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

Printing date 06.06.2021

Version number 4

Revision: 06.06.2021

 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 3.3 Details of the supplier of the safety data sheet · Manufacturer/Supplier: Kulzer GmbH Leipziger Straße 2, 63450 Hanau (Germany) Tel.: +49 (0)800 437252 ·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 according to Regulation (EC) No 1272/2008 Skin Irrit. 2 H315 Causes skin 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 bictograms	SECTION 1: Ider undertaking	ntification of the substance/	mixture and of the company
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· Results of PBT and vPvB assessment

• **PBT:** Not applicable.

• **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

3.2 Chemical characterisation: Mixtures

Description: -		
 Dangerous components: 		
CAS: 41637-38-1 EC number: 609-946-4 Reg.nr.: 01-2119980659-17- XXXX	(1-methylethylidene)bis(4,1-phenyleneoxy-2,1- ethanediyloxy-2,1-ethanediyl) bismethacrylate Aquatic Chronic 4, H413	<i>≥</i> 10-<25%
CAS: 13760-80-0 EINECS: 237-354-2	ytterbium trifluoride Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	<i>≥</i> 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	<i>≥</i> 10-<25%
CAS: 131-57-7 EINECS: 205-031-5	Oxybenzone Aquatic Acute 1, H400; Aquatic Chronic 2, H411	<i>≥</i> 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.
- 5.3 Advice for firefighters

Protective equipment: No special measures required.

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· 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.

· DNELs

41637-38-1 (1-methylethylidene)bis(4,1-phenyleneoxy-2,1-ethanediyloxy-2,1-ethanediyl) bismethacrylate
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Oral	ge.pop., l.te, syst.	0.5 mg/Kg (nd)
Dermal	worker industr., l.te., syst.	2 mg/Kg/d (nd)
	ge.pop., l.te, syst.	1 mg/Kg/d (nd)
Inhalative	worker industr., l.te., syst.	3.52 mg/m3 (nd)
	ge.pop., l.te, syst.	0.87 mg/m3 (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.

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(Contd. of page 3) 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.

· 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 protection: Safety glasses
- · Body protection: Light weight protective clothing

SECTION 9: Physical and chem	ical properties	
9.1 Information on basic physical and	chemical properties	
General Information		
· Appearance:	_ /	
· Form:	Pasty	
· Colour:	White	
· Smell:	Yellowish 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.	



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Solubility in / Miscibility with Water:	Not miscible or difficult to mix	
· Partition coefficient: n-octanol	/water: Not determined.	
· Viscosity: · dynamic: · kinematic:	Not determined. Not determined.	
· 9.2 Other information	No further relevant information available.	

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 (1-methylethylidene)bis(4,1-phenyleneoxy-2,1-ethanediyloxy-2,1-ethanediyl) bismethacrylate

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

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

72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate

Oral LD50 >5,000 mg/kg (rat) (OECD 401)

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

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

Oral LD50 14,900 mg/kg (rat)

· Primary irritant effect:

Skin corrosion/irritation

Causes skin irritation.

Serious eye damage/irritation

Causes serious eye irritation.

 Respiratory or skin sensitisation May cause an allergic skin reaction.

· Additional toxicological information:

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.

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· 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.

· 12.1 Toxici	íty l
· Aquatic	toxicity:
41637-38-1	(1-methylethylidene)bis(4,1-phenyleneoxy-2,1-ethanediyloxy-2,1-ethanediyl) bismethacrylate
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)
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate
LC50/96h	10.1 mg/l (fish)
12.3 Bioaco 12.4 Mobili Addition Gene 12.5 Result PBT: No vPvB: N	atence and degradability No further relevant information available. cumulative potential No further relevant information available. ity in soil No further relevant information available. nal ecological information: eral notes: Avoid transfer into the environment. its of PBT and vPvB assessment ot applicable. lot applicable. adverse effects No further relevant information available.

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	



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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 Transport in bulk according to Ann Marpol and the IBC Code	ex II of 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** 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. Abbreviations and acronyms: ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement ADR: Accord relating au transport international des marchandises dangere Concerning the International Carriage of Dangerous Goods by Road) IMDG: International Miritime 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) 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. 1: Skin sensitisation – Category 1 Skin Sens. 1B: Skin sensitisation - Category 1B Repr. 1B: Reproductive toxicity - Category 1B STOT SE 3: Specific target organ toxicity (single exposure) - Category 3 (Contd. on page 8) GB



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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 • * Data compared to the previous version altered.

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