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

Printing date 17.11.2022

Version number 5 (replaces version 4)

Revision: 17.11.2022

SECTION 1: Identification of the substance/mixture and of the company/ undertaking
· 1.1 Product identifier
· Trade name: Signum ceramis
• 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 Veneering resin
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 Sens. 1 H317 May cause an allergic skin reaction.
Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.
• 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: 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate Bisphenol A Diglycidylether Diacrylate (BADGE-DA) triethylen glycol dimethacrylate 2-propenoic acid, 1,1'-[(1-methyl-1,2-ethanediyl))bis[oxy(methyl-2,1-ethanediyl)]]ester, reaction products with diethylamine Hazard statements 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. Additional information: 8.3 % of the mixture consists of component(s) of unknown toxicity. Contains 8.3 % of components with unknown hazards to the aquatic environment. 2.3 Other hazards - Results of PBT and vPvB assessment PBT: Not applicable. vPvB: Not applicable.
GB- GB- (Contil on page 3)

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Trade name: Signum ceramis

3.2 Mixtures Description: -		
 Dangerous components: 		
CAS: 72869-86-4 EINECS: 276-957-5 Reg.nr.: 01-2120751202-68-xxx	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	<i>≥</i> 5-<25%
CAS: 55818-57-0 NLP: 500-130-2 Reg.nr.: 01-2119490020-53- XXXX	Bisphenol A Diglycidylether Diacrylate (BADGE-DA) Aquatic Chronic 2, H411 Skin Sens. 1, H317	≥2.5- <i>≤</i> 10%
CAS: 109-16-0 EINECS: 203-652-6 Reg.nr.: 01-2119969287-21-xxx	triethylen glycol dimethacrylate Skin Sens. 1B, H317 x	<i>≥</i> 1- <i>≤</i> 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	<i>≥</i> 0.1-<1%

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 Allergic reactions
- 4.3 Indication of any immediate medical attention and special treatment needed No further relevant information available.
 - lo further relevant information available.

SECTION 5: Firefighting measures

· 5.1 Extinguishing media

- Suitable extinguishing agents
 - Use fire fighting measures that suit the environment.
- CO2, extinguishing powder or water jet. Fight larger fire with alcohol-resistant foam.
- 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.

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Trade name: Signum ceramis

· Additional information -

SECTION 6: Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures Wear protective clothing.
- · 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
- See Section 7 for information on safe handling
- See Section 8 for information on personal protection equipment.
- See Section 13 for information on disposal.

SECTION 7: Handling and storage

· 7.1 Precautions for safe handling Ensure good ventilation/exhaustion at the workplace. 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: No special requirements.
 - · Information about storage in one common storage facility: Not required.
 - Further information about storage conditions: None.
- · 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 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) worker industrial, long term, systemic 1.3 mg/Kg/d (not defined) Dermal 0.7 mg/Kg/d (not defined) general population, long term, systemic Inhalative worker industrial, long term, systemic 3.3 mg/m3 (not defined) general population, long term, systemic 0.6 mg/m3 (not defined) 55818-57-0 Bisphenol A Diglycidylether Diacrylate (BADGE-DA) 17.5 mg/Kg/d (not defined) Dermal worker industrial, long term, systemic 122.5 mg/m3 (not defined) Inhalative worker industrial, long term, systemic 109-16-0 triethylen glycol dimethacrylate Oral general population, long term, systemic 8.33 mg/Kg (not defined) worker industrial, long term, systemic 13.9 mg/Kg/d (not defined) Dermal (Contd. on page 4) GR



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	general population. long	term, systemic 8.33 mg/Kg/d (not defined) (Contd. of page		
Inhalative				
	general population, long			
·PN	• • •			
		hyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diy		
	bismethacrylate			
freshwate	r	0.01 mg/l (not defined)		
marine wa		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)		
		ylether Diacrylate (BADGE-DA)		
freshwate		0.1 mg/l (not defined)		
marine wa		0.01 mg/l (not defined)		
intermediate water release		1 mg/l (not defined)		
sewage treatment plant		10 mg/l (not defined)		
	dry weight, freshwater	35.8 mg/Kg (not defined)		
soil, dry w	-	71 mg/Kg (not defined)		
	triethylen glycol dimetha	-		
freshwate		0.016 mg/l (not defined)		
marine water		0.002 mg/l (not defined)		
sewage treatment plant		1.7 mg/l (not defined)		
sediment, dry weight, freshwater sediment, dry weight, marine water		0.185 mg/Kg (not defined)		
soil, dry w	-	0.027 mg/Kg (not defined)		
^ ^ ~	ditional information: The	e lists that were valid during the compilation were used as basis.		
· Add				
· 8.2 Expos	sure controls			
8.2 Expos	sure controls lual protection measure	s, such as personal protective equipment		
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8.2 Expos Individ Gen Inst Wa Bre Not pro Han If s sen Che recc	sure controls fual protection measure neral protective and hyg antly remove any soiled a sh hands during breaks a sathing equipment: neccessary with efficient tective mask (filter A). nd protection kin contact cannot be a sitization. eck protective gloves prior ommended Material of gloves The selection of the suit further marks of quality an oreparation of several s	is, such as personal protective equipment inenic measures and impregnated garments. nd at the end of the work. t local exhaust. If exposition to vapours is possible, use breathin voided, protective gloves are recommended to avoid possib		



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Printing date 17.11.2022 Version number 5 (replaces version 4) Revision: 17.11.2022 Trade name: Signum ceramis (Contd. of page 4) · 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 Brown White Pink · 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) 400 °C · Ignition temperature: Decomposition temperature: Not determined. SADT pН 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 1.86 g/cm3 · Relative density Not determined. · Vapour density Not determined. No further relevant information available. · 9.2 Other information Appearance: Form: Pasty

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· Important information on protection of		
health and environment, and on safety.		
Self-inflammability:	Product is not selfigniting.	
· Explosive properties:	Product is not explosive.	
	Not determined.	
· Solvent content:		
· Water:	3.4-<4.4 %	
· Solids content:	70.2 %	
[.] 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 lĭquids	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: -

11.1 Inform	mation on ha toxicity Base	izard classes as defined in Regulation (EC) No 1272/2 d on available data, the classification criteria are not met.	008
· LD/	LC50 values	that are relevant for classification:	
65997-18-	4 frits, chem	icals	
Oral	LD50	>2,000 mg/kg (rat) (OECD 423)	
Dermal	LD50	>2,000 mg/kg (rat) (OECD 402)	



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	licon dioxide	, chemically prepared (Contd. of pag
Oral	LD50	>5,000 mg/kg (rat)
Dermal	LD50	>5,000 mg/kg (rabbit)
)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-di
Oral	LD50	>5,000 mg/kg (rat) (OECD 401)
Dermal	LD50	>2,000 mg/kg (rat) (OECD 402)
		ylpropyl methacrylate
Oral	LD50	>2,000 mg/kg (rat)
Dermal	LD50	>2,000 mg/kg (rab)it)
55818-57-0 E	Bisphenol A I	Diglycidylether Diacrylate (BADGE-DA)
Oral	LD0	>2,000 mg/kg (rat) (OECD 401)
Dermal	LD0	>2,000 mg/kg (rat) (OECD 402)
Sensitisation	sensitization	
		(mouse) (LLNA)
109-16-0 trie	thylen glycol	dimethacrylate
Oral	LD50	8,300 mg/kg (rat)
Dermal	LD50	>2,000 mg/kg (mouse)
111497-86-0	2-propenoic ester, reaction	acid, 1,1'-[(1-methyl-1,2-ethanediyl)bis[oxy(methyl-2,1-ethanediyl on products with diethylamine
Oral	LD50	>5,000 mg/kg (rat) (OECD 401)
Dermal	LD50	>2,000 mg/kg (rat) (OECD 402)
Serious e Respirato	eye damage/ii ory or skin se	on Based on available data, the classification criteria are not met. rritation Based on available data, the classification criteria are not met. insitisation kin reaction
Serious e Respirato May cause Germ cell Carcinoge Reproduc STOT-sin STOT-rep Aspiration 11.2 Informa Endocrine	eye damage/ii ory or skin se e an allergic s I mutagenicit enicity Based ctive toxicity gle exposure peated expos n hazard Bas tion on other e disrupting	rritation Based on available data, the classification criteria are not met. Insitisation kin reaction. Based on available data, the classification criteria are not met. If on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the cla
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	mg/l (fish) (OECD 203)
	8 mg/l (algae) (OECD 201)
NOEC / 72h 0.21	mg/l (algae) (OECD 201)
	thoxysilylpropyl methacrylate
	0 mg/l (daphnia) (EU C2.)
LC50/96h >100	0 mg/l (fish) (EU C.1)
	enol A Diglycidylether Diacrylate (BADGE-DA)
	0 mg/l (algae) (OECD 201)
	mg/l (fish) (OECD 203)
	n glycol dimethacrylate
	mg/L (daphnia) (OECD 211)
LC50/96h 16.4	mg/l (fish) (OECD 203)
	ng/l (daphnia) (OECD 211)
ErC50 / 72 h >100	0 mg/l (algae) (OECD 201)
NOEC / 72h 18.6	mg/l (algae) (OECD 201)
EbC50 / 72h 72.8	mg/l (algae) (OECD 201)
· 12.2 Persistence	and degradability
	or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl ethacrylate
Biodegradation 22	2 % /28d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)
2530-85-0 3-trime	thoxysilylpropyl methacrylate
	9 % /28d (not defined) (OECD 301F; ISO 9408/ EEC 92/69/V, C.4-D)
109-16-0 triethyle	n glycol dimethacrylate
Biodegradation 85	5 % /28d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)
 12.4 Mobility in set 12.5 Results of Plands PBT: Not applied vPvB: Not applied 12.6 Endocrine dia For information on 12.7 Other advers Additional eco General no Do not allow guantities. 	licable. i srupting properties endocrine disrupting properties see section 11. se effects ological information:
	Disposal considerations
13.1 Waste treatn Recommendat Must not be dis system.	

system. Disposal must be made according to official regulations.

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· Uncleaned packagings:

· Recommendation:

Disposal must be made according to official regulations. Non contaminated packagings can be used for recycling.

SECTION 14: Transport information	tion	
14.1 UN number or ID 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 Maritime transport in bulk accordi IMO instruments	ng to 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

· Directive 2012/18/EU

• Named dangerous substances - ANNEX I None of the ingredients is listed.

· 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.
- H411 Toxic 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)

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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 (UK REACH)
PNEC: Predicted No-Effect Concentration (UK REACH)
LC50: Lethal concentration, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Skin Init. 2: Skin corrosion/irritation - Category 2
Eye Irrit. 2: Serious eye damage/eye irritation - Category 2
Skin Sens. 1: Skin sensitisation - Category 1B
Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard - Category 3
* Data compared to the previous version altered.

GB