapour. Void Void Void Void Void
 Aerosols Oxidising gases Gases under pressure Flammable liquids Flammable solids Self-reactive substances and mixtures Pyrophoric liquids Pyrophoric solids Self-heating substances and mixtures Substances and mixtures, which emit 	Void Void Highly flammable liquid and vapour. Void Void Void Void Void



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 · Organic peroxides
 Void

 · Corrosive to metals
 Void

 · Desensitised explosives
 Void

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 hazard classes as defined in Regulation (EC) No 1272/2008 • Acute toxicity Based on available data, the classification criteria are not met.

LD/LC50 values that are relevant for classification:

· LD/	/LC50 valu	les that are relevant for classification:
67-64-1 a	cetone	
Oral	LD50	5,800 mg/kg (rat)
Dermal	LD50	>15,800 mg/kg (rabbit)
Inhalative	LC50/4 h	76 mg/l (rat)
72869-86		r 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl nacrylate
Oral	LD50	>5,000 mg/kg (rat) (OECD 401)
Dermal	LD50	>2,000 mg/kg (rat) (OECD 402)
70293-55	-9 4-metha	cryloxyethyltrimellitic acid anhydride
Oral	LD50	>2,000 mg/kg (mouse)
Dermal	LD50	>2,000 mg/kg (mouse)
Cause Seriou Cause Respin May ca Germ Carcin Repro	s sérious e ratory or s ause an alle cell mutag nogenicity	tion. nage/irritation eye irritation. kin sensitisation ergic skin reaction. genicity Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. xicity Based on available data, the classification criteria are not met.
May ca	ause drows	siness or dizziness. exposure Based on available data, the classification criteria are not met.
		rd Based on available data, the classification criteria are not met.

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List II

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· 11.2 Information on other hazards

• Endocrine disrupting properties 128-37-0 2,6-di-tert-butyl-p-cresol

12.1 Toxicity • Aquatic toxicity:				
EC50/48h	8,800 mg/l (daphnia)			
LC50/96h	6,210 mg/l (fish) (OECD 203)			
k	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diy Dismethacrylate			
EC50/48h	>1.2 mg/l (daphnia) (OECD 202)			
	10.1 mg/l (fish) (OECD 203)			
	>0.68 mg/l (algae) (OECD 201)			
NOEC / 72h	0.21 mg/l (algae) (OECD 201)			
12.2 Persiste	ence and degradability			
67-64-1 acet				
	on 90.9 % /28d (not defined) (OECD 301D)			
k	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diy Dismethacrylate			
	on 22 % /28d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)			
12.4 Mobility 12.5 Results PBT: Not vPvB: No 12.6 Endocri For informatic 12.7 Other a Additiona Gener Do not	umulative potential No further relevant information available.v in soil No further relevant information available.of PBT and vPvB assessmentapplicable.t applicable.ine disrupting propertieson on endocrine disrupting properties see section 11.dverse effectsal ecological information:al notes:r allow product to reach ground water, water bodies or sewage system.r to drinking water if even small quantities leak into soil.			
Dange	13: Disposal considerations			



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• Uncleaned packagings: • Recommendation: Disposal must be made according to official regulations.

14.1 UN number or ID number · ADR, IMDG, IATA	UN1090
14.2 UN proper shipping name ADR IMDG, IATA	1090 ACETONE mixture ACETONE mixture
14.3 Transport hazard class(es)	
ADR	
· Class	3 (F1) Flammable liquids.
· Label · IMDG, IATA	
· Class · Label	3 Flammable liquids. 3
14.4 Packing group · ADR, IMDG, IATA	11
14.5 Environmental hazards: Marine pollutant:	No
14.6 Special precautions for user	Warning: Flammable liquids.
· Kemler Number: · EMS Number:	33 F-E,S-D
· Stowage Category	E
14.7 Maritime transport in bulk according instruments	to IMO Not applicable.
· Transport/Additional information:	-
ADR	
· Limited quantities (LQ)	1L Codo: 52
Excepted quantities (ÉQ)	Code: E2 Maximum net quantity per inn
	packaging: 30 ml Maximum net quantity per outer

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· · Transport category · Tunnel restriction code	packaging: 500 ml 2 D/E
· 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":	UN 1090 ACETONE MIXTURE, 3, II

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Directive 2012/18/EU

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

• 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.
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- Causes serious eve irritation. H319
- H335 May cause respiratory irritation.
- H336 May cause drowsiness or dizziness.
- H411 Toxic to aquatic life with long lasting effects.
- EUH066 Repeated exposure may cause skin dryness or cracking.

EUH204 Contains isocyanates. May produce an allergic reaction.

Abbreviations and acronyms:

SADT: Self Accelerating Decomposition Temperature

ADR: Accelerating Decomposition Temperature 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 (UK REACH)

PNEC: Predicted No-Effect Concentration (UK REACH)

LC50: Lethal concentration, 50 percent

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LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative Flam. Liq. 2: Flammable liquids – Category 2 Acute Tox. 4: Acute toxicity – Category 4 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.