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

Printing date 16.11.2022 Version number 3 Revision: 16.11.2022

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

- · 1.1 Product identifier
 - · Trade name: Venus
- · 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 Dental filling material
- · 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.

- · 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:

triethylen glycol dimethacrylate

· Hazard statements

H317 May cause an allergic skin reaction.

Precautionary statements

P280 Wear protective gloves / eye protection.

P280 Wear protective clothing.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P363 Wash contaminated clothing before reuse.

· 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

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· Dangerous components:		
CAS: 109-16-0 EINECS: 203-652-6 Reg.nr.: 01-2119969287-21-xxxx	triethylen glycol dimethacrylate Skin Sens. 1B, H317	≥5-≤10%
CAS: 79-41-4 EINECS: 201-204-4	methacrylic acid Acute Tox. 3, H311 Skin Corr. 1A, H314; Eye Dam. 1, H318 Acute Tox. 4, H302; Acute Tox. 4, H332; STOT SE 3, H335 ATE: LD50 oral: 1,320 mg/kg LD50 dermal: 500 mg/kg LC50/4 h inhalative: 11 mg/l Specific concentration limit: STOT SE 3; H335: C ≥ 1 %	<1%
CAS: 131-57-7 EINECS: 205-031-5	Oxybenzone Aquatic Acute 1, H400; Aquatic Chronic 2, H411	<0.25%

[·] 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
 - General information No special measures required.
 - After skin contact

Instantly wash with water and soap and rinse thoroughly.

If skin irritation or rash occurs: Get medical advice/attention.

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

No further relevant information available.

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 Wear protective equipment. Keep unprotected persons away.

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· 6.2 Environmental precautions:

Do not allow product to reach sewage system or water bodies.

Do not allow to enter the ground/soil.

· 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 13 for information on disposal.

See Section 8 for information on personal protection equipment.

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.
 - 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. DAIL

· DNE	ELS		
109-16-0 triethylen 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)	
79-41-4 m	ethacrylic acid		
Dermal	worker industrial, long term, systemic	4.25 mg/Kg/d (not defined)	
	general population, long term, systemic	2.55 mg/Kg/d (not defined)	
Inhalative	worker industrial, long term, local	88 mg/m3 (not defined)	
	worker professional, long term, systemic	29.6 mg/m3 (not defined)	
	general population, long term, systemic	6.3 mg/m3 (not defined)	
	general population, long term, local	6.55 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)	
			(Contd. on page



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general population, long	term, systemic 6.8 mg/m3 (not defined)	
· PNECs		
109-16-0 triethylen glycol dimeth	acrylate	
freshwater	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	0.185 mg/Kg (not defined)	
sediment, dry weight, marine water	0.018 mg/Kg (not defined)	
soil, dry weight	0.027 mg/Kg (not defined)	
79-41-4 methacrylic acid		
freshwater	0.82 mg/l (not defined)	
marine water	0.82 mg/l (not defined)	
sewage treatment plant	10 mg/l (not defined)	
soil, dry weight	1.2 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)	

[·] 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

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 Safety glasses
- Body protection: Light weight protective clothing

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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: Different according to colour

· Smell: Odourless

Odour threshold: Not determined. · Melting point/freezing point: Not determined

· Boiling point or initial boiling point and

boiling range Not determined · Flammability Not applicable.

· Lower and upper explosion limit

Not determined. Lower: Upper: Not determined.

>150 °C (109-16-0 triethylen glycol · Flash point:

dimethacrylate)

· 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

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:

Form: Pasty

· 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

Void **Explosives** 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

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· 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:			
65997-18-	65997-18-4 frits, chemicals		
Oral	LD50	>2,000 mg/kg (rat) (OECD 423)	
Dermal	LD50	>2,000 mg/kg (rat) (OECD 402)	
1565-94-2	1 (1-meth bismetha	ylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] acrylate	
Oral	LD50	>5,000 mg/kg (rat)	
109-16-0	triethylen	riethylen glycol dimethacrylate	
Oral	LD50	8,300 mg/kg (rat)	
Dermal	LD50	>2,000 mg/kg (mouse)	
Pyrogeni	Pyrogenic silica, silanized		
Oral	LD50	10,000 mg/kg (rat)	
2530-85-0	2530-85-0 3-trimethoxysilylpropyl methacrylate		
Oral	LD50	>2,000 mg/kg (rat)	
Dermal	LD50	>2,000 mg/kg (rabbit)	
79-41-4 m	nethacrylic	ethacrylic acid	
Oral	LD50	1,320 mg/kg (rat) (OECD 401)	
Dermal	LD50	500-1,000 mg/kg (rabbit)	
Inhalative	LC50/4 h	7.1 mg/l (rat) (OECD 403)	
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131-57-7	131-57-7 Oxybenzone (Contd. of page		
Oral	LD50	>12,800 mg/kg (rat) (OECD 401)	
Dermal	LD50	>16,000 mg/kg (rabbit) (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			
· Aquatic toxicity:			
65997-17-3	Glaspulver		
EC50/72h	>1,000 mg/l (daphnia)		
LC50/96h	>1,000 mg/l (fish)		
ErC50 / 72 h	>1,000 mg/l (algae)		
NOEC / 72h	1,000 mg/l (algae)		
	1,000 mg/l (daphnia)		
65997-18-4 f	rits, chemicals		
LC50/96h	≥3.09 mg/l (fish)		
ErC50 / 72 h	≥2.4 mg/l (algae)		
	-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)]		
	smethacrylate		
LC50/96h	>100 mg/l (fish) (OECD 203)		
	thylen glycol dimethacrylate		
EC50/21d	51.9 mg/L (daphnia) (OECD 211)		
	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)		
2530-85-0 3-trimethoxysilylpropyl methacrylate			
EC50/48h	>100 mg/l (daphnia) (EU C2.)		
LC50/96h	>100 mg/l (fish) (EU C.1)		
79-41-4 metl	nacrylic acid		
EC50/48h	>130 mg/l (daphnia) (EPA OTS 797.1300)		
LC50/96h	85 mg/l (fish) (EPA OTS 797.1400)		
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		53 mg/l (daphnia)		
		45 mg/l (algae) (OECD 201)		
		8.2 mg/l (algae) (OECD 201)		
	NOEC / 96h	12 mg/l (fish) (EPA OTS 797.1400)		
	NOEC / 48h	130 mg/l (daphnia) (EPA OTS 797.1300)		
	NOEC/ 35d	10 mg/L (fish) (OECD 210)		
	LC50/ 35d	42 mg/L (fish) (OECD 210)		
	131-57-7 Oxybenzone			
	EC50/48h	1.87 mg/l (daphnia) (OECD 202)		
	LC50/96h	3.8 mg/l (fish) (OECD 203)		
	ErC50 / 72 h	0.67 mg/l (algae) (OECD 201)		
	NOEC / 72h	0.18 mg/l (algae) (OECD 201)		
	NOEC / 96h	0.72 mg/l (fish) (OECD 203)		
	NOEC / 48h	1.15 mg/l (daphnia) (OECD 202)		
	12.2 Persistence and degradability			
	1565-94-2 (1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate			
	Biodegradation	on 21 % /28d (not defined) (OECD 301F; ISO 9408/ EEC 92/69/V, C.4-D)		
	109-16-0 trie	thylen glycol dimethacrylate		
		on 85 % /28d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)		
		trimethoxysilylpropyl methacrylate		
		on 69 % /28d (not defined) (OECD 301F; ISO 9408/ EEC 92/69/V, C.4-D)		
		nacrylic acid		
		on 86 % /28d (not defined) (OECD 301D)		
	131-57-7 Oxybenzone			
	Biodegradation	on 60-70 % /28d (not defined)		
	· 12.3 Bioaccu	ımulative potential		
	131-57-7 Ox			
	Bloconcentra	tion 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.
 - 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.

· European waste catalogue

18 01 06 chemicals consisting of or containing dangerous substances

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Uncleaned packagings:

· Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information	on	
· 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 according 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

No further relevant information available.

- · REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3
- 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

H302 Harmful if swallowed.

H311 Toxic in contact with skin.

H314 Causes severe skin burns and eye damage.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H332 Harmful if inhaled.

H335 May cause respiratory irritation.

H400 Very toxic to aquatic life.

H411 Toxic to aquatic life with long lasting effects.

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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

IMDG: International Mantime 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 (REACH)
PNEC: Predicted No-Effect Concentration (REACH)

LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

PST. Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Acute Tox. 4: Acute toxicity – Category 4
Acute Tox. 3: Acute toxicity – Category 3
Skin Corr. 1A: Skin corrosion/irritation – Category 1A
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
Skin Sens. 1: Skin sensitisation – Category 1
Skin Sens. 1B: Skin sensitisation – Category 1B
STOT SE 3: Specific terget organ toxicity (single exposure)

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
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.