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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

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SECTION 2: Hazards identification

· **2.1 Classification of the substance or mixture**
· **Classification according to Regulation (EC) No 1272/2008**
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:**
2-Propenoic acid, (octahydro-4,7-methano-1H-indene-5 -diyl)bis(methyleneiminocarbonyloxy-2,1-ethanediyl) ester
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate
2-Propenoic acid, 1,1'-[(octahydro-4,7-methano-1H-indene-5,?-diyl) bis(methyleneoxycarbonylamino-2,1-ethanediyl)] ester
triethylen glycol dimethacrylate
· **Hazard statements**
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 / eye protection.
P280 Wear protective clothing.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

· **2.3 Other hazards** -

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

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SECTION 3: Composition/information on ingredients

· **3.2 Mixtures**
· **Description:** -

· **Dangerous components:**		
CAS: 861437-11-8	2-Propenoic acid, (octahydro-4,7-methano-1H-indene-5 -diyl)bis(methyleneiminocarbonyloxy-2,1-ethanediyl) ester Skin Sens. 1, H317 Aquatic Chronic 3, H412	≥5-≤10%
CAS: 72869-86-4 EINECS: 276-957-5 Index number: 607-134-00-4 Reg.nr.: 01-2120751202-68-xxxx	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	≥2.5-≤5%
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	≥2.5-≤5%
CAS: 109-16-0 EINECS: 203-652-6 Index number: 607-134-00-4 Reg.nr.: 01-2119969287-21-xxxx	triethylen glycol dimethacrylate Skin Sens. 1B, H317	≥1-≤5%
CAS: 131-57-7 EINECS: 205-031-5	Oxybenzone 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.

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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** -

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.
-

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

· **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.

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· **DNELs**

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	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)
109-16-0 triethylen glycol dimethacrylate		
Oral	general population, long term, systemic	8.33 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	13.9 mg/Kg/d (not defined)
	general population, long term, systemic	8.33 mg/Kg/d (not defined)
Inhalative	worker industrial, long term, systemic	48.5 mg/m3 (not defined)
	general population, long term, systemic	14.5 mg/m3 (not defined)
131-57-7 Oxybenzone		
Oral	general population, long term, systemic	2 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	39 mg/Kg/d (not defined)
	general population, long term, systemic	20 mg/Kg/d (not defined)
Inhalative	worker industrial, long term, systemic	27.7 mg/m3 (not defined)
	general population, long term, systemic	6.8 mg/m3 (not defined)

· **PNECs**

72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate	
freshwater	0.01 mg/l (not defined)
marine water	0.001 mg/l (not defined)
sewage treatment plant	3.61 mg/l (not defined)
sediment, dry weight, freshwater	4.56 mg/Kg (not defined)
sediment, dry weight, marine water	0.46 mg/Kg (not defined)
soil, dry weight	0.91 mg/Kg (not defined)
109-16-0 triethylen glycol dimethacrylate	
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 (not defined)
soil, dry weight	0.027 mg/Kg (not defined)
131-57-7 Oxybenzone	
freshwater	0.00067 mg/l (not defined)
marine water	0.000067 mg/l (not defined)
sewage treatment plant	10 mg/l (not defined)

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sediment, dry weight, freshwater	0.066 mg/Kg (not defined)
sediment, dry weight, marine water	0.007 mg/Kg (not defined)
soil, dry weight	0.013 mg/Kg (not defined)

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

· **8.2 Exposure controls**
· **Appropriate engineering controls** No further data; see section 7.
· **Individual protection measures, such as 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.
· **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
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
· **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**	Fluid
· **Colour:**	White Yellowish
· **Smell:**	Odourless
· **Odour threshold:**	Not determined.
· **Melting point/freezing point:**	Not determined
· **Boiling point or initial boiling point and boiling range**	Not determined

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· **Flammability**	Not applicable.
· **Lower and upper explosion limit**	
· **Lower:**	Not determined.
· **Upper:**	Not determined.
· **Flash point:**	>150 °C (109-16-0 triethylen glycol dimethacrylate)
· **Decomposition temperature:**	Not determined.
· **SADT**	
· **pH**	Not determined.
· **Viscosity:**	
· **Kinematic viscosity**	Not determined.
· **Kinematic viscosity**	
· **dynamic:**	Not determined.
· **Solubility**	
· **Water:**	Not miscible or difficult to mix
· **Partition coefficient n-octanol/water (log value)**	Not determined.
· **Steam pressure:**	Not determined.
· **Vapour pressure:**	
· **Density and/or relative density**	
· **Density at 20 °C**	2.23 g/cm³
· **Relative density**	Not determined.
· **Vapour density**	Not determined.
· **9.2 Other information**	No further relevant information available.
· **Appearance:**	
· **Form:**	Pasty
· **Important information on protection of health and environment, and on safety.**	
· **Self-inflammability:**	Product is not selfigniting.
· **Explosive properties:**	Product is not explosive.
· **Change in condition**	
· **Evaporation rate**	Not determined.
· **Information with regard to physical hazard classes**	
· **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

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· **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:** -

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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:**		
861437-11-8 2-Propenoic acid, (octahydro-4,7-methano-1H-indene-5 -diyl) bis(methyleneiminocarbonyloxy-2,1-ethanediyl) ester		
Oral	LD50	>2,000 mg/kg (rat)
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)
109-16-0 triethylen glycol dimethacrylate		
Oral	LD50	8,300 mg/kg (rat)
Dermal	LD50	>2,000 mg/kg (mouse)
131-57-7 Oxybenzone		
Oral	LD50	>12,800 mg/kg (rat) (OECD 401)
Dermal	LD50	>16,000 mg/kg (rabbit) (OECD 402)

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

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· **11.2 Information on other hazards**

· **Endocrine disrupting properties**
None of the ingredients is listed.

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SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**	
65997-17-3 Glaspulver	
EC50/72h	>1,000 mg/l (daphnia)
LC50/96h	>1,000 mg/l (fish)
ErC50 / 72 h	>1,000 mg/l (algae)
NOEC / 72h	1,000 mg/l (algae)
	1,000 mg/l (daphnia)
861437-11-8 2-Propenoic acid, (octahydro-4,7-methano-1H-indene-5 -diyl) bis(methyleneiminocarbonyloxy-2,1-ethanediyl) ester	
EC50/48h	24.9 mg/l (daphnia)
72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl 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)
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)
NOEC / 72h	18.6 mg/l (algae) (OECD 201)
EbC50 / 72h	72.8 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)

· **12.2 Persistence and degradability**

72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate	
Biodegradation	22 % /28d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)

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109-16-0 triethylen glycol dimethacrylate	
Biodegradation	85 % /28d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)
131-57-7 Oxybenzone	
Biodegradation	60-70 % /28d (not defined)

· **12.3 Bioaccumulative potential**

131-57-7 Oxybenzone	
Bioconcentration 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:**
Do not allow product to reach ground water, water bodies or sewage system.
Danger to drinking water if even small quantities leak into soil.

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.

SECTION 14: Transport information

· **14.1 UN number or ID 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, IMDG, IATA**	Void
· **14.5 Environmental hazards:**	
· **Marine pollutant:**	No

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· **14.6 Special precautions for user**	Not applicable.
· **14.7 Maritime transport in bulk according to IMO instruments**	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**
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.
EUH204 Contains isocyanates. May produce an allergic reaction.
· **Date of previous version:** 26.01.2022
· **Version number of previous version:** 3
· **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
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.**