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Tel.: +49 (0)800 4372522

Safety Data Sheet acc. to OSHA HCS

Printing date 11/16/2022 Reviewed on 11/16/2022

1 Identification

- · Product identifier
 - Trade name: VENUS Diamond 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(s) identification

Classification of the substance or mixture

Skin Irritation 2 H315 Causes skin irritation.

Eye Irritation 2A H319 Causes serious eye irritation.

Sensitization - Skin 1 H317 May cause an allergic skin reaction. Toxic to Reproduction 1B H360 May damage fertility or the unborn child.

· Label elements

GHS label elements

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

Hazard pictograms





GHS07 GHS08

· Signal word Danger

· Hazard-determining components of labeling:

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

2-ethylhexyl 4-(dimethylamino)benzoate

Hazard statements

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

May damage fertility or the unborn child.

Precautionary statements

Avoid release to the environment.

Wear protective gloves / protective clothing.

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Specific treatment (see on this label).

Take off contaminated clothing and wash it before reuse.

If skin irritation occurs: Get medical advice/attention.

If eye irritation persists: Get medical advice/attention.

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· Classification system

NFPA ratings for USA (scale 0-4)



· HMIS-Ratings (Scale 0-4)



Health = 2Fire = 1 REACTIVITY 0 Reactivity = 0

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

3 Composition/information on ingredients

· Chemical characterization: Mixtures

Description: -

2000			
	· Dangerous components:		
	13760-80-0	ytterbium trifluoride	≥10-<20%
		Skin Irritation 2, H315; Eye Irritation 2A, H319; Specific Target Organ Toxicity - Single Exposure 3, H335	
	72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate	10-25%
		Sensitization - Skin 1B, H317	
	21245-02-3	2-ethylhexyl 4-(dimethylamino)benzoate	≥0.1-<1%
		Toxic to Reproduction 1B, H360	

4 First-aid measures

- · Description of first aid measures
 - General information No special measures required.
 - · After inhalation Supply fresh air; consult doctor in case of complaints.
 - After skin contact Immediately 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.

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.



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5 Fire-fighting measures

- Extinguishing media
 - · Suitable extinguishing agents

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

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.
- · Additional information -

6 Accidental release measures

- · Personal precautions, protective equipment and emergency procedures Not required.
- Environmental precautions: No special measures required.
- Methods and material for containment and cleaning up: Pick up mechanically.
- 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 No special measures required.
 - 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:

Store in dry conditions.

Keep cool, if possible (not above 25 °C).

Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

- · 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

Wash hands before breaks and at the end of work.

· Breathing equipment: Not required.

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· 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.

· 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: Safety glasses

· Body protection: Light weight protective clothing

9 Physical and chemical propert

Information on basic physical and chemical properties General Information			
· App <u>e</u> arance:	5 (
· Form:	Pasty		
· Color:	White		
· Odor:	Yellowish Odorless		
· Odor threshold:	Not determined.		
· pH-value:	Not determined.		
· Change in condition · Melting point/Melting range: · Boiling point/Boiling range:	undetermined undetermined		
· Flash point:	>100 °C (>212 °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):	1.9 g/cm³ (15.8555 lbs/gal)		
· Relative density	Not determined.		
· Vapor density	Not determined.		

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Not determined. · Evaporation rate

· Solubility in / Miscibility with

· Water: Not miscible or difficult to mix

· Partition coefficient (n-octanol/water): Not determined.

· Viscosity:

· dynamic: Not determined. · kinematic: Not determined.

No further relevant information available. · Other information

10 Stability and reactivity

- · Reactivity No further relevant information available.
- · Possibility of hazardous reactions No dangerous reactions known

41637-38-1 bisphenol A polyethnylene glycol diether dimethacrylate

- · Conditions to avoid No further relevant information available.
- Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: none
- · Additional information: -

11 Toxicological information

· Information on toxicological effects

· Acute toxicity: · LD/LC50 values that are relevant for classification:

١	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-diazahexadecan bismethacrylate			
	Oral	LD50	>5,000 mg/kg (rat) (OECD 401)
	Dermal	LD50	>2,000 mg/kg (rat) (OECD 402)
	131-57-	7 Oxyl	benzone

LD50 >12,800 mg/kg (rat) (OECD 401) Oral Dermal LD50 >16,000 mg/kg (rabbit) (OECD 402)

109-16-0 triethylen glycol dimethacrylate

LD50 8,300 mg/kg (rat)

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

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

Oral LD50 14,900 mg/kg (rat)

Primary irritant effect:

on the skin: No irritant effect. on the eye: No irritating effect.

· Sensitization: No sensitizing effects known.

Additional toxicological information:

The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:

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When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

· Carcinogenic categories			
· IARC (International Agency for Research on Cancer)			
7631-86-9 silicon dioxide, chemically prepared	3		
128-37-0 2,6-di-tert-butyl-p-cresol	3		
· NTP (National Toxicology Program)			
None of the ingredients is listed.			
· OSHA-Ca (Occupational Safety & Health Administration)			
None of the ingredients is listed.			
· Reproductive toxicity			
21245-02-3 2-ethylhexyl 4-(dimethylamino)benzoate			
Oral NOAEL (Fruchtbarkeit) 50 mg/kg/d /64 d (rat) (OECD 421)			

12 Ecological information

· Toxicity

Toxicity			
· Aquatic toxicity:			
41637-38-1 bisphenol 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)			
72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diy			
bismethacrylate			
EC50/48h >1.2 mg/l (daphnia) (OECD 202)			
LC50/96h 10.1 mg/l (fish) (OECD 203)			
ErC50 / 72 h >0.68 mg/l (algae) (OECD 201)			
NOEC / 72h 0.21 mg/l (algae) (OECD 201)			
131-57-7 Oxybenzone			
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 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)			
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NOEC / 72h | 18.6 mg/l (algae) (OECD 201) EbC50 / 72h | 72.8 mg/l (algae) (OECD 201)

Develotes and desired bility

Persistence and degradability

41637-38-1 bisphenol A polyethnylene glycol diether dimethacrylate

biodegradability 24 % /28d (not defined) (OECD 301D)

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

biodegradability 22 % /28d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)

131-57-7 Oxybenzone

biodegradability 60-70 % /28d (not defined)

109-16-0 triethylen glycol dimethacrylate

biodegradability 85 % /28d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)

· Behavior in environmental systems:

· Bioaccumulative potential

131-57-7 Oxybenzone

Biokonzentrationefaktor (BCF) | >33-<160 (fish) (OECD 305)

- · 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.

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.

· UN-Number		
· DOT, ADR, ADN, IMDG, IATA	Void	
UN proper shipping name DOT, ADR, ADN, IMDG, IATA	Void	
· Transport hazard class(es)	VOIG	
DOT, ADR, ADN, IMDG, IATA		
Class	Void	
· Packing group		
· DOŤ, ĂDR, IMDG, IATA	Void	
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Environmental hazards: Marine pollutant:	No	
· Special precautions for user	Not applicable.	
Transport in bulk according to Annex MARPOL73/78 and the IBC Code	II 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 Section 355 (extremely hazardous substances)

None of the ingredients is listed.

SARA Section 313 (specific toxic chemical listings)

None of the ingredients is listed.

- Proposition 65
 - Prop 65 Chemicals known to cause cancer

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

- · Cancerogenity categories
 - EPA (Environmental Protection Agency)

None of the ingredients is listed.

· TLV (Threshold Limit Value)

128-37-0 2,6-di-tert-butyl-p-cresol

A4

· NIOSH-Ca (National Institute for Occupational Safety and Health)

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

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.

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Date of preparation / last revision 11/16/2022

Abbreviations and acronyms:

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

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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic VPVB: very Persistent and very Bioaccumulative NIOSH: National Institute for Occupational Safety OSHA: Occupational Safety & Health TLV: Threshold Limit Value PEL: Permissible Exposure Limit REL: Recommended Exposure Limit

Skin Irritation 2: Skin corrosion/irritation – Category 2
Eye Irritation 2A: Serious eye damage/eye irritation – Category 2A

Sensitization - Skin 1: Skin sensitisation - Category 1
Sensitization - Skin 1: Skin sensitisation - Category 1
Sensitization - Skin 1B: Skin sensitisation - Category 1B
Toxic to Reproduction 1B: Reproductive toxicity - Category 1B
Specific Target Organ Toxicity - Single Exposure 3: Specific target organ toxicity (single exposure) - Category 3

* Data compared to the previous version altered.

US