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 GB CLP regulation.

· **Hazard pictograms**

GHS07

· **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**
CO_2, 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.
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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.
· **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 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 methacrylic 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)

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	general population, long term, systemic	6.8 mg/m3 (not defined)

· **PNECs**

109-16-0 triethylen glycol dimethacrylate	
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**	
· **Lower:**	Not determined.
· **Upper:**	Not determined.
· **Flash point:**	>150 °C (109-16-0 triethylen glycol 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 value)**	Not determined.
· **Steam pressure:**	Not determined.
· **Density and/or relative density**	
· **Density**	Not determined
· **Relative density**	Not determined.
· **Vapour density**	Not determined.
· **9.2 Other information**	No further relevant information available.
· **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**	
· **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

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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.
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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.

· **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)
1565-94-2 (1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate		
Oral	LD50	>5,000 mg/kg (rat)
109-16-0 triethylen glycol dimethacrylate		
Oral	LD50	8,300 mg/kg (rat)
Dermal	LD50	>2,000 mg/kg (mouse)
Pyrogenic silica, silanized		
Oral	LD50	10,000 mg/kg (rat)
2530-85-0 3-trimethoxysilylpropyl methacrylate		
Oral	LD50	>2,000 mg/kg (rat)
Dermal	LD50	>2,000 mg/kg (rabbit)
79-41-4 methacrylic 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 Oxybenzone		
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 frits, chemicals	
LC50/96h	≥3.09 mg/l (fish)
ErC50 / 72 h	≥2.4 mg/l (algae)
1565-94-2 (1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	
LC50/96h	>100 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)
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 methacrylic 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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NOEC / 21d	53 mg/l (daphnia)
ErC50 / 72 h	45 mg/l (algae) (OECD 201)
NOEC / 72h	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	21 % /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)
2530-85-0 3-trimethoxysilylpropyl methacrylate	
Biodegradation	69 % /28d (not defined) (OECD 301F; ISO 9408/ EEC 92/69/V, C.4-D)
79-41-4 methacrylic acid	
Biodegradation	86 % /28d (not defined) (OECD 301D)
131-57-7 Oxybenzone	
Biodegradation	60-70 % /28d (not defined)

· **12.3 Bioaccumulative potential**

131-57-7 Oxybenzone	
Bioconcentration 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 system.

Disposal must be made according to official regulations.

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

SECTION 14: Transport information

· **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 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.

· **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.

· **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

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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
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 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.***