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Safety Data Sheet according to WHS Regulations

Printing date 17.11.2022 Version number 5 Revision: 17.11.2022

Hazardous according to criteria of Australian Safety and Compensation Council.

1 Identification

- · Product identifier
 - · Trade name: Signum ceramic bond II
 - · 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
- · Details of the supplier of the safety data sheet
 - Manufacturer/Supplier: Kulzer Australia Pty Ltd Unit 20, 53 Lorraine St PEAKHURST NSW 2210

Australia Tel: +61 (02) 9153 0311

- Informing department: see above
- Emergency telephone number:

Poison Information Number: Australia 13 11 26 & New Zealand 0800 764 766

2 Hazard(s) Identification

· Classification of the substance or mixture

Eye Irritation 2A H319 Causes serious eye irritation.

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

- · Label elements
 - GHS label elements

The product is classified and labelled according to the Globally Harmonised System (GHS).

· Hazard pictograms



GHS07

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

propylidynetrimethanol, ethoxylated, esters with acrylic acid

1,4-butandioldimethacrylate

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

2-propenoic acid, 1,1'-[(1-methyl-1,2-ethanediyl)bis[oxy(methyl-2,1-ethanediyl)]]ester, reaction products with diethylamine

· Hazard statements

Causes serious eye irritation.

May cause an allergic skin reaction.

Precautionary statements

Avoid release to the environment.

Wear protective gloves / eye protection.

If eye irritation persists: Get medical advice/attention.

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

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· vPvB: Not applicable.

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3 Composition and Information on Ingredients

- · Chemical characterisation: Mixtures
 - · Description: Product based on methacrylates

· Dangerou	is components:	
28961-43-5	propylidynetrimethanol, ethoxylated, esters with acrylic acid	<i>≥</i> 10- <i>≤</i> 50%
	Eye Irritation 2A, H319; Skin Sens. 1, H317	
2082-81-7	1,4-butandioldimethacrylate	≥10- <i>≤</i> 25%
	Skin Sens. 1B, H317	
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-	≥10-<25%
	1,16-diyl bismethacrylate	
	Skin Sens. 1B, H317	
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	≥1-<2.5%
	Repr. 2, H361	
	Skin Séns. 1B, H317	
111497-86-0	2-propenoic acid, 1,1'-[(1-methyl-1,2-ethanediyl)bis[oxy(methyl-2,1-	<i>≥1-≤</i> 5%
	ethanediyl)]]ester, reaction products with diethylamine	
	Skin Irrit. 2, H315; Skin Sens. 1B, H317	

[·] Additional information For the wording of the listed hazard phrases refer to section 16.

4 First Aid Measures

- · 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. 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.

- · Information for doctor
 - Most important symptoms and effects, both acute and delayed No further relevant information available.
 - Indication of any immediate medical attention and special treatment needed No further relevant information available.

5 Fire Fighting Measures

- · 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.

· Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

· Advice for firefighters

· Protective equipment: No special measures required.

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· Additional information -

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6 Accidental Release Measures

- Personal precautions, protective equipment and emergency procedures Avoid contact with eyes and skin.
- · Environmental precautions: Prevent material from reaching sewage system, holes and cellars.
- Methods and material for containment and cleaning up:
- Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).
- Reference to other sections

No dangerous materials are released.

See Section 8 for information on personal protection equipment.

7 Handling and Storage

- · Handling
 - **Precautions for safe handling** Keep containers tightly sealed.
 - · Information about protection against explosions and fires: No special measures required.
- 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).
- · Specific end use(s) No further relevant information available.

8 Exposure controls and personal protection

- · Additional information about design of technical systems: No further data; see item 7.
- · 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.

Not required.

· DNELs

2082-81-7	1,4-butandioldimethacrylate	
Oral	general population, long term, systemic	2.5 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	4.2 mg/Kg/d (not defined)
	general population, long term, systemic	2.5 mg/Kg/d (not defined)
Inhalative	worker professional, long term, systemic	14.5 mg/m3 (not defined)
	general population, long term, systemic	4.3 mg/m3 (not defined)
72869-86-	4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo- bismethacrylate	-3,14-dioxa-5,12-diazahexadecane-1,16-diyl
Oral	general population, long term, systemic	0.3 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	1.3 mg/Kg/d (not defined)
	general population, long term, systemic	0.7 mg/Kg/d (not defined)
Inhalative	worker industrial, long term, systemic	3.3 mg/m3 (not defined)
	general population, long term, systemic	0.6 mg/m3 (not defined)
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75000 60	8 diphenyl(2,4,6-trimeth	w/bonzov/)nbor	(Contd. of page
7 3 9 6 0 -	2	• • • • • • • • • • • • • • • • • • • •	0.0833 mg/Kg (not defined)
	general population, long term, systemic worker industrial, long term, systemic		,
Dermal		•	0.233 mg/Kg/d (not defined)
	general population, long	•	0.0833 mg/Kg/d (not defined)
innaiative	worker industrial, long te		0.822 mg/m3 (not defined)
	general population, long	term, systemic	0.145 mg/m3 (not defined)
	PNECs		
2082-81-7 1,4-butandioldimethacrylate			
freshwater	•	0.043 mg/l (not defined)	
marine wa	ter	0.004 mg/l (not defined)	
sewage tre	eatment plant	2 mg/l (not defined)	
sediment, dry weight, freshwater		3.12 mg/Kg (not defined)	
sediment, dry weight, marine water		0.312 mg/Kg (not defined)	
soil, dry weight		0.573 mg/Kg (not defined)	
72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-di bismethacrylate			
freshwater	•	0.01 mg/l (not d	lefined)
marine water		0.001 mg/l (not defined)	
sewage tre	eatment plant	3.61 mg/l (not defined)	
sediment,	dry weight, freshwater	4.56 mg/Kg (not defined)	
sediment, dry weight, marine water		0.46 mg/Kg (not defined)	
		0.91 mg/Kg (no	t defined)
75980-60-8 diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide			
freshwater		0.0014 mg/l (no	ot defined)
marine water		0.00014 mg/l (r	not defined)
sediment, dry weight, freshwater		0.115 mg/Kg (n	ot defined)
		• • •	•
soil, dry weight		0.0222 mg/Kg (•

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

· 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 neccessary 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.

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· 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: Tightly sealed safety glasses.

· Body protection: Light weight protective clothing

9 Physical and Chemical Properties · Information on basic physical and chemical properties General Information Appearance: Form: Fluid Colourless Colour: Smell: Ester-like · Odour threshold: Not determined. Not determined. · pH-value: · Change in condition Melting point/freezing point: Not determined Initial boiling point and boiling range: 100 °C >100 °C · Flash point: · Inflammability (solid, gaseous) Not applicable. 265.0 °C · Ignition temperature: · Decomposition temperature: Not determined. · Self-inflammability: Product is not selfigniting. Product is not explosive. · Explosive properties: · Critical values for explosion: · Lower: Not determined. · Upper: Not determined. · Steam pressure at 20 °C: 40 hPa · Density at 20 °C 0.850 g/cm3 · Relative density Not determined. Not determined. · Vapour density · 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.

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· Other information

No further relevant information available.

10 Stability and Reactivity

- Reactivity No further relevant information available.
- Chemical stability
 - **Conditions to be avoided:** No decomposition if used and stored according to specifications.
- · Possibility of hazardous reactions No dangerous reactions known
- · Conditions to avoid No further relevant information available.
- · Incompatible materials: No further relevant information available. · Hazardous decomposition products: None
- · Additional information:

If stored longer than recommended and/or above recommended temperature, product may polymerize generating heat.

11 Toxicological Information

· Information on toxicological effects

· Acute toxicity

Acute toxicity	
· LD/LC50 values that are relevant f	or classification:
28961-43-5 propylidynetrimethanol, etho	oxylated, esters with acrylic acid
Oral LD50 >2,000 mg/kg (rat) (OECD 4	401)
Dermal LD50 >13,200 mg/kg (rabbit)	
2530-85-0 3-trimethoxysilylpropyl metha	crylate
Oral LD50 >2,000 mg/kg (rat)	
Dermal LD50 >2,000 mg/kg (rabbit)	
2082-81-7 1,4-butandioldimethacrylate	
Oral LD50 10,066 mg/kg (rat) (OECD 4	401)
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 4	401)
Dermal LD50 >2,000 mg/kg (rat) (OECD 4	402)
68611-44-9 Silane, dichlorodimethyl-, re	action products with silica
Oral LD50 >5,000 mg/kg (rat)	
75980-60-8 diphenyl(2,4,6-trimethylbenz	oyl)phosphine oxide
Oral LD50 >5,000 mg/kg (rat) (OECD 4	401)
Dermal LD50 >2,000 mg/kg (rat) (OECD 4	402)
111497-86-0 2-propenoic acid, 1,1'-[(1-m ester, reaction products wit	nethyl-1,2-ethanediyl)bis[oxy(methyl-2,1-ethanediyl)]] th diethylamine
Oral LD50 >5,000 mg/kg (rat) (OECD 4	401)
Dermal LD50 >2,000 mg/kg (rat) (OECD 4	402)
Drive on a junito at offe et.	

- · Primary irritant effect:
 - Skin corrosion/irritation No irritant effect.
 - Serious eye damage/irritation Irritant effect.
- · Respiratory or skin sensitisation No sensitizing effect known.

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Additional toxicological information:

The product shows the following dangers according to the calculation method of the General EC Classification Guidelines for Preparations as issued in the latest version:

- CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
 Reproductive toxicity Based on available data, the classification criteria are not met.

· Toxicity	
· Aquatic to	oxicity:
2530-85-0 3-1	rimethoxysilylpropyl methacrylate
EC50/48h	>100 mg/l (daphnia) (EU C2.)
LC50/96h	>100 mg/l (fish) (EU C.1)
2082-81-7 1,4	1-butandioldimethacrylate
EC50/21d	14.1 mg/L (daphnia) (OECD 211)
EC50/48h	32.5 mg/l (fish)
NOEC / 21d	5.09 mg/l (daphnia) (OECD 211)
ErC50 / 72 h	9.79 mg/l (algae) (OECD 201)
NOEC / 72h	2.11 mg/l (algae) (OECD 201)
NOEC / 48h	25 mg/l (fish)
ErC10/72h	4.35 mg/L (algae) (OECD 201)
72869-86-4 7 b	,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diy ismethacrylate
EC50/48h	>1.2 mg/l (daphnia) (OECD 202)
LC50/96h	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)
	ilane, dichlorodimethyl-, reaction products with silica
LC50/96h	>10,000 mg/l (fish) (OECD 203)
ErC50 / 72 h	>10,000 mg/l (algae) (OECD 201)
EC50 / 24h	>10,000 mg/l (daphnia) (OECD 202)
	iphenyl(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)
	>2.01 mg/l (algae) (OECD 201)
ErC10/72h	1.56 mg/L (algae) (OECD 201)
Persistence	and degradability
2530-85-0 3-	rimethoxysilylpropyl methacrylate
Biodegradation	on 69 % /28d (not defined) (OECD 301F; ISO 9408/ EEC 92/69/V, C.4-D)
2082-81-7 1,4	1-butandioldimethacrylate
	on 84 % /28d (not defined) (OECD 310)
	,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diy ismethacrylate
	on 22 % /28d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)
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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)

Behaviour in environmental systems:

· Bioaccumulative potential

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

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

- · 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, even in small quantities.

Danger to drinking water if even extremely small quantities leak into soil.

- Results of PBT and vPvB assessment
 - · PBT: Not applicable.
 - · vPvB: Not applicable.
- Other adverse effects No further relevant information available.

13 Disposal considerations

- · 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.

UN-Number · ADG, ADN, IMDG, IATA	Void	
UN proper shipping name · ADG, ADN, IMDG, IATA	Void	
Transport hazard class(es)		
· ADG, ADN, IMDG, IATA · Class	Void	
Packing group · ADG, IMDG, IATA	Void	
Environmental hazards: • Marine pollutant:	No	
Special precautions for user	Not applicable.	
Transport in bulk according to Annex Marpol and the IBC Code	II of Not applicable.	
Transport/Additional information:	-	

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UN "Model Regulation":

Void

15 Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture No further relevant information available.

· Au	· Australian Inventory of Industrial Chemicals	
	propylidynetrimethanol, ethoxylated, esters with acrylic acid	
2530-85-0	3-trimethoxysilylpropyl methacrylate	
2082-81-7	1,4-butandioldimethacrylate	
41137-60-4	diurethandimethacrylate	
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	
128-37-0	2,6-di-tert-butyl-p-cresol	

[·] Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

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.

H361 Suspected of damaging fertility or the unborn child.

Abbreviations and acronyms:

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

IATA: International Air Transport Association

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
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irritation 2A: Serious eye damage/eye irritation – Category 2A

Skin Sens. 1: Skin sensitisation – Category 1 Skin Sens. 1B: Skin sensitisation – Category 1B

Repr. 2: Reproductive toxicity - Category 2

* Data compared to the previous version altered.