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

Printing date 09.07.2020 Version number 4 Revision: 28.11.2017

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

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

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



- · Signal word Warning

· Hazard-determining components of labelling: 2-Propenoic acid, 1,1'-[(octahydro-4,7-methano-1H-indene-5,?-diyl) bis(methyleneoxycarbonylamino-2,1-ethanediyl)] ester

diurethandimethacrylate

triethylen glycol dimethacrylate

· Hazard statements

H317 May cause an allergic skin reaction.

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P280 Wear protective gloves.

P362+P364 Take off contaminated clothing and wash it before reuse. P333+P313 If skin irritation or rash occurs. Get medical advice/attention.

P321 Specific treatment (see on this label). Wash contaminated clothing before reuse. P363

Additional information:

Contains isocyanates. May produce an allergic reaction.

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

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· vPvB: Not applicable.

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SECTION 3: Composition/information on ingredients

- · 3.2 Chemical characterisation: Mixtures
 - · Description: -

· Dangerous components:		
CAS: 945656-78-0	2-Propenoic acid, 1,1'-[(octahydro-4,7-methano-1H-indene-5,?-diyl)bis(methyleneoxycarbonylamino-2,1-ethanediyl)] ester Skin Sens. 1, H317 Aquatic Chronic 3, H412	≥10-<25%
CAS: 72869-86-4 EINECS: 276-957-5 Reg.nr.: 01-2120751202-68-XXXX	diurethandimethacrylate Aquatic Chronic 2, H411 Skin Sens. 1B, H317	≥2.5-<5%
CAS: 109-16-0 EINECS: 203-652-6 Reg.nr.: 01-2119969287-21-0000	triethylen glycol dimethacrylate Skin Sens. 1B, H317	≥1-≤5%
CAS: 131-57-7 EINECS: 205-031-5	2-Hydroxy-4-methoxy benzophenone Aquatic Acute 1, H400; Aquatic Chronic 2, H411	≥0.25-<1%

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

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
 - 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.

Seek immediate medical advice.

· 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

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

5.3 Advice for firefighters

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



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SECTION 6: Accidental release measures

- · 6.1 Personal precautions, protective equipment and emergency procedures Not required.
- · 6.2 Environmental precautions: Dilute with much water.
- 6.3 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 containers.

6.4 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 information on disposal.

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SECTION 7: Handling and storage

· 7.1 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.
- · 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: None.
- · 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

- · Additional information about design of technical systems: No further data; see item 7.
- · 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

109-16-0 triethylen glycol dimethacrylate

Dermal worker industr., l.te., syst. 13.9 mg/Kg/d (nd) Inhalative worker industr., l.te., syst. 48.5 mg/m3 (nd)

· PNECs

109-16-0 triethylen glycol dimethacrylate

marine water 0.0164 mg/l (nd) sedim., dw, fre.wat. 1.85 mg/Kg (nd) sedim., dw, mar.wat. 0.185 mg/Kg (nd) soil,dw 0.274 mg/Kg (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

Instantly remove any soiled and impregnated garments. Wash hands during breaks and at the end of the 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

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 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

· Density at 20 °C

Eye protection: Safety glasses

· Body protection: Light weight protective clothing

SECTION 9: Physical and chemical properties

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9.1 Information on basic physical and	l chemical properties	
· General Information		
· Appearance:		
Form:	Pasty	
· Colour:	White	
	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	range: Not determined	
· Flash point:	> 165 °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.	

2.23 g/cm³

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Relative density
 Vapour density
 Evaporation rate
 Not determined.
 Not determined.

· 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.

• 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.

. Г	LD/LC30	vaiues	tnat are	relevant fol	ciassification:
2869.	86-4 diu	rethano	limethac	rvlate	

LD/LCEO values that are relevant for also ification

72009-00-4 diurethandimethacrylate

Oral LD50 >5,000 mg/kg (rat) (OECD 401)
Dermal LD50 >2,000 mg/kg (rat) (OECD 402)

109-16-0 triethylen glycol dimethacrylate

Oral | LD50 | 8,300 mg/kg (rat) Dermal | LD50 | >2,000 mg/kg (mouse)

131-57-7 2-Hydroxy-4-methoxy benzophenone

Oral | LD50 | 12,800 mg/kg (rat) (OECD 401)

Dermal LD50 >16,000 mg/kg (rabbit) (OECD 402)

- · Primary irritant effect:
 - · Skin corrosion/irritation Based on available data, the classification criteria are not met.
 - · Serious eye damage/irritation

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

Respiratory or skin sensitisation

May cause an allergic skin reaction.

- · 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.

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

SECTION 12: Ecological information

- · 12.1 Toxicity
 - Aquatic toxicity:

72869-86-4 diurethandimethacrylate

LC50/96h 10.1 mg/l (fish)

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:

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

Danger to drinking water if even small quantities leak into soil.

- · 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, IAŤA	Void	
14.5 Environmental hazards:		
· Marine pollutant:	No	

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· 14.6 Special precautions for user	Not applicable.	
· 14.7 Transport in bulk according to Anne. Marpol and the IBC Code	x 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
 - 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

H317 May cause an allergic skin reaction.

H400 Very toxic to aquatic life.

H411 Toxic to aquatic life with long lasting effects.

H412 Harmful to aquatic life with long lasting effects.

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

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

* Data compared to the previous version altered.