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

Printing date 16.11.2022 Version number 4 (replaces version 3) Revision: 16.11.2022

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

- · 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)

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

H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation. Skin Sens. 1 H317 May cause an allergic skin reaction.

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

· 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-determining components of labelling:

7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate

triethylen glycol dimethacrylate

· Hazard statements

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

H412 Harmful to aquatic life with long lasting effects.

· Precautionary statements

P273 Avoid release to the environment.

P280 Wear protective gloves / protective clothing.

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.

Additional information:

Contains isocyanates. May produce an allergic reaction.

· 2.3 Other hazards -

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

SECTION 3: Composition/information on ingredients

- · 3.2 Mixtures
 - Description: -

Description.		
· Dangerous components:		
CAS: 41637-38-1 EC number: 609-946-4 Reg.nr.: 01-2119980659-17-xxx.	bisphenol A polyethnylene glycol diether dimethacrylate Aquatic Chronic 4, H413	≥10-<25%
CAS: 13760-80-0 EINECS: 237-354-2	ytterbium trifluoride Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	≥10-<20%
CAS: 72869-86-4 EINECS: 276-957-5 Reg.nr.: 01-2120751202-68-xxx.	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12- diazahexadecane-1,16-diyl bismethacrylate Aquatic Chronic 2, H411 Skin Sens. 1B, H317 EUH204	≥10-<25%
CAS: 131-57-7 EINECS: 205-031-5	Oxybenzone Aquatic Acute 1, H400; Aquatic Chronic 2, H411	≥0.25-<1%
CAS: 21245-02-3 EINECS: 244-289-3 Reg.nr.: 01-2120766649-35- XXXX	2-ethylhexyl 4-(dimethylamino)benzoate Repr. 1B, H360	<0.3%

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.

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- 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.

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 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

· DNI	ELs	
41637-38-	1 bisphenol A polyethnylene glycol di	ether dimethacrylate
Oral	general population, long term, systemic	5 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	140 mg/Kg/d (not defined)
	general population, long term, systemic	50 mg/Kg/d (not defined)
Inhalative	worker industrial, long term, systemic	98.7 mg/m3 (not defined)
	general population, long term, systemic	17.4 mg/m3 (not defined)
72869-86-	4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo bismethacrylate	o-3,14-dioxa-5,12-diazahexadecane-1,16-diyl
Oral	general population, long term, systemic	0.3 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	1.3 mg/Kg/d (not defined)
	general population, long term, systemic	0.7 mg/Kg/d (not defined)
Inhalative	worker industrial, long term, systemic	3.3 mg/m3 (not defined)
	general population, long term, systemic	0.6 mg/m3 (not defined)
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	Oxybenzone			
Oral	general population, long	-	,	
Dermal worker industrial, long ter		-	39 mg/Kg/d (not defined)	
general population, long to				
Inhalative	worker industrial, long te	•	27.7 mg/m3 (not defined)	
general population, long te			6.8 mg/m3 (not defined)	
109-16-0 t	riethylen glycol dimetha			
Oral	general population, long	term, systemic	8.33 mg/Kg (not defined)	
Dermal	worker industrial, long te	rm, systemic	13.9 mg/Kg/d (not defined)	
	general population, long	term, systemic	8.33 mg/Kg/d (not defined)	
Inhalative	worker industrial, long te	rm, systemic	48.5 mg/m3 (not defined)	
	general population, long	term, systemic	14.5 mg/m3 (not defined)	
· PNE	Cs			
72869-86-	4 7,7,9(or 7,9,9)-trimetl bismethacrylate	hyl-4,13-dioxo	o-3,14-dioxa-5,12-diazahexadecane-1,16-diyl	
freshwater		0.01 mg/l (not defined)		
marine wa	ter	0.001 mg/l (not defined)		
sewage treatment plant		3.61 mg/l (not defined)		
,		4.56 mg/Kg (not defined)		
sediment,			,	
soil, dry we		0.91 mg/Kg (not defined)		
	Oxybenzone		,	
freshwater		0.00067 mg/l (not defined)		
marine wa	ter	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	· · · · · · · · · · · · · · · · · ·		
soil, dry weight		0.013 mg/Kg (not defined)		
109-16-0 triethylen glycol dimetha		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 (0.018 mg/Kg (not defined)	
soil, dry weight		0.027 mg/Kg (i	not defined)	

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

· 8.2 Exposure controls

- 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 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

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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

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

General Information

Physical state
 Colour:
 White
 Yellowish
 Odourless

· Odour threshold:
· Melting point/freezing point:

Not determined

Not determined

Boiling point or initial boiling point and

boiling range
Not determined
Plammability
Not applicable.

· Lower and upper explosion limit

Lower: Not determined.
Upper: Not determined.

Flash point: >100 °C (72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-

1,16-diyl bismethacrylate)

Decomposition temperature: Not determined.

·SADT

· **pH** Not determined.

· Viscosity:

Kinematic viscositydynamic:Not determined.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 at 20 °C 1.9 g/cm³
• Relative density Not determine

Relative density
Vapour density
Not determined.
Not determined.

• 9.2 Other information No further relevant information available.

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Appearance:	
Form:	Pasty
Important information on protection of	-
health and environment, and on safety.	

Self-inflammability:
Explosive properties:
Change in condition

Product is not selfigniting.
Product is not explosive.

• Evaporation rate Not determined.

· Information with regard to physical hazard classes

40000	
· 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
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: -

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:

41637-38-1 bisphenol A polyethnylene glycol diether dimethacrylate

Oral LD50 >2,000 mg/kg (rat) (OECD 423)
Dermal LD50 >2,000 mg/kg (rat) (OECD 402)

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6 4 7	(Contd. of page 6)
60-4 7, i bis	7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl smethacrylate
	>5,000 mg/kg (rat) (OECD 401)
LD50	>2,000 mg/kg (rat) (OECD 402)
7 Oxyl	benzone
	>12,800 mg/kg (rat) (OECD 401)
LD50	>16,000 mg/kg (rabbit) (OECD 402)
0 trietl	nylen glycol dimethacrylate
LD50	8,300 mg/kg (rat)
LD50	>2,000 mg/kg (mouse)
2-3 2-0	ethylhexyl 4-(dimethylamino)benzoate
LD50	14,900 mg/kg (rat)
	bis LD50 LD50 7 Oxyl LD50 LD50 0 trietl LD50 LD50 2-3 2-0

- · Skin corrosion/irritation
- Causes skin irritation.
- Serious eye damage/irritation Causes serious eye irritation.

- 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

21245-02-3 2-ethylhexyl 4-(dimethylamino)benzoate

Oral NOAEL (Fertility) 50 mg/kg/d /64 d (rat) (OECD 421)

- 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 Loxicity	/
· Aquatic t	oxicity:
41637-38-1 k	pisphenol A polyethnylene glycol diether dimethacrylate
EC50/72h	>100 mg/l (algae) (OECD 201)
LL50/96h	>100 mg/L (fish) (OECD 203)
EL50/48h	>100 mg/L (daphnia) (OECD 202)
EL50/72h	>100 mg/L (algae) (OECD 201)
NOEC / 21d	≥22.4 mg/l (daphnia) (OECD 211)
NOEC 28d	14.3 mg/l (bacteria)
NOELR	100 mg/L /48h (daphnia) (OECD 202)
	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl
k	pismethacrylate
EC50/48h	>1.2 mg/l (daphnia) (OECD 202)
LC50/96h	10.1 mg/l (fish) (OECD 203)
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ErC50 / 72 h	>0.68 mg/l (algae) (OECD 201)
NOEC / 72h	0.21 mg/l (algae) (OECD 201)
131-57-7 Ox	ybenzone
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)
109-16-0 trie	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)
· 12.2 Persiste	ence and degradability
41637-38-1 k	bisphenol A polyethnylene glycol diether dimethacrylate
Biodegradation	on 24 % /28d (not defined) (OECD 301D)
	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate
Biodegradati	on 22 % /28d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)
131-57-7 Ox	ybenzone
	on 60-70 % /28d (not defined)
109-16-0 trie	thylen glycol dimethacrylate
Biodegradati	on 85 % /28d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)
· 12.3 Bioaccı	umulative potential
131-57-7 Ox	
Bloconcentra	ation factor (BCF) >33-<160 (fish) (OECD 305)

concentration 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
 - · 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.

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Uncleaned packagings:

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

14.1 UN number or ID number	Void	
· 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
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.
- H335 May cause respiratory irritation.
- H360 May damage fertility or the unborn child.
- H400 Very toxic to aquatic life.
- H411 Toxic to aquatic life with long lasting effects.
- H413 May cause long lasting harmful effects to aquatic life.
- EUH204 Contains isocyanates. May produce an allergic reaction.
- Date of previous version: 12.05.2021
- Version number of previous version: 3

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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 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 (REACH)
PNEC: Predicted No-Effect Concentration (REACH)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent Bioaccumulative and Toxic

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

Eye Irrit. 2: Serious eye damage/eye irritation — Category 2
Skin Sens. 1: Skin sensitisation — Category 1B
Repr. 1B: Reproductive toxicity — 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
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard — Category 3
Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard — Category 4
**Pote compared to the previous version of the serious serious extension extension

* Data compared to the previous version altered.