



**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 flow**

· **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

methyl methacrylate

· **Hazard statements**

H317 May cause an allergic skin reaction.

· **Precautionary statements**

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

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

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

P321 Specific treatment (see on this label).

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	≥10-≤25%
CAS: 131-57-7 EINECS: 205-031-5	Oxybenzone Aquatic Acute 1, H400; Aquatic Chronic 2, H411	≥0.25-<1%
CAS: 80-62-6 EINECS: 201-297-1	methyl methacrylate Flam. Liq. 2, H225 Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	≥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**
 - **General information** Instantly remove any clothing soiled by the product.
 - **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**
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.
- **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).

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· 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**

Wear protective equipment. Keep unprotected persons away.

Please observe the additional instructions in the product's instructions for use.

· 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)

80-62-6 methyl 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**

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)

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sediment, dry weight, marine water	0.018 mg/Kg (not defined)
soil, dry weight	0.027 mg/Kg (not defined)
80-62-6 methyl methacrylate	
freshwater	0.94 mg/l (aqua)
	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**

Keep away from foodstuffs, beverages and food.

Instantly remove any soiled and impregnated garments.

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

Avoid contact with the eyes and skin.

· **Breathing equipment:** Not required.

· **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

Solvent resistant gloves

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 through 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:**

Different according to colour

· **Smell:**

Characteristic

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· Odour threshold: · Melting point/freezing point: · Boiling point or initial boiling point and boiling range · Flammability · Lower and upper explosion limit · Lower: · Upper: · Flash point: · Decomposition temperature: · SADT · pH · Viscosity: · Kinematic viscosity · dynamic: · Solubility · Water: · Partition coefficient n-octanol/water (log value) · Steam pressure: · Density and/or relative density · Density at 20 °C · Relative density · Vapour density	Not determined. Not determined Not determined Not applicable. Not determined. Not determined. >150 °C (109-16-0 triethylen glycol dimethacrylate) Not determined. Not determined. Not determined. Not determined. Not determined. Not determined. Not determined. Not determined. 1.8 g/cm³ Not determined. Not determined.
· 9.2 Other information · Appearance: · Form: · Important information on protection of health and environment, and on safety. · Self-inflammability: · Explosive properties: · Change in condition · Evaporation rate	No further relevant information available. Pasty Product is not selfigniting. Product is not explosive. Not determined.
· Information with regard to physical hazard classes · Explosives · Flammable gases · Aerosols · Oxidising gases · Gases under pressure · Flammable liquids · Flammable solids · Self-reactive substances and mixtures · Pyrophoric liquids · Pyrophoric solids · Self-heating substances and mixtures · Substances and mixtures, which emit flammable gases in contact with water · Oxidising liquids · Oxidising solids · Organic peroxides · Corrosive to metals	Void Void Void Void Void Void Void Void Void Void Void Void Void Void Void Void Void Void Void Void

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· **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	8300 mg/kg (rat)
Dermal	LD50	>2000 mg/kg (mouse)

80-62-6 methyl methacrylate

Oral	LD50	~7900 mg/kg (rat)
Dermal	LD50	>5000 mg/kg (rab) (OECD 402)
Inhalative	LC50/4 h	29.8 mg/l (rat)

- **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** Guinea-Pig Maximisation Test (OECD 406): negative
- **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	>1000 mg/l (daphnia)
LC50/96h	>1000 mg/l (fish)
ErC50 / 72 h	>1000 mg/l (algae)

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NOEC / 72h	1000 mg/l (algae) 1000 mg/l (daphnia)
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)
80-62-6 methyl methacrylate	
EC50/21d	49 mg/L (daphnia) (OECD 211)
EC50/48h	69 mg/l (daphnia) (EPA OTS 797.1300)
NOEC / 21d	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 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)
80-62-6 methyl methacrylate	
Biodegradation	94 % /14d (not defined) (OECD 301C)

- **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:** Avoid transfer into the environment.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
 - **Recommendation**
Small quantities can be polymerized by light and the cured solid material can be disposed of with the regular garbage. Larger quantities must be disposed of following the regulations of the local authorities.
 - **Uncleaned packagings:**
 - **Recommendation:** Disposal must be made according to official regulations.

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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**

- H225 Highly flammable liquid and vapour.
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- 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
- 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
- LD50: Lethal dose, 50 percent
- PBT: Persistent, Bioaccumulative and Toxic

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vPvB: very Persistent and very Bioaccumulative

Flam. Liq. 2: Flammable liquids – Category 2

Skin Irrit. 2: Skin corrosion/irritation – Category 2

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.**

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