



**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 ceramic 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** Auxiliary for manufacture of dental prothesis

· **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**

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.

· **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**



GHS07

· **Signal word** Warning

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

propylidynetrimethanol, ethoxylated, esters with acrylic acid
diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

· **Hazard statements**

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

· **Precautionary statements**

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P321 Specific treatment (see on this label).

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P337+P313 If eye irritation persists: Get medical advice/attention.

· **2.3 Other hazards -**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.



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

Printing date 10.02.2018

Version number 4

Revision: 10.02.2018

Trade name: Signum ceramic bond II

(Contd. of page 1)

SECTION 3: Composition/information on ingredients

· **3.2 Chemical characterisation: Mixtures**

· **Description:** Product based on methacrylates

· **Dangerous components:**

CAS: 28961-43-5	propylidynetrimehanol, ethoxylated, esters with acrylic acid Eye Irrit. 2, H319; Skin Sens. 1, H317	10-25%
CAS: 2082-81-7 EINECS: 218-218-1 Reg.nr.: 02-2119849716-25	tetramethylene dimethacrylate Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	10-25%
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 rinse with water.

· **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.

In case of persistent symptoms consult doctor.

Seek immediate medical advice.

· **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.

Use fire fighting measures that suit the environment.

· **5.2 Special hazards arising from the substance or mixture**

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** Not required.

· **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).

· **6.4 Reference to other sections**

No dangerous materials are released.

See Section 8 for information on personal protection equipment.

(Contd. on page 3)



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

Printing date 10.02.2018

Version number 4

Revision: 10.02.2018

Trade name: Signum ceramic bond II

(Contd. of page 2)

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** *Keep containers tightly sealed.*
 - **Information about protection against explosions and fires:** *No special measures required.*
- **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).*
- **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:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
 - **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:**
Not necessary with efficient local exhaust. If exposition to vapours is possible, use breathing protective mask (filter A).
 - **Protection of hands:**
*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:** *Protective goggles are recommended.*
 - **Body protection:** *Light weight protective clothing*

GB

(Contd. on page 4)



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

Printing date 10.02.2018

Version number 4

Revision: 10.02.2018

Trade name: Signum ceramic bond II

(Contd. of page 3)

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:	136 °C
· Inflammability (solid, gaseous)	Not applicable.
· Ignition temperature:	265.0 °C
· Decomposition temperature:	Not determined.
· Self-inflammability:	Product is not selfigniting.
· Explosive properties:	Product is not explosive.
· Critical values for explosion:	
· Lower:	Not determined.
· Upper:	Not determined.
· Steam pressure at 20 °C:	40 hPa
· Density at 20 °C	
· Relative density	0.850 g/cm ³
· Vapour density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with	
· Water:	Not miscible or difficult to mix
· Partition coefficient: n-octanol/water: Not determined.	
· Viscosity:	
· dynamic:	Not determined.
· kinematic:	Not determined.
· Solvent content:	
· VOC EU	g/l
· Solids content:	10.8 %
· 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.

(Contd. on page 5)



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

Printing date 10.02.2018

Version number 4

Revision: 10.02.2018

Trade name: Signum ceramic bond II

· **10.6 Hazardous decomposition products:** None

(Contd. of page 4)

· **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:**

2530-85-0 3-trimethoxysilylpropyl methacrylate

Oral LD50 >2000 mg/kg (rat)

Dermal LD50 >2000 mg/kg (can)

2082-81-7 tetramethylene dimethacrylate

Oral LD50 10120 mg/kg (rat)

53879-55-3 penta erythritol, propoxylated, tetraacrylate

Oral LD50 >2000 mg/kg (rat)

41137-60-4 diurethandimethacrylate

Oral LD50 >5000 mg/kg (rat)

amorphe Kieselsäure

Oral LD50 >5000 mg/kg (rat)

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

Oral LD50 > 5000 mg/kg (rat)

· **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.

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

· **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.

(Contd. on page 6)



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

Printing date 10.02.2018

Version number 4

Revision: 10.02.2018

Trade name: Signum ceramic bond II

(Contd. of page 5)

- **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, ADN, IMDG, IATA | Void |
| · 14.2 UN proper shipping name
· ADR, ADN, IMDG, IATA | Void |
| · 14.3 Transport hazard class(es)
· ADR, ADN, IMDG, IATA
· Class | Void |
| · 14.4 Packing group
· ADR, IMDG, IATA | Void |
| · 14.5 Environmental hazards:
· Marine pollutant: | No |
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · Transport/Additional information: | - |
| · UN "Model Regulation": | Void |

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
 - **REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3**

(Contd. on page 7)



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

Printing date 10.02.2018

Version number 4

Revision: 10.02.2018

Trade name: Signum ceramic bond II

(Contd. of page 6)

· **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**

- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.
- 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)
- VOCV: Lenkungsabgabe auf flüchtigen organischen Verbindungen, Schweiz (Swiss Ordinance on volatile organic compounds)
- LC50: Lethal concentration, 50 percent
- LD50: Lethal dose, 50 percent
- PBT: Persistent, Bioaccumulative and Toxic
- vPvB: very Persistent and very Bioaccumulative
- 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
- 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

· * **Data compared to the previous version altered.**