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Safety Data Sheet according to HPR, Schedule 1

Printing date 11/16/2022

Reviewed on 11/16/2022

Tel.: +49 (0)800 4372522

1 Identification

- · Product identifier
 - · Trade name: Venus flow

- · Application of the substance / the mixture Dental filling material
- · Details of the supplier of the safety data sheet
 - Manufacturer/Supplier:

Kulzer GmbH

Leipziger Straße 2, 63450 Hanau (Germany)

· Information department:

Tel. +1 (800) 431-1785 Fax: +1 (800) 522-1545 e-mail: customer.servicehkna@kulzer-dental.com

Emergency telephone number:

Emergency CONTACT (24-Hour-Number) ID 105860: (domestic) 1 800 535 5053 or international (001) 352 323 3500

2 Hazard identification

Classification of the substance or mixture

Skin Sensitizer - Category 1 H317 May cause an allergic skin reaction.

- · Label elements
 - GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

Hazard pictograms



GHS07

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

triethylen glycol dimethacrylate methyl methacrylate

· Hazard statements

May cause an allergic skin reaction.

· Precautionary statements

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

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

If on skin: Wash with plenty of water.

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

Specific treatment (see on this label).

Wash contaminated clothing before reuse.

Dispose of contents/container in accordance with local/regional/national/international regulations.

- · Classification system
 - NFPA ratings for USA (scale 0-4)



Health = 0Fire = 1 Reactivity = 0

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· HMIS-Ratings (Scale 0-4)

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Health = 0*Fire* = 1 REACTIVITY 0 Reactivity = 0

· Other hazards -

3 Composition/Information on ingredients

- · Chemical characterization: Mixtures
 - **Description:** Composition based on methacrylates

_	erous components:	
109-16-0	triethylen glycol dimethacrylate	≥10- <i>≤</i> 25% w/w *
	Skin Sensitizer - Category 1B, H317	
80-62-6	methyl methacrylate	≥0,1-<0,2% w/w *
	Flammable Liquids - Category 2, H225 Skin Irritation - Category 2, H315; Skin Sensitizer - Category 1, H317; Specific Target Organ Toxicity - Single Exposure - Category 3, H335	
	al accomplishing range and with hald as a treat a second	

^{*} Actual concentration ranges are withheld as a trade secret.

4 First-aid measures

- · Description of first aid measures
 - General information Immediately remove any clothing soiled by the product.
 - After inhalation Supply fresh air; consult doctor in case of complaints.
 - After skin contact

Immediately 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 a doctor.

· After swallowing

Rinse out mouth and then drink plenty of water.

If symptoms persist consult doctor.

Information for doctor

· Most important symptoms and effects, both acute and delayed

No further relevant information available.

· Indication of any immediate medical attention and special treatment needed No further relevant information available.

5 Fire-fighting measures

- · Extinguishing media
 - Suitable extinguishing agents

CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant

Use fire fighting measures that suit the environment.

- · Special hazards arising from the substance or mixture No further relevant information available.
- Advice for firefighters
 - **Protective equipment:** No special measures required.

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[·] Additional information For the wording of the listed hazard phrases refer to section 16.



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· Additional information -

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6 Accidental release measures

- · Personal precautions, protective equipment and emergency procedures
- Wear protective equipment. Keep unprotected persons away.
- · Environmental precautions:

Do not allow product to reach sewage system or any water course.

Do not allow to penetrate the ground/soil.

Methods and material for containment and cleaning up:

Absorb with liquid binding material (diatomite, universal binders, for small amounts tissues).

Reference to other sections

See Section 13 for disposal information.

See Section 8 for information on personal protection equipment.

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7 Handling and storage

- · Handling
 - · 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.
- · Conditions for safe storage, including any incompatibilities
 - · Storage
 - · Requirements to be met by storerooms and receptacles: No special requirements.
 - · Information about storage in one common storage facility: Not required.
 - Further information about storage conditions: Keep cool, if possible (not above 25 °C).
- · Specific end use(s) No further relevant information available.

8 Exposure controls/ Personal protection

- · Additional information about design of technical systems: No further data; see item 7.
- · Control parameters
 - Components with limit 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.

- · Additional information: The lists that were valid during the creation were used as basis.
- · Exposure controls
 - Personal protective equipment
 - · General protective and hygienic measures

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

- Avoid contact with the eyes and skin. Breathing equipment: Not required.
- · Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

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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 protection: Tightly sealed goggles. • Body protection: Light weight protective clothing

9 Physical and chemical properties

nformation on basic physical and che · General Information	anical properties
· Appearance:	
··Form:	Pasty
· Color:	Different according to coloring
· Odor:	Characteristic
· Odor threshold:	Not determined.
· pH-value:	Not determined.
· Change in condition	
· Melting point/Melting range:	undetermined
· Boiling point/Boiling range:	undetermined
· Flash point:	>150 °C (>302 °F)
· Flammability (solid, gaseous)	Not applicable.
Decomposition temperature:	Not determined.
· Auto igniting:	Product is not selfigniting.
· Danger of explosion:	Product does not present an explosion hazard.
· Explosion limits:	
·Lower:	Not determined.
· Upper:	Not determined.
· Vapor pressure:	Not determined.
· Density at 20 °C (68 °F):	1,8 g/cm³ (15,021 lbs/gal)
· Relative density	Not determined.
· Vapor density	Not determined.
· Evaporation rate	Not determined.

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· Solubility in / Miscibility with · Water:	Not miscible or difficult to mix	
· Partition coefficient (n-octano	ol/water): Not determined.	
Viscosity: dynamic: kinematic:	Not determined. Not determined.	
Solvent content: VOC USA	0.0 g/l / 0.00 lb/gl	
· Other information	No further relevant information available.	

10 Stability and reactivity

- · Reactivity No further relevant information available.
- · Possibility of hazardous reactions No dangerous reactions known
- · Conditions to avoid No further relevant information available.
- · Incompatible materials: No further relevant information available.
- Hazardous decomposition products: none
- · Additional information:

Product might polymerize after considerable exceeding of recommended storage time or temperature.

11 Toxicological information

Information on toxicological effects Acute toxicity:

· LD/LC50 values that are relevant for classification:			
109-16-0 t	109-16-0 triethylen glycol dimethacrylate		
Oral	LD50	8300 mg/kg (rat)	
Dermal	LD50	>2000 mg/kg (mouse)	
80-62-6 m	80-62-6 methyl methacrylate		
Oral	LD50	~7900 mg/kg (rat)	
Dermal	LD50	>5000 mg/kg (rab) (OECD 402)	
Inhalative		29,8 mg/l (rat)	

- · Primary irritant effect:
 - on the skin: Irritant to skin and mucous membranes.
 - on the eye: Irritating effect.
- Sensitization: Guinea-Pig Maximisation Test (OECD 406): negative
- Additional toxicological information:
 - · Carcinogenic categories

· IARC (International Agency for Research on Cancer)	
80-62-6 methyl methacrylate	3
NTD (Nettonal Taria la una Brasana)	

· NTP (National Toxicology Program)

None of the ingredients is listed.

· Reproductive toxicity Based on available data, the classification criteria are not met.

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Toxicity	
Aquatic to	oxicity:
65997-17-3 G	Glaspulver
EC50/72h	>1000 mg/l (daphnia)
LC50/96h	>1000 mg/l (fish)
ErC50 / 72 h	>1000 mg/l (algae)
NOEC / 72h	1000 mg/l (algae)
	1000 mg/l (daphnia)
	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)
80-62-6 meth	nyl methacrylate
EC50/21d	49 mg/L (daphnia) (OECD 211)
EC50/48h	69 mg/l (daphnia) (EPA OTS 797.1300)
	37 mg/l (daphnia) (OECD 211)
ErC50 / 72 h	>110 mg/l (algae) (OECD 201)
	110 mg/l (algae) (OECD 201)
	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)
Persistence	and degradability
	thylen glycol dimethacrylate
biodegradabi	lity 85 % /28d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)

- Behavior in environmental systems:
 Bioaccumulative potential No further relevant information available.
 Mobility in soil No further relevant information available.
 Additional ecological information:
 General notes: Avoid transfer into the environment.
- Results of PBT and vPvB assessment
 - · PBT: Not applicable.
 - vPvB: Not applicable.
- · Other adverse effects No further relevant information available.



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13 Disposal considerations

- · 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.

4 Transport information		
UN-Number DOT/TDG, ADR, ADN, IMDG, IATA	Void	
· UN proper shipping name · DOT/TDG, ADN, IMDG, IATA · ADR	Void Void	
· Transport hazard class(es)		
DOT, ADR, ADN, IMDG, IATA Class	Void	
Packing group DOT/TDG, ADR, IMDG, IATA	Void	
· Environmental hazards: · Marine pollutant:	No	
· Special precautions for user	Not applicable.	
· Transport in bulk according to Annex I MARPOL73/78 and the IBC Code	l of Not applicable.	
· Transport/Additional information:	-	
· UN "Model Regulation":	Void	

15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture No further relevant information available.
 - · Sara
 - SARA Section 355 (extremely hazardous substances)

None of the ingredients is listed.

· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

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.

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H317 May cause an allergic skin reaction. H335 May cause respiratory irritation.

Date of the latest revision of the safety data sheet 11/16/2022

· Abbreviations and acronyms:

IMDG: International Maritime Code for Dangerous Goods DOT: US Department of Transportation

DOT: US Department of Transportation
IATA: International Air Transport Association
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)
NFPA: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)
VOC: Volatile Organic Compounds (USA, EU)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
PVB: very Persistent and very Bioaccumulative

vPvB: very Persistent and very Bioaccumulative

* Data compared to the previous version altered.