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

1.1 Product identifier
· Trade name: Gluma 2Bond

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 Dam. 1 H318 Causes serious eye damage.
  Resp. Sens. 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
  Skin Sens. 1 H317 May cause an allergic skin reaction.
  STOT SE 3 H335 May cause respiratory irritation.

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  GHS05  GHS07  GHS08

· Signal word Danger

· Hazard-determining components of labelling:
  2-hydroxyethyl methacrylate
  glutaral
  4-methacryloxyethyltrimellitic acid anhydride

· Hazard statements
  H226 Flammable liquid and vapour.
  H315 Causes skin irritation.
  H318 Causes serious eye damage.
  H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
  H317 May cause an allergic skin reaction.
  H335 May cause respiratory irritation.

(Contd. on page 2)
Trade name: Gluma 2Bond

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.
P310 Immediately call a POISON CENTER/doctor.
P405 Store locked up.

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:

- Ethanol: CAS: 64-17-5, EINECS: 200-578-6, Reg.nr.: 2119457610-43-xxxx
- 2-hydroxyethyl methacrylate: CAS: 868-77-9, EINECS: 212-782-2
- Poly(methacrylic-oligo-acrylic acid): CAS: 70293-55-9
- 4-methacryloxyethyltrimellitic acid anhydride: CAS: 111-30-8
- Diurethandimethacrylate: CAS: 72869-86-4

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

General information

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

After inhalation: Supply fresh air; consult doctor in case of symptoms.

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.
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: Put on breathing apparatus.
- 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: Do not allow to enter the ground/soil.

6.3 Methods and material for containment and cleaning up:
Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).
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.
Prevent formation of aerosols.
Please observe the additional instructions in the product's instructions for use.
- 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: No special requirements.
  - Information about storage in one common storage facility: Not required.
  - Further information about storage conditions: Store cool (not above 25 °C).
SECTION 8: Exposure controls/personal protection

8.1 Control parameters

- Components with critical values that require monitoring at the workplace:

<table>
<thead>
<tr>
<th>Component</th>
<th>Long-term value</th>
<th>Short-term value (WEL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>64-17-5 ethanol</td>
<td>1920 mg/m³, 1000 ppm</td>
<td>0.2 mg/m³, 0.05 ppm</td>
</tr>
<tr>
<td>111-30-8 glutaral</td>
<td>0.2 mg/m³, 0.05 ppm</td>
<td>0.2 mg/m³, 0.05 ppm</td>
</tr>
</tbody>
</table>

- DNELs

<table>
<thead>
<tr>
<th>Component</th>
<th>Oral</th>
<th>Dermal</th>
<th>Inhalative</th>
</tr>
</thead>
<tbody>
<tr>
<td>ge.pop., l.te, syst.</td>
<td>87 mg/Kg (nd)</td>
<td>343 mg/Kg/d (nd)</td>
<td>206 mg/Kg/d (nd)</td>
</tr>
<tr>
<td>ge.pop., l.te, syst.</td>
<td>343 mg/Kg/d (nd)</td>
<td>950 mg/Kg/d (nd)</td>
<td>1900 mg/m³ (nd)</td>
</tr>
<tr>
<td>ge.pop., l.te, syst.</td>
<td>950 mg/Kg/d (nd)</td>
<td>1900 mg/m³ (nd)</td>
<td>114 mg/m³ (nd)</td>
</tr>
</tbody>
</table>

- PNECs

<table>
<thead>
<tr>
<th>Component</th>
<th>freshwater</th>
<th>marine water</th>
<th>STP</th>
<th>sedim., dw, fre.wat.</th>
<th>soil, dw</th>
</tr>
</thead>
<tbody>
<tr>
<td>64-17-5 ethanol</td>
<td>0.96 mg/l (nd)</td>
<td>0.79 mg/l (nd)</td>
<td>580 mg/l (nd)</td>
<td>3.6 mg/Kg (nd)</td>
<td>0.63 mg/Kg (nd)</td>
</tr>
</tbody>
</table>

- 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.
  - Do not inhale gases / fumes / aerosols.
  - Avoid contact with the eyes and skin.

  Breathing equipment: Breathing protection recommended.

  Protection of hands:
  - 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.

- **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 protection**: not absolutely neccessary

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

---

**SECTION 9: Physical and chemical properties**

- **9.1 Information on basic physical and chemical properties**

  - **Appearance**: 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**: Not determined

  - **Flash point**: 24 °C
  - **Inflammability (solid, gaseous)**: Not applicable.
  - **Ignition temperature**: 425 °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**: Not determined
43.0.7

· Relative density  Not determined.
· Vapour density  Not determined.
· Evaporation rate  Not determined.
· Solubility in / Miscibility with  
  · Water:  Partly soluble
· 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:  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
· 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:

<table>
<thead>
<tr>
<th>Compound</th>
<th>Oral LD50</th>
<th>Oral LC50/4h</th>
<th>Inhalative LC50/4h</th>
</tr>
</thead>
<tbody>
<tr>
<td>64-17-5 ethanol</td>
<td>6200 mg/kg (rat)</td>
<td>95.6 mg/l (rat)</td>
<td></td>
</tr>
<tr>
<td>41137-60-4 diurethandimethacrylate</td>
<td>&gt;5000 mg/kg (rat)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>868-77-9 2-hydroxyethyl methacrylate</td>
<td>5564 mg/kg (rat)</td>
<td>&gt;3000 mg/kg (can)</td>
<td></td>
</tr>
<tr>
<td>Poly(methacrylic-oligo-acrylic acid)</td>
<td>&gt;5000 mg/kg (rat)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>70293-55-9 4-methacryloyethyltrimellitic acid anhydride</td>
<td>&gt; 2000 mg/kg (mouse)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>72869-86-4 diurethandimethacrylate</td>
<td>&gt;5000 mg/kg (rat)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Safety data sheet
according to 1907/2006/EC, Article 31
Printing date 03.06.2017 Revised: 03.06.2017
Version number 3

Trade name: Gluma 2Bond

- **Primary irritant effect:**
  - Skin corrosion/irritation
    Causes skin irritation.
  - Serious eye damage/irritation
    Causes serious eye damage.
  - Respiratory or skin sensitisation
    May cause allergy or asthma symptoms or breathing difficulties if inhaled.
    May cause an allergic skin reaction.
  - CMR effects (carcinogenity, 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 respiratory irritation.
  - 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)
    - 72869-86-4 diurethandimethacrylate
      LC50/96h 10.1 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: Avoid transfer into the environment.

- **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

(Contd. on page 8)
### SECTION 14: Transport information

<table>
<thead>
<tr>
<th>14.1 UN-Number</th>
<th>ADR, IMDG, IATA</th>
<th>1170</th>
</tr>
</thead>
<tbody>
<tr>
<td>14.2 UN proper shipping name</td>
<td>ADR</td>
<td>1170 ETHANOL (ETHYL ALCOHOL) mixture</td>
</tr>
<tr>
<td></td>
<td>IMDG</td>
<td>ETHANOL (ETHYL ALCOHOL), mixture</td>
</tr>
<tr>
<td></td>
<td>IATA</td>
<td>ETHANOL, mixture</td>
</tr>
<tr>
<td>14.3 Transport hazard class(es)</td>
<td>ADR</td>
<td>Class 3 (F1) Flammable liquids.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Label 3</td>
</tr>
<tr>
<td></td>
<td>IMDG, IATA</td>
<td>Class 3 Flammable liquids.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Label 3</td>
</tr>
<tr>
<td>14.4 Packing group</td>
<td>ADR, IMDG, IATA</td>
<td>III</td>
</tr>
<tr>
<td>14.5 Environmental hazards:</td>
<td>Marine pollutant:</td>
<td>No</td>
</tr>
<tr>
<td>14.6 Special precautions for user</td>
<td>Kemler Number:</td>
<td>Warning: Flammable liquids. 30</td>
</tr>
<tr>
<td></td>
<td>EMS Number:</td>
<td>F-E,S-D</td>
</tr>
<tr>
<td>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</td>
<td>Not applicable.</td>
<td></td>
</tr>
<tr>
<td>Transport/Additional information:</td>
<td>ADR</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Limited quantities (LQ)</td>
<td>LQ7</td>
</tr>
<tr>
<td></td>
<td>Transport category</td>
<td>3</td>
</tr>
</tbody>
</table>
Trade name: Gluma 2Bond

**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.
  - H301 Toxic if swallowed.
  - H314 Causes severe skin burns and eye damage.
  - H315 Causes skin irritation.
  - H317 May cause an allergic skin reaction.
  - H319 Causes serious eye irritation.
  - H331 Toxic if inhaled.
  - H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
  - H400 Very toxic to aquatic life.
  - H412 Harmful to aquatic life with long lasting effects.

- **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
  - Flam. Liq. 3: Flammable liquids – Category 3
  - Acute Tox. 3: Acute toxicity – Category 3
  - Skin Corr. 1B: Skin corrosion/irritation – Category 1B
  - Skin Irrit. 2: Skin corrosion/irritation – Category 2

(Contd. on page 10)
<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye Dam. 1</td>
<td>Serious eye damage/eye irritation – Category 1</td>
</tr>
<tr>
<td>Eye Irrit. 2</td>
<td>Serious eye damage/eye irritation – Category 2</td>
</tr>
<tr>
<td>Resp. Sens. 1</td>
<td>Respiratory sensitisation – Category 1</td>
</tr>
<tr>
<td>Skin Sens. 1</td>
<td>Skin sensitisation – Category 1</td>
</tr>
<tr>
<td>STOT SE 3</td>
<td>Specific target organ toxicity (single exposure) – Category 3</td>
</tr>
<tr>
<td>Aquatic Acute 1</td>
<td>Hazardous to the aquatic environment - acute aquatic hazard – Category 1</td>
</tr>
<tr>
<td>Aquatic Chronic 3</td>
<td>Hazardous to the aquatic environment - long-term aquatic hazard – Category 3</td>
</tr>
</tbody>
</table>

*Data compared to the previous version altered.*