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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**

Eye Irrit. 2	H319 Causes serious eye irritation.
Skin Sens. 1	H317 May cause an allergic skin reaction.
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 GB CLP regulation.

· **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**
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.
H412 Harmful to aquatic life with long lasting effects.

· **Precautionary statements**
P273 Avoid release to the environment.
P280 Wear protective gloves / eye protection.
P337+P313 If eye irritation persists: Get medical advice/attention.

· **Additional information:**
15 % of the mixture consists of component(s) of unknown toxicity.
Contains 15 % of components with unknown hazards to the aquatic environment.

· **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 Mixtures***
· ***Description:*** *Product based on methacrylates*

· ***Dangerous components:***		
CAS: 28961-43-5	*propylidynetrimethanol, ethoxylated, esters with acrylic acid* *Eye Irrit. 2, H319; Skin Sens. 1, H317* *Aquatic Chronic 3, H412*	*≥10-≤50%*
CAS: 2082-81-7 *EINECS: 218-218-1*	*1,4-butandioldimethacrylate* *Skin Sens. 1B, H317*	*≥10-≤25%*
CAS: 72869-86-4 *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%*
CAS: 75980-60-8 *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%*
CAS: 111497-86-0 *EC number: 601-101-8* *Reg.nr.: 01-2119961351-42-XXXX*	*2-propenoic acid, 1,1'-[(1-methyl-1,2-ethanediyl) bis[oxy(methyl-2,1-ethanediyl)]]ester, reaction products with diethylamine* *Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1B, H317* *EUH208*	*≥1-≤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.
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.
· ***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.
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**
Avoid contact with eyes and skin.
· **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.
-

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

· **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.
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)

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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	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)
75980-60-8 diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide		
Oral	general population, long term, systemic	0.0833 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	0.233 mg/Kg/d (not defined)
	general population, long term, systemic	0.0833 mg/Kg/d (not defined)
Inhalative	worker industrial, long term, systemic	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 water	0.004 mg/l (not defined)
sewage treatment 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-diyl bismethacrylate	
freshwater	0.01 mg/l (not defined)
marine water	0.001 mg/l (not defined)
sewage treatment 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)
soil, dry weight	0.91 mg/Kg (not defined)
75980-60-8 diphenyl(2,4,6-trimethylbenzoyl)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**
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.

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· ***Breathing equipment:***
Not neccessary with efficient local exhaust. If exposition to vapours is possible, use breathing protective mask (filter A).
· ***Hand protection***
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*** *Tightly sealed safety glasses.*
· ***Body protection:*** *Light weight protective clothing*

*

SECTION 9: Physical and chemical properties

· ***9.1 Information on basic physical and chemical properties***	
· ***General Information***	
· ***Physical state***	*Fluid*
· ***Colour:***	*Colourless*
· ***Smell:***	*Ester-like*
· ***Odour threshold:***	*Not determined.*
· ***Melting point/freezing point:***	*Not determined*
· ***Boiling point or initial boiling point and boiling range***	*100 °C*
· ***Flammability***	*Not applicable.*
· ***Lower and upper explosion limit***	
· ***Lower:***	*Not determined.*
· ***Upper:***	*Not determined.*
· ***Flash point:***	*>100 °C (72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate)*
· ***Ignition temperature:***	*265.0 °C*
· ***Decomposition temperature:***	*Not determined.*
· ***SADT***	
· ***pH***	*Not determined.*
· ***Viscosity:***	
· ***Kinematic viscosity***	*Not determined.*
· ***dynamic:***	*Not determined.*
· ***Solubility***	
· ***Water:***	*Not miscible or difficult to mix*
· ***Partition coefficient n-octanol/water (log value)***	*Not determined.*
· ***Steam pressure at 20 °C:***	*40 hPa*
· ***Density and/or relative density***	
· ***Density at 20 °C***	*0.850 g/cm³*

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· **Relative density**	Not determined.
· **Vapour density**	Not determined.
· **9.2 Other information**	No further relevant information available.
· **Appearance:**	
· **Form:**	Fluid
· **Important information on protection of health and environment, and on safety.**	
· **Self-inflammability:**	Product is not selfigniting.
· **Explosive properties:**	Product is not explosive.
· **Solvent content:**	
· **VOC EU**	g/l
· **Change in condition**	
· **Evaporation rate**	Not determined.
· **Information with regard to physical hazard classes**	
· **Explosives**	Void
· **Flammable gases**	Void
· **Aerosols**	Void
· **Oxidising gases**	Void
· **Gases under pressure**	Void
· **Flammable liquids**	Void
· **Flammable solids**	Void
· **Self-reactive substances and mixtures**	Void
· **Pyrophoric liquids**	Void
· **Pyrophoric solids**	Void
· **Self-heating substances and mixtures**	Void
· **Substances and mixtures, which emit flammable gases in contact with water**	Void
· **Oxidising liquids**	Void
· **Oxidising solids**	Void
· **Organic peroxides**	Void
· **Corrosive to metals**	Void
· **Desensitised explosives**	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.

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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.

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· **LD/LC50 values that are relevant for classification:**		
28961-43-5 propylidynetrimethanol, ethoxylated, esters with acrylic acid		
Oral	LD50	>2,000 mg/kg (rat) (OECD 401)
Dermal	LD50	>13,200 mg/kg (rabbit)
2530-85-0 3-trimethoxysilylpropyl methacrylate		
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 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 401)
Dermal	LD50	>2,000 mg/kg (rat) (OECD 402)
68611-44-9 Silane, dichlorodimethyl-, reaction products with silica		
Oral	LD50	>5,000 mg/kg (rat)
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)
111497-86-0 2-propenoic acid, 1,1'-[(1-methyl-1,2-ethanediyl)bis[oxy(methyl-2,1-ethanediyl)]] ester, reaction products with diethylamine		
Oral	LD50	>5,000 mg/kg (rat) (OECD 401)
Dermal	LD50	>2,000 mg/kg (rat) (OECD 402)

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

· **11.2 Information on other hazards**

· **Endocrine disrupting properties**
None of the ingredients is listed.

*

SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**	
2530-85-0 3-trimethoxysilylpropyl methacrylate	
EC50/48h	>100 mg/l (daphnia) (EU C2.)
LC50/96h	>100 mg/l (fish) (EU C.1)
2082-81-7 1,4-butandioldimethacrylate	
EC50/21d	14.1 mg/L (daphnia) (OECD 211)

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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 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate	
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)
68611-44-9 Silane, 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)
75980-60-8 diphenyl(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)

· **12.2 Persistence and degradability**

2530-85-0 3-trimethoxysilylpropyl methacrylate	
Biodegradation	69 % /28d (not defined) (OECD 301F; ISO 9408/ EEC 92/69/V, C.4-D)
2082-81-7 1,4-butandioldimethacrylate	
Biodegradation	84 % /28d (not defined) (OECD 310)
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)

· **12.3 Bioaccumulative potential**

75980-60-8 diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	
Bioconcentration 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, even in small quantities.

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

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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.

*
SECTION 14: Transport information

· **14.1 UN number or ID number**	
· **ADR, ADN, IMDG, IATA**	Void
· **14.2 UN proper shipping name**	
· **ADR**	Void
· **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 Maritime transport in bulk according to IMO instruments**	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**
No further relevant information available.
· **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.

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· **Relevant phrases**
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H361f Suspected of damaging fertility.
H411 Toxic to aquatic life with long lasting effects.
H412 Harmful to aquatic life with long lasting effects.
EUH204 Contains isocyanates. May produce an allergic reaction.
EUH208 Contains . **May produce an allergic reaction.**

· **Abbreviations and acronyms:**
SADT: Self Accelerating Decomposition 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
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)
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
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
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.**