



**Safety Data Sheet  
according to WHS Regulations**

Printing date 21.12.2023

Version number 4

Revision: 21.12.2023

Hazardous according to criteria of Australian Safety and Compensation Council.

## 1 Identification

· **Product identifier**

· Trade name: **VENUS Pearl**

· **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

· **Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier:**  
Kulzer Australia Pty Ltd  
Unit 20, 53 Lorraine St  
PEAKHURST NSW 2210  
Australia

Tel: +61 (02) 9153 0311

· **Informing department:** see above

· **Emergency telephone number:**  
Poison Information Number: Australia 13 11 26 & New Zealand 0800 764 766

## 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 labelled according to the Globally Harmonised System (GHS).

· **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-dioxo-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.

· **Other hazards** -

(Contd. on page 2)

AU



**Safety Data Sheet  
according to WHS Regulations**

Printing date 21.12.2023

Version number 4

Revision: 21.12.2023

**Trade name: VENUS Pearl**

**Results of PBT and vPvB assessment**

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

(Contd. of page 1)

**3 Composition and Information on Ingredients**

**Chemical characterisation: Mixtures**

**Description:** -

**Dangerous components:**

861437-11-8	2-Propenoic acid, (octahydro-4,7-methano-1H-indene-5 -diyl) bis(methyleneiminocarbonyloxy-2,1-ethanediy) ester Skin Sens. 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 Skin Sens. 1B, H317	≥1-≤10%
945656-78-0	2-Propenoic acid, 1,1'-[(octahydro-4,7-methano-1H-indene-5,?-diyl) bis(methyleneoxycarbonylamino-2,1-ethanediy)] ester Skin Sens. 1, H317	≥1-≤10%
109-16-0	triethylen glycol dimethacrylate Skin Sens. 1B, H317	≥1-≤5%

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

**4 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.  
If skin irritation continues, consult a doctor.
- **After eye contact** Rinse opened eye for several minutes under running water. Then consult doctor.
- **After swallowing**  
Rinse out mouth and then drink plenty of water.  
In case of persistent symptoms 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.

**5 Fire Fighting Measures**

- **Suitable extinguishing agents**  
Use fire fighting measures that suit the environment.  
CO<sub>2</sub>, extinguishing powder or water jet. Fight larger fires with water jet 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.
- **Protective equipment:** No special measures required.

(Contd. on page 3)



**Safety Data Sheet  
according to WHS Regulations**

Printing date 21.12.2023

Version number 4

Revision: 21.12.2023

Trade name: **VENUS Pearl**

· **Additional information -**

(Contd. of page 2)

**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 drainage system, surface or ground water.  
Do not allow to enter 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 material collected 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 information on disposal.

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

**8 Exposure controls and personal protection**

- **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.

· <b>DNELs</b>		
<b>72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyI bismethacrylate</b>		
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)
<b>109-16-0 triethylen glycol dimethacrylate</b>		
Oral	general population, long term, systemic	8.33 mg/Kg (not defined)

(Contd. on page 4)



**Safety Data Sheet  
according to WHS Regulations**

Printing date 21.12.2023

Version number 4

Revision: 21.12.2023

**Trade name: VENUS Pearl**

(Contd. of page 3)

<i>Dermal</i>	<i>worker industrial, long term, systemic</i>	13.9 mg/Kg/d (not defined)
	<i>general population, long term, systemic</i>	8.33 mg/Kg/d (not defined)
<i>Inhalative</i>	<i>worker industrial, long term, systemic</i>	48.5 mg/m <sup>3</sup> (not defined)
	<i>general population, long term, systemic</i>	14.5 mg/m <sup>3</sup> (not defined)

**131-57-7 Oxybenzone**

<i>Oral</i>	<i>general population, long term, systemic</i>	2 mg/Kg (not defined)
<i>Dermal</i>	<i>worker industrial, long term, systemic</i>	39 mg/Kg/d (not defined)
	<i>general population, long term, systemic</i>	20 mg/Kg/d (not defined)
<i>Inhalative</i>	<i>worker industrial, long term, systemic</i>	27.7 mg/m <sup>3</sup> (not defined)
	<i>general population, long term, systemic</i>	6.8 mg/m <sup>3</sup> (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**

<i>freshwater</i>	0.01 mg/l (not defined)
<i>marine water</i>	0.001 mg/l (not defined)
<i>sewage treatment plant</i>	3.61 mg/l (not defined)
<i>sediment, dry weight, freshwater</i>	4.56 mg/Kg (not defined)
<i>sediment, dry weight, marine water</i>	0.46 mg/Kg (not defined)
<i>soil, dry weight</i>	0.91 mg/Kg (not defined)

**109-16-0 triethylen glycol dimethacrylate**

<i>freshwater</i>	0.016 mg/l (not defined)
<i>marine water</i>	0.002 mg/l (not defined)
<i>sewage treatment plant</i>	1.7 mg/l (not defined)
<i>sediment, dry weight, freshwater</i>	0.185 mg/Kg (not defined)
<i>sediment, dry weight, marine water</i>	0.018 mg/Kg (not defined)
<i>soil, dry weight</i>	0.027 mg/Kg (not defined)

**131-57-7 Oxybenzone**

<i>freshwater</i>	0.00067 mg/l (not defined)
<i>marine water</i>	0.000067 mg/l (not defined)
<i>sewage treatment plant</i>	10 mg/l (not defined)
<i>sediment, dry weight, freshwater</i>	0.066 mg/Kg (not defined)
<i>sediment, dry weight, marine water</i>	0.007 mg/Kg (not defined)
<i>soil, dry weight</i>	0.013 mg/Kg (not defined)

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

· **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.

· **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.

(Contd. on page 5)



**Safety Data Sheet  
according to WHS Regulations**

Printing date 21.12.2023

Version number 4

Revision: 21.12.2023

**Trade name: VENUS Pearl**

(Contd. of page 4)

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

· **General Information**

· **Appearance:**

· **Form:**

Pasty

· **Colour:**

Different according to colour

· **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:**

>100 °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.

· **Density at 20 °C**

2.1 g/cm<sup>3</sup>

· **Relative density**

Not determined.

· **Vapour 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.

(Contd. on page 6)

AU



**Safety Data Sheet  
according to WHS Regulations**

Printing date 21.12.2023

Version number 4

Revision: 21.12.2023

Trade name: **VENUS Pearl**

(Contd. of page 5)

**Other information**

No further relevant information available.

**10 Stability and Reactivity**

- **Reactivity** No further relevant information available.
- **Conditions to be avoided:** No decomposition if used and stored according to specifications.
- **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** 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-ethanediy) 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)

**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.

(Contd. on page 7)



**Safety Data Sheet  
according to WHS Regulations**

Printing date 21.12.2023

Version number 4

Revision: 21.12.2023

**Trade name: VENUS Pearl**

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

(Contd. of page 6)

**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)

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**

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

**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)

(Contd. on page 8)

AU



**Safety Data Sheet  
according to WHS Regulations**

Printing date 21.12.2023

Version number 4

Revision: 21.12.2023

Trade name: **VENUS Pearl**

(Contd. of page 7)

· **Behaviour 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.

**14 Transport information**

· **UN-Number**

· **ADG, ADN, IMDG, IATA** Void

· **UN proper shipping name**

· **ADG** Void

· **ADN, IMDG, IATA** Void

· **Transport hazard class(es)**

· **ADG, ADN, IMDG, IATA**  
· **Class** Void

· **Packing group**

· **ADG, IMDG, IATA** Void

· **Environmental hazards:**

· **Marine pollutant:** No

· **Special precautions for user**

Not applicable.

· **Transport in bulk according to Annex II of  
Marpol and the IBC Code**

Not applicable.

· **Transport/Additional information:**

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(Contd. on page 9)





**Safety Data Sheet  
according to WHS Regulations**

Printing date 21.12.2023

Version number 4

Revision: 21.12.2023

**Trade name: VENUS Pearl**

(Contd. of page 8)

· **UN "Model Regulation":**

Void

**15 Regulatory information**

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**  
No further relevant information available.

· **Australian Inventory of Industrial Chemicals**

112945-52-5	Amorphous silica
7732-18-5	water, distilled, conductivity or of similar purity
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazaheptadecane-1,16-diyl bismethacrylate
109-16-0	triethylen glycol dimethacrylate
131-57-7	Oxybenzone
2530-85-0	3-trimethoxysilylpropyl methacrylate
21245-02-3	2-ethylhexyl 4-(dimethylamino)benzoate
10373-78-1	dl-bornane-2,3-dione
84434-11-7	ethyl phenyl(2,4,6-trimethylbenzoyl)phosphinate
7775-14-6	sodium dithionite
579-07-7	1-Phenyl-1,2-propandion
80-62-6	methyl methacrylate
3006-82-4	tert-butyl peroxy(2-ethylhexanoate)
64-19-7	acetic acid
2682-20-4	2-methyl-2H-isothiazol-3-one
68186-91-4	Kupfer-, Chrom-, Eisenoxid-Spinell
128-37-0	2,6-di-tert-butyl-p-cresol
4948-15-6	C.I. Pigment Red 149

· **Australia: Priority Existing Chemicals**

None of the ingredients is listed.

· **National regulations**

The product is subject to classification in accordance with the prevailing version of the regulations on hazardous materials.

· **Other regulations, limitations and prohibitive regulations**

· **AICS - Australian Inventory of Chemical Substances**

112945-52-5	Amorphous silica
7732-18-5	water, distilled, conductivity or of similar purity
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazaheptadecane-1,16-diyl bismethacrylate
109-16-0	triethylen glycol dimethacrylate
131-57-7	Oxybenzone

(Contd. on page 10)

AU



**Safety Data Sheet**  
**according to WHS Regulations**

Printing date 21.12.2023

Version number 4

Revision: 21.12.2023

**Trade name: VENUS Pearl**

(Contd. of page 9)

2530-85-0	3-trimethoxysilylpropyl methacrylate
21245-02-3	2-ethylhexyl 4-(dimethylamino)benzoate
10373-78-1	dl-bornane-2,3-dione
84434-11-7	ethyl phenyl(2,4,6-trimethylbenzoyl)phosphinate
7775-14-6	sodium dithionite
579-07-7	1-Phenyl-1,2-propandion
	Diethyl-(2,5-dihydroxyterephthalat)
80-62-6	methyl methacrylate
3006-82-4	tert-butyl peroxy(2-ethylhexanoate)
64-19-7	acetic acid
	Chrome Antimony Titanate
2682-20-4	2-methyl-2H-isothiazol-3-one
68186-91-4	Kupfer-, Chrom-, Eisenoxid-Spinell
128-37-0	2,6-di-tert-butyl-p-cresol
4948-15-6	C.I. Pigment Red 149

· **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.

· **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

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)

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

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