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

Printing date 16.12.2019 Version number 3 Revision: 21.11.2019

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

- · 1.1 Product identifier
 - · Trade name: VENUS Diamond 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)

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 Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

- · 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



- GHS07
- · Signal word Warning
- · Hazard statements

H315 Causes skin irritation.

H319 Causes serious eye irritation.

Precautionary statements

P280 Wear protective gloves / eye protection / face protection.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove

contact lenses, if present and easy to do. Continue rinsing.

P321 Specific treatment (see on this label).

P362+P364 Take off contaminated clothing and wash it before reuse.
P332+P313 If skin irritation occurs: Get medical advice/attention.
P337+P313 If eye irritation persists: Get medical advice/attention.

· Additional information:

Contains triethylen glycol dimethacrylate. May produce an allergic reaction.

- · 2.3 Other hazards -
 - · Results of PBT and vPvB assessment
 - · PBT: Not applicable.
 - · vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

· 3.2 Chemical characterisation: Mixtures

· Description: -

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· Dangerous components:		
CAS: 13760-80-0	ytterbium trifluoride	10-25%
EINECS: 237-354-2	Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	
CAS: 109-16-0	triethylen glycol dimethacrylate	< 1%
EINECS: 203-652-6	Skin Sens. 1B, H317	
Reg.nr.: 01-2119969287-21-0000	,	

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
 - General information No special measures required.
 - After inhalation Supply fresh air; consult doctor in case of symptoms.
 - After skin contact Instantly wash with water and soap and rinse thoroughly.
 - · After eye contact Rinse opened eye for several minutes under running water.
 - · 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 Not required.
- 6.2 Environmental precautions: No special measures required.
- 6.3 Methods and material for containment and cleaning up: Collect mechanically.
- · 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.

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- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions:

Store under dry 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

Notreq	uncu.		
· <u>I</u>	DNELs		
41637-38-	1 Ethoxyli	ertes bispheno	l A dimethacrylat
Oral	ge.pop., l.t	e, syst.	0.5 mg/Kg (nd)
Dermal	worker ind	ustr., l.te., syst.	2 mg/Kg/d (nd)
	ge.pop., l.t	e, syst.	1 mg/Kg/d (nd)
Inhalative	worker ind	ustr., l.te., syst.	3.52 mg/m3 (nd)
	ge.pop., l.t	e, syst.	0.87 mg/m3 (nd)
109-16-0 t	riethylen g	glycol dimethad	crylate
Dermal	worker ind	ustr., l.te., syst.	13.9 mg/Kg/d (nd)
Inhalative	worker ind	ustr., I.te., syst.	48.5 mg/m3 (nd)
· I	PNECs		
109-16-0 t	riethylen g	glycol dimethad	crylate
marine wa	ter	0.0164 mg/l (no	d)
sedim., dv	, fre.wat.	1.85 mg/Kg (nd	()
sedim., dพ	ı, mar.wat.	0.185 mg/Kg (n	nd)
soil,dw		0.274 mg/Kg (n	nd)

[·] Additional information: The lists that were valid during the compilation were used as basis.

· 8.2 Exposure controls

Personal protective equipment

- General protective and hygienic measures
- Wash hands during breaks and at the end of the work.
- · Breathing equipment: Not required.
- Protection of hands:

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.

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· 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:

· kinematic:

· 9.2 Other information

Butyl rubber, BR
Nitrile rubber, NBR
• Eye protection: Safety glasses
• Body protection: Light weight protective clothing

SECTION 9: Physical and chem	ical properties	
9.1 Information on basic physical and General Information Appearance:	chemical properties	
Form:	Pasty	
· Colour:	White	
Colour.	Yellowish	
· Smell:	Odourless	
Odour threshold:	Not determined.	
· pH-value:	Not determined.	
Change in condition		
Melting point/freezing point:	Not determined	
Initial boiling point and boiling i	range: Not determined	
· Flash point:	> 100 °C	
Inflammability (solid, gaseous)	Not applicable.	
Decomposition temperature:	Not determined.	
· Self-inflammability:	Product is not selfigniting.	
· Explosive properties:	Product is not explosive.	
· Critical values for explosion:		
· Lower:	Not determined.	
· Upper:	Not determined.	
· Steam pressure:	Not determined.	
· Density at 20 °C	1.9 g/cm³	
Relative density	Not determined.	
· Vapour density	Not determined.	
· Evaporation rate	Not determined.	
· Solubility in / Miscibility with		
· Water:	Not miscible or difficult to mix	
· Partition coefficient: n-octanol/wat	er: Not determined.	
· Viscosity:		
· dynamic:	Not determined.	
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Not determined.

No further relevant information available.



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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: -

SECTION 11: Toxicological information

- · 11.1 Information on toxicological effects
 - · Acute toxicity Based on available data, the classification criteria are not met.

· LD/LC50 values that are relevant	for classification:

41637-38-1 Ethoxyliertes bisphenol A dimethacrylat

Oral LD50 >2,000 mg/kg (rat)
Dermal LD50 >2,000 mg/kg (rat)

41137-60-4 diurethandimethacrylate

Oral | LD50 | >5,000 mg/kg (rat)

109-16-0 triethylen glycol dimethacrylate

Oral LD50 >5,000 mg/kg (rat)
Dermal LD50 >2,000 mg/kg (mouse)

- · Primary irritant effect:
 - · Skin corrosion/irritation

Causes skin irritation.

· Serious eve damage/irritation

Causes serious eye irritation.

Respiratory or skin sensitisation

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

- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- 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.

SECTION 12: Ecological information

· 12.1 Toxicity

· Aquatic	toxicity:
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41637-38-1 Ethoxyliertes bisphenol A dimethacrylat

EC50/72h >100 mg/l (algae) (OECD 201) EC50/48h >100 mg/l (daphnia) (OECD 202) LC50/96h >100 mg/l (fish) (OECD 203)

NOEC 28d 14.3 mg/l (bacteria)

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109-16-0 triethylen glycol dimethacrylate

EC50/72h >100 mg/l (algae)

- 12.2 Persistence and degradability No further relevant information available.
- · 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
 - · Additional ecological information:
 - · General notes: Avoid transfer into the environment.
- · 12.5 Results of PBT and vPvB assessment
 - · PBT: Not applicable.
 - · vPvB: Not applicable.
- 12.6 Other adverse effects No further relevant information available.

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.

14.1 UN-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, IMĎĞ, IATA	Void	
14.5 Environmental hazards:		
· Marine pollutant:	No	
14.6 Special precautions for user	Not applicable.	
14.7 Transport in bulk according to Annex	c II of	
Marpol and the IBC Code	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
 - · REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

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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

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning

the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods

INDS: International Mantanic Code to 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 (REACH)

PNEC: Predicted No-Effect Concentration (REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
Skin Sens. 1B: Skin sensitisation – Category 1B
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

* Data compared to the previous version altered.