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Revision: 17.11.2022

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

Printing date 17.11.2022

Version number 5 (replaces version 4)

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.

- · 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



- · 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.

- IE



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SECTION 3: Composition/information on ingredients

- · 3.2 Mixtures

	· Description: -		
	· Dangerous components:		
ĒΙ	AS: 72869-86-4 NECS: 276-957-5 eg.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	≥5-<25%
NI Re	AS: 55818-57-0 LP: 500-130-2 eg.nr.: 01-2119490020-53- XXX	Bisphenol A Diglycidylether Diacrylate (BADGE-DA) Aquatic Chronic 2, H411 Skin Sens. 1, H317	<i>≥</i> 2.5- <i>≤</i> 10%
ĒΙ	AS: 109-16-0 NECS: 203-652-6 eg.nr.: 01-2119969287-21-xxxx	triethylen glycol dimethacrylate Skin Sens. 1B, H317	≥1-≤5%
E0 Re	AS: 111497-86-0 C number: 601-101-8 eg.nr.: 01-2119961351-42- XXX	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	≥0.1-<1%

[·] 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 Allergic reactions
- 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

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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· 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.

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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.

· DNI		
72869-86-	4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo bismethacrylate	o-3,14-dioxa-5,12-diazahexadecane-1,16-diy
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)
55818-57-	0 Bisphenol A Diglycidylether Diacryl	ate (BADGE-DA)
Dermal	worker industrial, long term, systemic	17.5 mg/Kg/d (not defined)
Inhalative	worker industrial, long term, systemic	122.5 mg/m3 (not defined)
109-16-0 1	riethylen glycol dimethacrylate	
Oral	general population, long term, systemic	8.33 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	13.9 mg/Kg/d (not defined)
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				(Contd. of page 3	
	eneral population, long		3.33 mg/Kg/d (not defined)		
Inhalative w	orker industrial, long tei	rm, systemic 4	18.5 mg/m3 (not defined)		
ge	eneral population, long	term, systemic 14	4.5 mg/m3 (not defined)		
· PNEC	s				
	7,7,9(or 7,9,9)-trimetl bismethacrylate	hyl-4,13-dioxo-3	3,14-dioxa-5,12-diazahexad	decane-1,16-diyl	
freshwater	_	0.01 mg/l (not de	efined)		
marine water	r	0.001 mg/l (not d	defined)		
sewage trea	tment plant	3.61 mg/l (not de	efined)		
sediment, dr	sediment, dry weight, freshwater		4.56 mg/Kg (not defined)		
sediment, dry weight, marine water soil, dry weight		0.46 mg/Kg (not	defined)		
		0.91 mg/Kg (not	defined)		
55818-57-0	Bisphenol A Diglycidy	lether Diacrylate	e (BADGE-DA)		
freshwater		0.1 mg/l (not defined)			
marine water		0.01 mg/l (not defined)			
intermediate water release		1 mg/l (not defined)			
sewage treatment plant		10 mg/l (not defined)			
sediment, dry weight, freshwater		35.8 mg/Kg (not defined)			
soil, dry weight		71 mg/Kg (not de	efined)		
109-16-0 trie	ethylen glycol dimetha	acrylate			
freshwater		0.016 mg/l (not defined)			
marine water		0.002 mg/l (not d	defined)		
sewage treatment plant 1.7 mg/l (not defined)					
sediment, dr	ry weight, freshwater	0.185 mg/Kg (no	ot defined)		
sediment, dr	y weight, marine water	0.018 mg/Kg (no	ot defined)		
soil, dry weig	ght	0.027 mg/Kg (no	ot defined)		

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

· 8.2 Exposure controls

· Individual protection measures, such as personal protective equipment

General protective and hygienic measures
Instantly remove any soiled and impregnated garments.

Wash hands during breaks and at the end of the work.

· Breathing equipment:

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

Hand protection

If skin contact cannot be avoided, protective gloves are recommended to avoid possible sensitization.

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 greation calculated in advance and has therefore to be checked prior to the application.

(Contd. on page 5) preparation of several substances, the resistance of the glove material can not be



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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/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

· Smell:

· Physical state Fluid
· Colour: Colourless
Brown
White

Pink Ester-like

· Odour threshold:
· Melting point/freezing point:
· Boiling point or initial boiling point and

Not determined
Not determined

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: 400 °C

Decomposition temperature: Not determined.

SADT

· **pH** Not determined.

· Viscosity:

* Kinematic viscosity Not determined. 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
 Relative density
 Vapour density
 Not determined.
 Not determined.

• **9.2 Other information** No further relevant information available.

· Appearance:

Form: Pasty

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Important information on protection of health and environment, and on safety.

• Self-inflammability:
• Explosive properties:

Product is not selfigniting.
Product is not explosive.
Not determined.

· Solvent content:

Change in condition

· Evaporation rate Not determined.

Information with regard to physical hazard classes

· Explosives Void · Flammable gases Void · Aerosols Void · Oxidising gases · Gases under pressure Void Void · Flammable liquids Void · Flammable solids Void Void Self-reactive substances and mixtures 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: -

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/LC50 values that are relevant for classification:

65997-18-4 frits, chemicals

 Oral
 LD50
 >2,000 mg/kg (rat) (OECD 423)

 Dermal
 LD50
 >2,000 mg/kg (rat) (OECD 402)

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		(Contd. of page	
7631-86-9 si	licon dioxide	, chemically prepared	
Oral	LD50	>5,000 mg/kg (rat)	
Dermal	LD50	>5,000 mg/kg (rabbit)	
	7,7,9(or 7,9,9 pismethacryla)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diy ate	
Oral	LD50	>5,000 mg/kg (rat) (OECD 401)	
Dermal	LD50	>2,000 mg/kg (rat) (OECD 402)	
2530-85-0 3-	trimethoxysil	ylpropyl methacrylate	
Oral	Oral LD50 >2,000 mg/kg (rat)		
Dermal	LD50	>2,000 mg/kg (rabbit)	
55818-57-0 E	Bisphenol A L	Diglycidylether Diacrylate (BADGE-DA)	
Oral LD0 >2,000 mg/kg (rat) (OECD 401)			
Dermal	LD0	>2,000 mg/kg (rat) (OECD 402)	
Sensitisation	sensitization	(human)	
		(mouse) (LLNA)	
109-16-0 trie	thylen glycol	dimethacrylate	
Oral	LD50	8,300 mg/kg (rat)	
Dermal	LD50	>2,000 mg/kg (mouse)	
		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)	

- Skin corrosion/irritation Based on available data, the classification criteria are not met.
- · 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.
 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

	12.1 TOXICILY		
	· Aquatic toxicity:		
65997-18-4 frits, chemicals		rits, chemicals	
	LC50/96h	≥3.09 mg/l (fish)	
	ErC50 / 72 h	≥2.4 mg/l (algae)	
	72869-86-47,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,1 bismethacrylate		
	EC50/48h	>1.2 mg/l (daphnia) (OECD 202)	
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	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)	
	2530-85-0 3-	trimethoxysilylpropyl methacrylate	
	EC50/48h	>100 mg/l (daphnia) (EU C2.)	
	LC50/96h	>100 mg/l (fish) (EU C.1)	
	55818-57-0 E	Bisphenol A Diglycidylether Diacrylate (BADGE-DA)	
	EC50/72h	>110 mg/l (algae) (OECD 201)	
	LC50/96h	>79 mg/l (fish) (OECD 203)	
	109-16-0 triethylen glycol dimethacrylate		
	EC50/21d	51.9 mg/L (daphnia) (OECD 211)	
	LC50/96h	16.4 mg/l (fish) (OECD 203)	
	NOEC / 21d	32 mg/l (daphnia) (OECD 211)	
	ErC50 / 72 h	>100 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		
	72869-86-4 7 b	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyloismethacrylate	
	Biodegradation	on 22 % /28d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)	
		trime the consilidade and method mulate	

2530-85-0 3-trimethoxysilylpropyl methacrylate

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

109-16-0 triethylen glycol dimethacrylate

Biodegradation 85 % /28d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)

- 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 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.

Danger to drinking water if even extremely 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.

· European waste catalogue

18 01 06* chemicals consisting of or containing hazardous substances

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· 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, 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 accordin IMO instruments	g 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. · REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

 - DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II

None of the ingredients is listed.

- REGULATION (EU) 2019/1148
 - Annex I RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

no information available

Annex II - REPORTABLE EXPLOSIVES PRECURSORS

no information available

Regulation (EC) No 273/2004 on drug precursors

None of the ingredients is listed.

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· Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

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 eve irritation.

Toxic to aquatic life with long lasting effects.

EUH204 Contains isocyanates. May produce an allergic reaction.

EUH208 Contains . May produce an allergic reaction.

Date of previous version: 17.11.2022

· Version number of previous version: 4 · Abbreviations and acronyms:

SADT: Self Accelerating Decomposition Temperature

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement

ACCOLO Telatif at transport International des marchandises dangere 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

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

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.