



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

Printing date 10.02.2018

Version number 4

Revision: 10.02.2018

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

· **1.1 Product identifier**

· **Trade name: Signum zirconia bond II**

· **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** Zirconia-Resin Bonding System

· **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](mailto: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.

Skin Sens. 1            H317 May cause an allergic skin reaction.

STOT SE 3            H335 May cause respiratory irritation.

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:**

methyl methacrylate

diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

· **Hazard statements**

H225 Highly flammable liquid and vapour.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H335 May cause respiratory irritation.

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.

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/shower.

P312                    Call a POISON CENTER/doctor if you feel unwell.

P403+P235            Store in a well-ventilated place. Keep cool.

· **2.3 Other hazards -**

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- **Results of PBT and vPvB assessment**
  - **PBT:** Not applicable.
  - **vPvB:** Not applicable.

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**SECTION 3: Composition/information on ingredients**

- **3.2 Chemical characterisation: Mixtures**
  - **Description:** Product based on methacrylates

· **Dangerous components:**

CAS: 80-62-6 EINECS: 201-297-1 Reg.nr.: 01-2119452498-28-0000	methyl methacrylate Flam. Liq. 2, H225; Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	50-75%
CAS: 75980-60-8 EINECS: 278-355-8 Reg.nr.: 01-2119972295-29	diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide Repr. 2, H361f; Aquatic Chronic 2, H411; Skin Sens. 1B, H317	0-5%

- **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; 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.
  - **After swallowing**  
Rinse out mouth and then drink plenty of water.  
In case of persistent symptoms consult doctor.  
Product based on methacrylates
- **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, sand, extinguishing powder. Do not use water.
  - **For safety reasons unsuitable extinguishing agents**  
Water.  
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.

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- **6.3 Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).
- **6.4 Reference to other sections**  
No dangerous materials are released.  
See Section 8 for information on personal protection equipment.
- 

### 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:**  
Store cool (not above 25 °C).  
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

- **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:**

**80-62-6 methyl methacrylate**

OEL ( )	Short-term value: 100 ppm Long-term value: 50 ppm
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- **DNELs**

**80-62-6 methyl methacrylate**

Dermal	worker industr., l.te., syst.	74.3 mg/Kg/d (human)
Inhalative	worker industr., l.te., syst.	210 mg/m <sup>3</sup> (human)

- **PNECs**

**80-62-6 methyl methacrylate**

freshwater	0.94 mg/l (aqua)
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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**

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 necessary with efficient local exhaust. If exposition to vapours is possible, use breathing protective mask (filter A).

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· **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.

Solvent resistant gloves

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:** not absolutely necessary

· **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:** Colourless

· **Smell:** Ester-like

· **Odour threshold:** Not determined.

· **pH-value:** Not determined.

· **Change in condition**

· **Melting point/freezing point:** Not determined

· **Initial boiling point and boiling range:** 100 °C

· **Flash point:** 10 °C

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

· **Ignition temperature:** 430.0 °C

· **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:** 2.1 Vol %

· **Upper:** 12.5 Vol %

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· <b>Steam pressure at 20 °C:</b>	47 hPa
· <b>Density at 20 °C</b>	1.000 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with</b>	
· <b>Water:</b>	Not miscible or difficult to mix
· <b>Partition coefficient: n-octanol/water:</b>	Not determined.
· <b>Viscosity:</b>	
· <b>dynamic:</b>	Not determined.
· <b>kinematic:</b>	Not determined.
· <b>Solvent content:</b>	
· <b>Solids content:</b>	8.0 %
· <b>9.2 Other information</b>	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:**  
If stored longer than recommended and/or above recommended temperature, product may polymerize generating heat.

**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:**

<b>80-62-6 methyl methacrylate</b>		
Oral	LD50	>5000 mg/kg (rat)
Dermal	LD50	>5000 mg/kg (rab)
Inhalative	LC50/4 h	29.8 mg/l (rat)
<b>41137-60-4 diurethandimethacrylate</b>		
Oral	LD50	>5000 mg/kg (rat)
<b>75980-60-8 diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide</b>		
Oral	LD50	> 5000 mg/kg (rat)

- **Primary irritant effect:**
  - **Skin corrosion/irritation**  
Causes skin irritation.
  - **Serious eye damage/irritation**  
Based on available data, the classification criteria are not met.

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- **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 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:**

**75980-60-8 diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide**

EC50/48h 10 100 mg/l (algae)

10 - 100 mg/l (daphnia)

- **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.  
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**

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

· **European waste catalogue**

18 01 06 chemicals consisting of or containing dangerous substances

· **Uncleaned packagings:**

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

**SECTION 14: Transport information**

· **14.1 UN-Number**

· **ADR, IMDG, IATA**

1247

· **14.2 UN proper shipping name**

· **ADR**

1247 METHYL METHACRYLATE MONOMER,  
STABILIZED, solution

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· <b>IMDG, IATA</b>	METHYL METHACRYLATE MONOMER, STABILIZED, solution
· <b>14.3 Transport hazard class(es)</b>	
· <b>ADR</b>	
	
· <b>Class</b>	3 (F1) Flammable liquids.
· <b>Label</b>	3
· <b>IMDG, IATA</b>	
	
· <b>Class</b>	3 Flammable liquids.
· <b>Label</b>	3
· <b>14.4 Packing group</b>	
· <b>ADR, IMDG, IATA</b>	II
· <b>14.5 Environmental hazards:</b>	
· <b>Marine pollutant:</b>	No
· <b>14.6 Special precautions for user</b>	Warning: Flammable liquids.
· <b>Kemler Number:</b>	339
· <b>EMS Number:</b>	F-E,S-D
· <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b>	Not applicable.
· <b>Transport/Additional information:</b>	-
· <b>UN "Model Regulation":</b>	UN1247, METHYL METHACRYLATE MONOMER, STABILIZED, solution, 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
    - **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.

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- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H335 May cause respiratory irritation.
- H361f Suspected of damaging fertility.
- H411 Toxic 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
- Skin Irrit. 2: Skin corrosion/irritation – Category 2
- Skin Sens. 1: Skin sensitisation – Category 1
- Skin Sens. 1B: Skin sensitisation – Category 1B
- Repr. 2: Reproductive toxicity – Category 2
- 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.**

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