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

Printing date 28.01.2018 Version number 4 Revision: 28.01.2018

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

- · 1.1 Product identifier
 - · Trade name: Signum metal 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 Metal-Resin Bonding System
- · 1.3 Details of the supplier of the safety data sheet
 - · Manufacturer/Supplier:

Kulzer GmbH

Leipziger Straße 2, 63450 Hanau (Germany)

· 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. 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.

· 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.

· Precautionary statements

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition

sources. No smoking.

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.

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 -

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

· 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.

If skin irritation continues, consult a doctor.

· 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.

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.

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: Wear self-contained 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 drainage system, surface or ground water.

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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.

Ensure good interior ventilation, especially at floor level. (Fumes are heavier than air).

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 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 (50-75%)

WEL Short-term value: 416 mg/m³, 100 ppm Long-term value: 208 mg/m³, 50 ppm

· DNELs

80-62-6 methyl methacrylate

worker industr., l.te., syst. 74.3 mg/Kg/d (human) Inhalative worker industr., I.te., syst. 210 mg/m3 (human)

· PNECs

80-62-6 methyl methacrylate

freshwater 0.94 mg/l (aqua)

- · 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.

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· Breathing equipment:

Not neccessary with efficient local exhaust. If exposition to vapours is possible, use breathing protective mask (filter A).

· 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 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: Safety glasses
- · Body protection: Protective work clothing.

SECTION 9: Physical and chemical properties

| 9.1 Information on basic physical and chemical properties · General Information | | | |
|---|--|--|--|
| · Appearance: | | | |
| Form: | Fluid | | |
| · Colour: | White | | |
| · Smell: | Characteristic | | |
| · Odour threshold: | Not determined. | | |
| · pH-value: | Not determined. | | |
| Change in condition Melting point/freezing point: Initial boiling point and boiling range: 100 °C | | | |
| · Flash point: | 10 ℃ | | |
| · Inflammability (solid, gaseous) | Not applicable. | | |
| · Ignition temperature: | 430 °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. | | |
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|---|--|--------------------|
| Critical values for explosion:Lower:Upper: | 2,1 Vol % 12,5 Vol % | |
| · Steam pressure at 20 °C: | 47 hPa | |
| Density Relative density Vapour density Evaporation rate | Not determined Not determined. Not determined. Not determined. | |
| · Solubility in / Miscibility with · Water: | Not miscible or difficult to mix | |
| · Partition coefficient: n-octanol/water: Not determined. | | |
| · Viscosity: · dynamic: · kinematic: · 9.2 Other information | Not determined. Not determined. 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: | | | | |
|---|---|----------|--------------------|--|--|
| | 80-62-6 methyl methacrylate | | | | |
| Γ | Oral | LD50 | >5000 mg/kg (rat) | | |
| | Dermal | LD50 | >5000 mg/kg (rab) | | |
| | Inhalative | LC50/4 h | 29.8 mg/l (rat) | | |
| | 41137-60-4 diurethandimethacrylate | | | | |
| Γ | Oral | LD50 | >5000 mg/kg (rat) | | |
| ľ | 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
 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 (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:

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.
- · 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

16 05 06 laboratory chemicals, consisting of or containing dangerous substances, including mixtures of laboratory chemicals

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

| SECTION 14: Transport information | N 14: Transport information | |
|---|---|--|
| · 14.1 UN-Number · ADR, IMDG, IATA | 1247 | |
| · 14.2 UN proper shipping name · ADR · IMDG. IATA | 1247 METHYL METHACRYLATE MONOMER, STABILIZED, solution METHYL METHACRYLATE MONOMER, | |
| iiiioo, ia ia | STABILIZED, solution (Contd. on page 7) | |

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· 14.3 Transport hazard class(es)

· ADR



· Class 3 (F1) Flammable liquids.

· Label

· IMDG, IATA



· Class 3 Flammable liquids.

· Label

· 14.4 Packing group · ADR, IMĎĞ, IATA II

· 14.5 Environmental hazards:

Marine pollutant: No

· 14.6 Special precautions for user Warning: Flammable liquids.

· Kemler Number: 339 · EMS Number: F-E,S-E

· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code Not applicable.

· Transport/Additional information:

METHYL METHACRYLATE · UN "Model Regulation":

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.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

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H335 May cause respiratory irritation. H361f Suspected of damaging fertility. H411 Toxic to aquatic life with long lasting effects.

· Abbreviations and acronyms:

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

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

* Data compared to the previous version altered.