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Revision: 16.11.2022

Tel.: +49 (0)800 4372522

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

Printing date 16.11.2022

Version number 4 (replaces version 3)

SECTION 1: Identification of the substance/mixture and of the company/ undertaking

- · 1.1 Product identifier
 - · Trade name: Signum matrix Matrix, Opal, MD, SD
- · 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)

· 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.

- · 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



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

triethylen glycol dimethacrylate

· Hazard statements

H317 May cause an allergic skin reaction.

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

· 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: Product based on methacrylates

Dangerous components:

CAS: 109-16-0 EINECS: 203-652-6

triethylen glycol dimethacrylate

Skin Sens. 1B, H317

Reg.nr.: 01-2119969287-21-xxx

≥10-≤25%

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Trade name: Signum matrix Matrix, Opal, MD, SD

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CAS: 131-57-7 Oxybenzone

≥0.25-<1%

EINECS: 205-031-5

Aquatic Acute 1, H400; Aquatic Chronic 2, H411

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

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

No further relevant information available.

- · 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

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 No special measures required.
 - 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.

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- · 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

109-16-0 t	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)			
	general population, long term, systemic	8.33 mg/Kg/d (not defined)			
Inhalative	worker industrial, long term, systemic	48.5 mg/m3 (not defined)			
	general population, long term, systemic	14.5 mg/m3 (not defined)			
41637-38-	41637-38-1 bisphenol a polyethylene glycol diether dimethacrylate				
Oral	general population, long term, systemic	5 mg/Kg (not defined)			
Dermal	worker industrial, long term, systemic	140 mg/Kg/d (not defined)			
	general population, long term, systemic	50 mg/Kg/d (not defined)			
Inhalative	worker industrial, long term, systemic	98.7 mg/m3 (not defined)			
	general population, long term, systemic	17.4 mg/m3 (not defined)			
131-57-7 (Oxybenzone				
Oral	general population, long term, systemic	2 mg/Kg (not defined)			
Dermal	worker industrial, long term, systemic	39 mg/Kg/d (not defined)			
	general population, long term, systemic	20 mg/Kg/d (not defined)			
Inhalative	worker industrial, long term, systemic	27.7 mg/m3 (not defined)			
	general population, long term, systemic	6.8 mg/m3 (not defined)			
80-62-6 m	ethyl methacrylate				
Oral	general population, long term, systemic	8.2 mg/Kg (not defined)			
Dermal	worker industrial, long term, systemic	13.67 mg/Kg/d (not defined)			
	general population, long term, systemic	8.2 mg/Kg/d (not defined)			
Inhalative	worker industrial, acute, local	416 mg/m3 (not defined)			
	worker industrial, long term, systemic	348.4 mg/m3 (not defined)			
	worker industrial, long term, local	208 mg/m3 (not defined)			
	general population, acute, local	208 mg/m3 (not defined)			
	general population, long term, systemic	74.3 mg/m3 (not defined)			

· PNECs

109-16-0 triethylen glycol dimethacrylate

0.016 mg/l (not defined) freshwater 0.002 mg/l (not defined) marine water sewage treatment plant 1.7 mg/l (not defined) sediment, dry weight, freshwater 0.185 mg/Kg (not defined)

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sediment, dry weight, marine water	0.018 mg/Kg (not defined)
soil, dry weight	0.027 mg/Kg (not defined)
131-57-7 Oxybenzone	
freshwater	0.00067 mg/l (not defined)
marine water	0.000067 mg/l (not defined)
sewage treatment plant	10 mg/l (not defined)
sediment, dry weight, freshwater	0.066 mg/Kg (not defined)
sediment, dry weight, marine water	0.007 mg/Kg (not defined)
soil, dry weight	0.013 mg/Kg (not defined)
80-62-6 methyl methacrylate	
freshwater	0.94 mg/l (not defined)
marine water	0.094 mg/l (not defined)
sewage treatment plant	10 mg/l (not defined)
sediment, dry weight, freshwater	10.2 mg/Kg (not defined)
sediment, dry weight, marine water	0.102 mg/Kg (not defined)
soil, dry weight	1.48 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

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

- · Breathing equipment: Not necessary if room is well-ventilated.
- 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

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

- GI



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· Explosives · Flammable gases

· Oxidising gases

· Flammable liquids

Flammable solids

Gases under pressure

· Aerosols

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SECTION 9: Physical and chemical properties · 9.1 Information on basic physical and chemical properties **General Information** · Physical state Fluid · Colour: Beige · Smell: Odourless Odour threshold: Not determined. · Melting point/freezing point: Not determined · Boiling point or initial boiling point and 250 °C boiling range · Flammability Not applicable. · Lower and upper explosion limit Not determined. Lower: Not determined. Upper: >150 °C (109-16-0 triethylen glycol dimethacrylate) · Flash point: · Decomposition temperature: Not determined. SADT · pH Not determined. Viscosity: Not determined. · Kinematic viscosity dynamic: Not determined. Solubility Not miscible or difficult to mix Water: · Partition coefficient n-octanol/water (log Not determined. value) · Steam pressure: Not determined. Density and/or relative density Not determined · Density Relative density Not determined. · Vapour density Not determined. No further relevant information available. · 9.2 Other information Appearance: Fluid Form: · 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: 2.3-<3.7 % · Water: Solids content: 0.0 % Change in condition Not determined. · Evaporation rate · Information with regard to physical hazard classes

Void

Void

Void

Void

Void

Void

Void

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· 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.

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:			
109-16-0 triethylen glycol dimethacrylate			
Oral	LD50	8,300 mg/kg (rat)	
Dermal	LD50	>2,000 mg/kg (mouse)	
68611-44-9 Silane, dichlorodimethyl-, reaction products with silica			
Oral	LD50	>5,000 mg/kg (rat)	
Inhalative	LC0/4h	0.477 mg/L (rat)	
41637-38-1 bisphenol a polyethylene glycol diether dimethacrylate			
Oral	LD50	>2,000 mg/kg (rat) (OECD 423)	
Dermal	LD50	>2,000 mg/kg (rat) (OECD 402)	
131-57-7 Oxybenzone			
Oral	LD50	>12,800 mg/kg (rat) (OECD 401)	
Dermal	LD50	>16,000 mg/kg (rabbit) (OECD 402)	
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)	
. Ckin o	orrocion/i	rritation Rased on available data, the classification criteria are not met	

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

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- 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.

12.1 Toxicity	12: Ecological information	
Aquatic to		
65997-17-3		
	>1,000 mg/l (daphnia)	
	>1,000 mg/l (fish)	
	>1,000 mg/l (algae)	
	1,000 mg/l (algae)	
	1,000 mg/l (daphnia)	
109-16-0 trie	thylen 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)	
68611-44-9 S	ilane, dichlorodimethyl-, reaction products with silica	
LC50/96h	>10,000 mg/l (fish) (OECD 203)	
	>10,000 mg/l (algae) (OECD 201)	
	>10,000 mg/l (daphnia) (OECD 202)	
	isphenol a polyethylene glycol diether dimethacrylate	
LL50/96h	>100 mg/L (fish) (OECD 203)	
EL50/48h	>100 mg/L (daphnia) (OECD 202)	
EL50/72h	>100 mg/L (algae) (OECD 201)	
	≥0.00224 mg/l (daphnia) (OECD 211)	
131-57-7 Oxy		
EC50/48h	1.87 mg/l (daphnia) (OECD 202)	
LC50/96h	3.8 mg/l (fish) (OECD 203)	
	0.67 mg/l (algae) (OECD 201)	
	0.18 mg/l (algae) (OECD 201)	
	0.72 mg/l (fish) (OECD 203)	
NOEC / 48h	1.15 mg/l (daphnia) (OECD 202)	(Contd. on pa



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80-62-6 methyl methacrylate			
	49 mg/L (daphnia) (OECD 211)		
	69 mg/l (daphnia) (EPA OTS 797.1300)		
	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)		
· 12.2 Persist	12.2 Persistence and degradability		
109-16-0 triethylen glycol dimethacrylate			
Biodegradation 85 % /28d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)			
41637-38-1 bisphenol a polyethylene glycol diether dimethacrylate			
Biodegradation 24 % /28d (not defined) (OECD 301D)			
131-57-7 Oxybenzone			
Biodegradation 60-70 % /28d (not defined)			
80-62-6 methyl methacrylate			
Biodegradation 94 % /14d (not defined) (OECD 301C)			
· 12.3 Bioaccumulative potential			

- Bloconcentration factor (BCF) >33-<160 (fish) (OECD 305) · 12.4 Mobility in soil No further relevant information available.
- 12.5 Results of PBT and vPvB assessment
 - - PBT: Not applicable.

131-57-7 Oxybenzone

- vPvB: Not applicable.
- 12.6 Endocrine disrupting properties
- For information on endocrine disrupting properties see section 11.
- · 12.7 Other adverse effects No further relevant information available.

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

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

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(Contd. of page 8) 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, IMĎĞ, IAŤA 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

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.

Relevant phrases

H317 May cause an allergic skin reaction.

H400 Very toxic to aquatic life.

H411 Toxic to aquatic life with long lasting effects.

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)
DNEL: Derived No-Effect Level (UK REACH)

PNEC: Predicted No-Effect Concentration (ÚK REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative Skin Sens. 1: Skin sensitisation – Category 1 Skin Sens. 1B: Skin sensitisation – Category 1B

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

* Data compared to the previous version altered.