Safety Data Sheet
acc. to OSHA HCS

Printing date 12/21/2023 Reviewed on 12/21/2023

1 Identification

· **Product identifier**

· **Trade name:** **VENUS Pearl**

· **-**

· **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) Tel.: +49 (0)800 4372522

· **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

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2 Hazard(s) identification

· **Classification of the substance or mixture**
Sensitization - Skin 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
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**
May cause an allergic skin reaction.

· **Precautionary statements**
Avoid release to the environment.
Wear protective gloves/protective clothing/eye protection/face protection.
If on skin: Wash with plenty of soap and water.
If skin irritation or rash occurs: Get medical advice/attention.

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

Health = 0
Fire = 1
Reactivity = 0

· **HMIS-Ratings (Scale 0-4)**

Health = 0
Fire = 1
Reactivity = 0

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

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3 Composition/information on ingredients

· **Chemical characterization: Mixtures**
· **Description:** -

· **Dangerous components:**		
861437-11-8	2-Propenoic acid, (octahydro-4,7-methano-1H-indene-5 -diyl) bis(methyleneiminocarbonyloxy-2,1-ethanediyl) ester Sensitization - Skin 1, H317	≥5-≤25%
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate Sensitization - Skin 1B, H317	≥1-≤10%
945656-78-0	2-Propenoic acid, 1,1'-[(octahydro-4,7-methano-1H-indene-5,?-diyl) bis(methyleneoxycarbonylamino-2,1-ethanediyl)] ester Sensitization - Skin 1, H317	≥1-≤10%
109-16-0	triethylen glycol dimethacrylate Sensitization - Skin 1B, H317	≥1-≤5%

· **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.
If skin irritation continues, consult a doctor.
· **After eye contact** Rinse opened eye for several minutes under running water. Then consult a doctor.
· **After swallowing**
Rinse out mouth and then drink plenty of water.
If symptoms persist consult doctor.

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· **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**
Use fire fighting measures that suit the environment.
CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
· **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** -

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
· **Environmental precautions:**
Do not allow to enter sewers/ surface or ground water.
Do not allow to penetrate the ground/soil.
· **Methods and material for containment and cleaning up:**
Absorb with liquid binding material (diatomite, universal binders, for small amounts tissues).
Dispose of the collected material according to regulations.
· **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.
-
· **Protective Action Criteria for Chemicals**

· **PAC-1:**		
112945-52-5	Amorphous silica	18 mg/m³
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate	120 mg/m³
109-16-0	triethylen glycol dimethacrylate	33 mg/m³
2530-85-0	3-trimethoxysilylpropyl methacrylate	71 mg/m³
7775-14-6	sodium dithionite	30 mg/m³
579-07-7	1-Phenyl-1,2-propandion	0.4 mg/m³
80-62-6	methyl methacrylate	17 ppm
64-19-7	acetic acid	5 ppm

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· **PAC-2:**		
112945-52-5	Amorphous silica	100 mg/m³
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate	1,300 mg/m³
109-16-0	triethylen glycol dimethacrylate	360 mg/m³
2530-85-0	3-trimethoxysilylpropyl methacrylate	780 mg/m³
7775-14-6	sodium dithionite	330 mg/m³
579-07-7	1-Phenyl-1,2-propandion	4.5 mg/m³
80-62-6	methyl methacrylate	120 ppm
64-19-7	acetic acid	35 ppm

· **PAC-3:**		
112945-52-5	Amorphous silica	630 mg/m³
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate	7,900 mg/m³
109-16-0	triethylen glycol dimethacrylate	2,100 mg/m³
2530-85-0	3-trimethoxysilylpropyl methacrylate	4,700 mg/m³
7775-14-6	sodium dithionite	2,000 mg/m³
579-07-7	1-Phenyl-1,2-propandion	27 mg/m³
80-62-6	methyl methacrylate	570 ppm
64-19-7	acetic acid	250 ppm

7 Handling and storage

· **Handling**
· **Precautions for safe handling** Ensure good ventilation/exhaustion at the workplace.
· **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

· **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.

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· **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:**
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 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:** Not absolutely necessary.
· **Body protection:** Light weight protective clothing

9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
· **Form:**	Pasty
· **Color:**	Different according to coloring
· **Odor:**	Odorless
· **Odor threshold:**	Not determined.
· **pH-value:**	Not determined.
· **Change in condition**	
· **Melting point/Melting range:**	undetermined
· **Boiling point/Boiling range:**	undetermined
· **Flash point:**	>100 °C (>212 °F)
· **Flammability (solid, gaseous)**	Not applicable.
· **Decomposition temperature:**	Not determined.
· **Ignition temperature:**	Product is not selfigniting.
· **Danger of explosion:**	Product does not present an explosion hazard.

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· **Explosion limits:**	
· **Lower:**	Not determined.
· **Upper:**	Not determined.
· **Vapor pressure:**	Not determined.
· **Density at 20 °C (68 °F):**	2.1 g/cm³ (17.5245 lbs/gal)
· **Relative density**	Not determined.
· **Vapor density**	Not determined.
· **Evaporation rate**	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.
· **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:** -

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11 Toxicological information

· **Information on toxicological effects**
· **Acute toxicity:**

· **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)
112945-52-5 Amorphous silica		
Oral	LD50	>5,000 mg/kg (rat) (OECD 401)
Dermal	LD50	>5,000 mg/kg (rabbit)

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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)

· **Primary irritant effect:**
· **on the skin:** No irritant effect.
· **on the eye:** No irritating effect.
· **Sensitization:** No sensitizing effects known.
· **Additional toxicological information:**

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**
None of the ingredients is listed.

· **NTP (National Toxicology Program)**
None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**
None of the ingredients is listed.

· **Reproductive toxicity** Based on available data, the classification criteria are not met.

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12 Ecological information

· **Toxicity**

· **Aquatic toxicity:**	
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)
112945-52-5 Amorphous silica	
LC50/96h	>10,000 mg/l (fish) (OECD 203)
EC50 / 24h	>1,000 mg/l (daphnia)
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)
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)

· **Persistence and degradability**
No further relevant information available.

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

· **Behavior in environmental systems:**

· **Bioaccumulative potential**	
131-57-7 Oxybenzone	
Bloconcentration factor (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.

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14 Transport information

· **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 II of MARPOL73/78 and the IBC Code**	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**

· **SARA Section 355 (extremely hazardous substances)**

None of the ingredients is listed.

· **SARA Section 313 (specific toxic chemical listings)**

80-62-6	methyl methacrylate

· **Hazardous Air Pollutants**

80-62-6	methyl methacrylate

· **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.

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· **Cancerogenity categories**

· **EPA (Environmental Protection Agency)**		
80-62-6	methyl methacrylate	E, NL

· **TLV (Threshold Limit Value)**
None of the ingredients is listed.

· **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**
H317 May cause an allergic skin reaction.

· **Date of preparation / last revision** 12/21/2023

· **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
Sensitization - Skin 1: Skin sensitisation – Category 1
Sensitization - Skin 1B: Skin sensitisation – Category 1B

· ***** Data compared to the previous version altered.**