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Safety Data Sheet acc. to OSHA HCS

Printing date 11/28/2017

Reviewed on 11/28/2017

Tel.: +49 (0)800 4372522

1 Identification

- · Product identifier
 - · Trade name: Venus Diamond
 - · 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)

GBK/Infotrac ID 105860: (domestic) 1 800 535 5053 or international (001) 352 323 3500

2 Hazard(s) identification

· Classification of the substance or mixture

Skin Sens. 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:

2-Propenoic acid, (octahydro-4,7-methano-1H-indene-5 -diyl)bis(methyleneiminocarbonyloxy-2,1-ethanediyl) ester

triethylen glycol dimethacrylate

· Hazard statements

May cause an allergic skin reaction.

Precautionary statements
 Avoid breathing dust/fume/gas/mist/vapors/spray

Wear protective gloves.

If on skin: Wash with plenty of water.

Specific treatment (see on this label).

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

Wash contaminated clothing before reuse.

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



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· HMIS-Ratings (Scale 0-4)

HEALTH 0
FIRE 1
REACTIVITY 0

Health = 0 Fire = 1 Reactivity = 0

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

3 Composition/information on ingredients

- · Chemical characterization: Mixtures
 - · Description: -

 Dangerous components:			
2-Propenoic acid, (octahydro-4,7-methano-1H-indene-5 -diyl) bis(methyleneiminocarbonyloxy-2,1-ethanediyl) ester Skin Sens. 1, H317	10-25%		
triethylen glycol dimethacrylate	0-5%		
Skin Sens. 1B, H317			

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

4 First-aid measures

- · Description of first aid measures
 - · 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.

Seek immediate medical advice.

- · 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 foam.

Use fire fighting measures that suit the environment.

· Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

- Advice for firefighters
 - · Protective equipment: No special measures required.
- · Additional information -

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6 Accidental release measures

- Personal precautions, protective equipment and emergency procedures Not required.
- · Environmental precautions: Dilute with plenty of water.
- Methods and material for containment and cleaning up:

Absorb with liquid binding material (diatomite, universal binders, for small amounts tissues). Send for recovery or disposal in suitable receptacles.

Reference to other sections

See Section 7 for information on safe handling See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7 Handling and storage

- · Handling
 - Precautions for safe handling

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: None.
- · 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.

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

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

- · Breathing equipment: Not required.
- Protection of hands:

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

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

If skin contact cannot be avoided, protective gloves are recommended to avoid possible sensitization.

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

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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 properties

31 hysical and chemical propertie			
Information on basic physical and che General Information Appearance:			
Form:	Pasty		
· Color:	White		
	Yellowish		
· Odor:	Odorless		
· Odor threshold:	Not determined.		
· pH-value:	Not determined.		
Change in condition			
· Melting point/Melting range:	undetermined		
· Boiling point/Boiling range:	undetermined		
<u> </u>			
· Flash point:	> 165 °C (>329 °F)		
· Flammability (solid, gaseous)	Not applicable.		
· Ignition temperature:			
 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):	2,23 g/cm³ (18.60935 lbs/gal)		
Relative density	Not determined.		
· Vapor density	Not determined.		
· Evaporation rate	Not determined.		
<u> </u>			
· Solubility in / Miscibility with	Not missible or difficult to mix		
· Water:	Not miscible or difficult to mix		
· Partition coefficient (n-octanol/wate	er): Not determined.		
· Viscosity:			
· dynamic:	Not determined.		
· kinematic:	Not determined.		
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· 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: -

11 Toxicological information

- · Information on toxicological effects
 - · Acute toxicity:
 - · LD/LC50 values that are relevant for classification:

861437-11-82-Propenoic acid, (octahydro-4,7-methano-1H-indene-5 -diyl) bis(methyleneiminocarbonyloxy-2,1-ethanediyl) ester

LD50 >2000 mg/kg (rat)

109-16-0 triethylen glycol dimethacrylate

LD50 > 5000 mg/kg (rat)

Dermal LD50 > 2000 mg/kg (mouse)

- · Primary irritant effect:
 - on the skin: No irritant effect.
- on the eye: No irritating effect.Sensitization: Sensitization possible through skin contact.
- · Additional toxicological information: Irritant
 - · Carcinogenic categories

· IARC (International	Agency	for Research	h on C	Cancer)
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7631-86-9 silicon dioxide, chemically prepared

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

3

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· NTP (National Toxicology Program)

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

12 Ecological information

- · Toxicity
 - · Aquatic toxicity:

861437-11-82-Propenoic acid, (octahydro-4,7-methano-1H-indene-5 -diyl) bis(methyleneiminocarbonyloxy-2,1-ethanediyl) ester

EC50/48h 24.9 mg/l (daphnia)

109-16-0 triethylen glycol dimethacrylate

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

· Persistence and degradability No further relevant information available.

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- · Behavior in environmental systems:
 - Bioaccumulative potential No further relevant information available.
 Mobility in soil No further relevant information available.
- · Additional ecological information:
 - General notes:

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

Danger to drinking water if even small quantities leak into the ground.

- · 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

- · 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)		
· DOT, ADR, ADN, IMDG, IATA · Class	Void	
Packing group · DOT, ADR, IMDG, IATA	Void	
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

· SARA Section 355 (extremely hazardous substances)

None of the ingredients is listed.

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- TSCA (Toxic Substances Control Act) Medical devices are exempted from TSCA.
- Cancerogenity categories
 - · TLV (Threshold Limit Value established by ACGIH)

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

Α4

GHS label elements

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

Hazard pictograms



· Signal word Warning

· Hazard-determining components of labeling:

2-Propenoic acid, (octahydro-4,7-methano-1H-indene-5 -diyl)bis(methyleneiminocarbonyloxy-2,1-ethanediyl) ester

triethylen glycol dimethacrylate

· Hazard statements

May cause an allergic skin reaction.

· Précautionary statements

Avoid breathing dust/fume/gas/mist/vapors/spray

Wear protective gloves.

If on skin: Wash with plenty of water.

Specific treatment (see on this label).

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

Wash contaminated clothing before reuse.

· 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

H317 May cause an allergic skin reaction.

· Date of preparation / last revision 11/28/2017 / 2

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

DOT: US Department of Transportation
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CASC Chemical Abstracts Service (division of the American Chemical Society)

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 OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit REL: Recommended Exposure Limit

Skin Sens. 1: Skin sensitisation - Category 1

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Skin Sens. 1B: Skin sensitisation – Category 1B

* * Data compared to the previous version altered.