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

Printing date 03.08.2022 Version number 5 (replaces version 4) Revision: 03.08.2022

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)

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

H225 Highly flammable liquid and vapour. Flam. Lig. 2

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 2 H411 Toxic 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 GB CLP regulation.

· Hazard pictograms







GHS02 GHS07 GHS09

- · Signal word Danger
- Hazard-determining components of labelling:

methyl methacrylate

7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate

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

tert-butyl perbenzoate

Hazard statements

H225 Highly flammable liquid and vapour.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H335 May cause respiratory irritation.

H411 Toxic 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.

P260 Do not breathe mist/vapours/spray. P273 Avoid release to the environment. P280

P280 Wear protective gloves / eye protection. P302+P352 IF ON SKIN: Wash with plenty of soap and water.

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- · 2.3 Other hazards -
 - · Results of PBT and vPvB assessment
 - · PBT: Not applicable.
 - · vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

· 3.2 Mixtures

Description: -

· Dangerous components:	Dangerous components:		
EINECS: 201-297-1	methyl methacrylate Flam. Liq. 2, H225 Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	≥50-≤75%	
EINECS: 276-957-5 Reg.nr.: 01-2120751202-68-xxxx	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate Aquatic Chronic 2, H411 Skin Sens. 1B, H317 EUH204	≥10-<25%	
EINECS: 278-355-8 Reg.nr.: 01-2119972295-29-xxxx	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide Repr. 2, H361f Aquatic Chronic 2, H411 Skin Sens. 1B, H317	≥1-<2.5%	
EINECS: 210-382-2	tert-butyl perbenzoate Org. Perox. C, H242 Aquatic Acute 1, H400 Acute Tox. 4, H332; Skin Irrit. 2, H315; Skin Sens. 1, H317 Aquatic Chronic 3, H412	≥0.1-<0.25%	

[·] 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.

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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.

Avoid contact with eyes and skin.

6.2 Environmental precautions:

Do not allow to enter drainage system, surface or ground water.

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.

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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.

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8.1 Contr	ol parameters			
		alues that require	e monitoring at the workplace:	
•	ethyl methacrylate		,	
WEL (Gre	at Britain) Short-	term value: 416 m	ng/m³, 100 ppm	
IOELV (E	uropean Union) Short-			
· DN		om value. ee ppi	··	
	nethyl methacrylate			
00-02-0 111 Oral		na term systemic	8.2 mg/Kg (not defined)	
Dermal	worker industrial, long	-	13.67 mg/Kg/d (not defined)	
Donnar	general population, lo	•	,	
Inhalative		-	416 mg/m3 (not defined)	
mmarativo	worker industrial, long		348.4 mg/m3 (not defined)	
	worker industrial, long		208 mg/m3 (not defined)	
	general population, a		208 mg/m3 (not defined)	
			74.3 mg/m3 (not defined)	
72869-86-			o-3,14-dioxa-5,12-diazahexadecane-1,16-	
	bismethacrylate		,,,	
Oral	general population, lo	ng term, systemic	0.3 mg/Kg (not defined)	
Dermal	worker industrial, long	term, systemic	1.3 mg/Kg/d (not defined)	
	general population, lo	ng term, systemic		
Inhalative	worker industrial, long	term, systemic	3.3 mg/m3 (not defined)	
	general population, lo	ng term, systemic	0.6 mg/m3 (not defined)	
	·8 diphenyl(2,4,6-trim			
Oral	1	-	0.0833 mg/Kg (not defined)	
Dermal	worker industrial, long		0.233 mg/Kg/d (not defined)	
	general population, lo		,	
Inhalative	worker industrial, long		0.822 mg/m3 (not defined)	
	general population, lo	ng term, systemic	0.145 mg/m3 (not defined)	
·PNI				
	ethyl methacrylate			
freshwate	r	0.94 mg/l (not	defined)	
marine wa		- '	0.094 mg/l (not defined)	
•	eatment plant	- '	10 mg/l (not defined)	
	dry weight, freshwater		10.2 mg/Kg (not defined)	
	dry weight, marine wa	,	0.102 mg/Kg (not defined)	
soil, dry weight			1.48 mg/Kg (not defined)	
72869-86-	4 7,7,9(or 7,9,9)-trin bismethacrylate	ethyl-4,13-diox	o-3,14-dioxa-5,12-diazahexadecane-1,16-d	
freshwater		0.01 mg/l (not	defined)	
marine wa	nter	0.001 mg/l (no	0.001 mg/l (not defined)	
		3.61 mg/l (not	defined)	



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sediment, dry weight, freshwater	4.56 mg/Kg (not defined)
sediment, dry weight, marine water	0.46 mg/Kg (not defined)
soil, dry weight	0.91 mg/Kg (not defined)
75980-60-8 diphenyl(2,4,6-trimeth	ylbenzoyl)phosphine oxide
freshwater	0.0014 mg/l (not defined)
marine water	0.00014 mg/l (not defined)
sediment, dry weight, freshwater	0.115 mg/Kg (not defined)
sediment, dry weight, marine water	0.0115 mg/Kg (not defined)
soil, dry weight	0.0222 mg/Kg (not defined)

[·] Additional information: The lists that were valid during the compilation were used as basis.

· 8.2 Exposure controls

- Appropriate engineering controls No further data; see item 7.
- Individual protection measures, such as 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 neccessary with efficient local exhaust. If exposition to vapours is possible, use breathing protective mask (filter A).

Hand protection

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/face 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**
 - Physical state Fluid

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Odour threshold:

· Melting point/freezing point:

· Colour: · Smell:

boiling range · Flammability

Lower:

Upper:

· Ignition temperature: · Decomposition temperature:

Kinematic viscosity

· Steam pressure at 20 °C:

Relative density

· Vapour density

Self-inflammability:

· Change in condition Evaporation rate

· Explosives

· Aerosols

Flammable gases

Flammable liquids

Flammable solids

· Pyrophoric liquids

Pyrophoric solids

· Oxidising gases · Gases under pressure

· Self-reactive substances and mixtures

classes

· Explosive properties:

· Density and/or relative density

Signum metal bond II > 60 °C

dynamic:

· Flash point:

Viscosity:

Solubility

value)

Water:

· Density

· 9.2 Other information Appearance: Form:

·SADT

(Contd. of page 5) White Characteristic Not determined. Not determined · Boiling point or initial boiling point and 100 °C Not applicable. · Lower and upper explosion limit 2.1 Vol % 12.5 Vol % 10 °C (80-62-6 methyl methacrylate) 430 °C Not determined. Mixture is non-soluble (in water). Not determined. Not determined. Not miscible or difficult to mix · Partition coefficient n-octanol/water (log Not determined. 47 hPa Not determined Not determined. Not determined. No further relevant information available. Fluid · Important information on protection of health and environment, and on safety. Product is not selfigniting. Product is not explosive. However, formation of explosive air/vapour mixtures is possible. Not determined. · Information with regard to physical hazard Void Void Void Void Void

Highly flammable liquid and vapour.

Void

Void

Void

Void

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tances and mixtures Void	
nixtures, which emit	
in contact with water Void	
Void	
Void	
Void	
Is Void	
osives Void	
Void S Void Is Void	

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 hazard classes as defined in Regulation (EC) No 1272/2008 · Acute toxicity Based on available data, the classification criteria are not met.

· LD/I	· LD/LC50 values that are relevant for classification:		
80-62-6 m	80-62-6 methyl methacrylate		
Oral	LD50	~7,900 mg/kg (rat)	
Dermal	LD50	>5,000 mg/kg (guinea pig) (OECD 402)	
Inhalative	LC50/4 h	29.8 mg/l (rat)	
72869-86-	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	>5,000 mg/kg (rat) (OECD 401)	
Dermal	LD50	>2,000 mg/kg (rat) (OECD 402)	
75980-60-	75980-60-8 diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide		
Oral	LD50	>5,000 mg/kg (rat) (OECD 401)	
Dermal	LD50	>2,000 mg/kg (rat) (OECD 402)	
614-45-9 t	614-45-9 tert-butyl perbenzoate		
Oral	LD0	2,000 mg/kg (rat) (OECD 423)	
Dermal	LD0	2,000 mg/kg (rat) (OECD 402)	
Inhalative	LC0/4h	1.01 mg/L (rat) (OECD 439)	
Oliver		4.9 mg/L (rat) (OECD 439)	

- · Skin corrosion/irritation
- Causes skin irritation.
- · Serious eye damage/irritation Based on available data, the classification criteria are not met.
- Respiratory or skin sensitisation May cause an allergic skin reaction.
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.

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- 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.
- · 11.2 Information on other hazards
 - Endocrine disrupting properties

None of the ingredients is listed.

12.1 Toxicity	<i>!</i>
· Aquatic t	oxicity:
80-62-6 metl	hyl methacrylate
EC50/21d	49 mg/L (daphnia) (OECD 211)
EC50/48h	69 mg/l (daphnia) (EPA OTS 797.1300)
NOEC / 21d	37 mg/l (daphnia) (OECD 211)
ErC50 / 72 h	>110 mg/l (algae) (OECD 201)
NOEC / 72h	110 mg/l (algae) (OECD 201)
NOEC / 48h	48 mg/l (daphnia) (EPA OTS 797.1300)
EbC50 / 72h	>110 mg/l (algae) (OECD 201)
NOEC/ 35d	9.4 mg/L (fish) (OECD 210)
LC50/ 35d	33.7 mg/L (fish) (OECD 210)
72869-86-4 7	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-c
	pismethacrylate
EC50/48h	>1.2 mg/l (daphnia) (OECD 202)
	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)
75980-60-8 c	liphenyl(2,4,6-trimethylbenzoyl)phosphine oxide
EC50/48h	10,100 mg/l (algae)
	3.53 mg/l (daphnia) (OECD 202)
LC50/96h	1.4 mg/l (fish) (OECD 203)
ErC50 / 72 h	>2.01 mg/l (algae) (OECD 201)
ErC10/72h	1.56 mg/L (algae) (OECD 201)

80-62-6 methyl methacrylate

Biodegradation 94 % /14d (not defined) (OECD 301C)

72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate

Biodegradation 22 % /28d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)

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

Biodegradation 0-10 % /28d (not defined) (OECD 301F; ISO 9408/ EEC 92/69/V, C.4-D)

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· 12.3 Bioaccumulative potential

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

Bloconcentration factor (BCF) 47-55 (not defined)

- · 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 Endocrine disrupting properties

For information on endocrine disrupting properties see section 11.

- · 12.7 Other adverse effects
 - 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.

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.

- · Uncleaned packagings:
 - · Recommendation:

Disposal must be made according to official regulations.

Non contaminated packagings can be used for recycling.

14.1 UN number or ID number · ADR, IMDG, IATA	UN1993
14.2 UN proper shipping name	
ADR	1993 FLAMMABLE LIQUID, N.O.S., speci provision 640D (METHYL METHACRYLAT MONOMER, STABILIZED)
· IMDG	FLAMMABLE LIQUIÓ, N.O.S. (METH) METHACRYLATE MONOMER, STABILIZED MARINE POLLUTANT
·IATA	FLAMMABLE LIQUID, N.O.S. (METH) METHACRYLATE MONOMER, STABILIZED)



· Class 3 (F1) Flammable liquids.

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Label	3
· IMDG	
3	
· Class	3 Flammable liquids.
· Label	3
· IATA	
Class	3 Flammable liquids.
Label	3
· 14.4 Packing group · ADR, IMDG, IATA	II
14.5 Environmental hazards:	11
· 14.5 Environmental nazaros: · Marine pollutant:	No
•	Symbol (fish and tree)
· Special marking (ADR):	Symbol (fish and tree)
14.6 Special precautions for user Kemler Number:	Warning: Flammable liquids. 33
· EMS Number:	5-5 F-E,S-E
· Stowage Category	В ~
14.7 Maritime transport in bulk according	
IMO instruments	Not applicable.
· Transport/Additional information:	
· ADR	41
· Limited quantities (LQ) · Excepted quantities (EQ)	1L Code: E2
	Maximum net quantity per inner packaging
	30 ml Maximum net quantity per outer packaging
	500 ml
Transport category	2
· Tunnel restriction code	D/E
· IMDG	1L
· Limited quantities (LQ) · Excepted quantities (EQ)	Code: E2
	Maximum net quantity per inner packaging
	30 ml Maximum net quantity per outer packaging
	500 ml



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UN "Model Regulation":

UN 1993 FLAMMABLE LIQUID, N.O.S., SPECIAL PROVISION 640D (METHYL METHACRYLATE MONOMER, STABILIZED), 3.

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 200 t
 - Qualifying quantity (tonnes) for the application of upper-tier requirements 500 t
- 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.

H242 Heating may cause a fire.

H315 Causes skin irritation.

May cause an allergic skin reaction. H317

H332 Harmful if inhaled.

May cause respiratory irritation. H335

H361f Suspected of damaging fertility.

H400 Very toxic to aquatic life.

Toxic to aquatic life with long lasting effects. H411

Harmful to aquatic life with long lasting effects.

EUH204 Contains isocyanates. May produce an allergic reaction.

Abbreviations and acronyms:

SADT: Self Accelerating Decomposition Temperature
SAPT: Self Accelerating Polymerisation Temperature
ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement
Concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods

IMAC: 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 (UK REACH)
PNEC: Predicted No-Effect Concentration (UK 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
Org. Perox. C: Organic peroxides – Type C/D

Acute Tox. 4: Acute toxicity - Category 4

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 Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1 Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2

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Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3 · * Data compared to the previous version altered.