Safety Data Sheet
according to HPR, Schedule 1

Printing date 06/29/2021 Reviewed on 06/29/2021

1 Identification

· **Product identifier**

· **Trade name:** **GLUMA Bond universal**

· **-**

· **Application of the substance / the mixture** Dental bonding material

· **Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier:**
Kulzer GmbH
Leipziger Straße 2, 63450 Hanau (Germany) Tel.: +49 (0)800 4372522

· **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 identification

· **Classification of the substance or mixture**

Flammable Liquids - Category 2	H225 Highly flammable liquid and vapour.
Skin Irritation - Category 2	H315 Causes skin irritation.
Eye Irritation - Category 2A	H319 Causes serious eye irritation.
Skin Sensitizer - Category 1	H317 May cause an allergic skin reaction.
Specific Target Organ Toxicity - Single Exposure - Category 3	H336 May cause drowsiness or dizziness.

· **Label elements**

· **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**

GHS02 GHS07

· **Signal word** Danger

· **Hazard-determining components of labeling:**
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**
Highly flammable liquid and vapour.
Causes skin irritation.
Causes serious eye irritation.
May cause an allergic skin reaction.
May cause drowsiness or dizziness.

· **Precautionary statements**
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
Avoid breathing mist/vapours/spray.
Avoid release to the environment.

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Wear protective gloves/protective clothing/eye protection/face protection.
IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

· **Classification system**

· **NFPA ratings for USA (scale 0-4)**

Health = 2
Fire = 3
Reactivity = 0

· **HMIS-Ratings (Scale 0-4)**

Health = 2
Fire = 3
Reactivity = 0

· **Other hazards** -

3 Composition/Information on ingredients

· **Chemical characterization: Mixtures**

· **Description:** -

· **Dangerous components:**

67-64-1	acetone Flammable Liquids - Category 2, H225 Eye Irritation - Category 2A, H319; Specific Target Organ Toxicity - Single Exposure - Category 3, H336	25-50% w/w *
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate Skin Sensitizer - Category 1B, H317	10-25% w/w *
70293-55-9	4-methacryloxyethyltrimellitic acid anhydride Skin Irritation - Category 2, H315; Eye Irritation - Category 2A, H319; Skin Sensitizer - Category 1, H317	10-25% w/w *

* Actual concentration ranges are withheld as a trade secret.

· **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 and to be sure call for a doctor.
In case of unconsciousness place patient stably in side position for transportation.

· **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 a doctor.

· **After swallowing**
If symptoms persist consult doctor.
Rinse out mouth and then drink plenty of water.

· **Information for doctor**

· **Most important symptoms and effects, both acute and delayed**
No further relevant information available.

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· **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 foam.
· **For safety reasons unsuitable extinguishing agents** Water with full jet.
· **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.
· **Advice for firefighters**
· **Protective equipment:** No special measures required.
· **Additional information** -

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
· **Environmental precautions:** Prevent seepage into sewage system, workpits and cellars.
· **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 receptacles.
· **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 disposal information.
-

7 Handling and storage

· **Handling**
· **Precautions for safe handling** Keep receptacles tightly sealed.
· **Information about protection against explosions and fires:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.

· **Conditions for safe storage, including any incompatibilities**
· **Storage**
· **Requirements to be met by storerooms and receptacles:** Store in a cool location.
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:**
Keep receptacle tightly sealed.
Protect from exposure to the light.
Store in cool, dry conditions in well sealed receptacles.
· **Specific end use(s)** No further relevant information available.

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8 Exposure controls/ Personal protection

· **Additional information about design of technical systems:** No further data; see item 7.

· **Control parameters**

· **Components with limit values that require monitoring at the workplace:**	
67-64-1 acetone	
EL	Short-term value: 500 ppm Long-term value: 250 ppm
EV	Short-term value: 750 ppm Long-term value: 500 ppm

· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**

· **Personal protective equipment**

· **General protective and hygienic measures**

Avoid contact with the eyes.
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:**

Use respiratory protective device 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

· **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 goggles.

· **Body protection:** Light weight protective clothing

9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

· **Form:** Liquid

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· **Color:**	Clear
· **Odor:**	Characteristic
· **Odor threshold:**	Not determined.
· **pH-value:**	Not determined.
· **Change in condition**	
· **Melting point/Melting range:**	undetermined
· **Boiling point/Boiling range:**	undetermined
· **Flash point:**	-19 °C (-2.2 °F)
· **Flammability (solid, gaseous)**	Not applicable.
· **Decomposition temperature:**	Not determined.
· **Auto igniting:**	Product is not selfigniting.
· **Danger of explosion:**	Product is not explosive. However, formation of explosive air/vapor mixtures are possible.
· **Explosion limits:**	
· **Lower:**	Not determined.
· **Upper:**	Not determined.
· **Vapor pressure:**	Not determined.
· **Density at 20 °C (68 °F):**	0.99 g/cm³ (8.26155 lbs/gal)
· **Relative density**	Not determined.
· **Vapor 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.
· **Other information**	No further relevant information available.

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
· **Additional information:** -

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11 Toxicological information

· **Information on toxicological effects**

· **Acute toxicity:**

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

67-64-1 acetone		
Oral	LD50	5800 mg/kg (rat)
Dermal	LD50	>15800 mg/kg (rabbit) weight of evidence
Inhalative	LC50/4 h	76 mg/l (rat) weight of evidence
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:**

· **on the skin:** No irritant effect.

· **on the eye:** Irritating effect.

· **Sensitization:** Sensitization possible through skin contact.

· **Additional toxicological information:** Irritant

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

None of the ingredients is listed.

· **NTP (National Toxicology Program)**

None of the ingredients is listed.

· **Reproductive toxicity** Based on available data, the classification criteria are not met.

12 Ecological information

· **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)

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· **Persistence and degradability**	
67-64-1 acetone	
biodegradability	90.9 % /28d (nd) (OECD 301D)
72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate	
biodegradability	22 % /28d (nd) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)

· **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.
  Danger to drinking water if even 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**
  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.

14 Transport information

· **UN-Number**	
· **DOT/TDG, ADR, IMDG, IATA**	UN1090
· **UN proper shipping name**	
· **DOT/TDG, IMDG, IATA**	ACETONE, mixture
· **ADR**	1090 ACETONE, mixture
· **Transport hazard class(es)**	
· **DOT/TDG (Transport dangerous goods):**	

· **Class**	3 Flammable liquids
· **Label**	3

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· **ADR**

· **Class** 3 (F1) Flammable liquids
· **Label** 3

· **IMDG, IATA**

· **Class** 3 Flammable liquids
· **Label** 3

· **Packing group**
· **DOT/TDG, ADR, IMDG, IATA** II

· **Environmental hazards:**
· **Marine pollutant:** No

· **Special precautions for user** Warning: Flammable liquids
· **Hazard identification number (Kemler code):** 33
· **EMS Number:** F-E,S-D

· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.

· **Transport/Additional information:** -

· **UN "Model Regulation":** UN1090, Acetone mixture, 3, 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.

· **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**
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.

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Safety Data Sheet
according to HPR, Schedule 1

Printing date 06/29/2021 Reviewed on 06/29/2021

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· **Date of the latest revision of the safety data sheet** 06/29/2021 / 3
· **Abbreviations and acronyms:**
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
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
· *** Data compared to the previous version altered.**