



**Safety Data Sheet  
according to WHS Regulations**

Printing date 16.11.2022

Version number 4

Revision: 16.11.2022

Hazardous according to criteria of Australian Safety and Compensation Council.

## 1 Identification

· **Product identifier**

· **Trade name:** **Venus Bulk Fill**

· **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 Irrit. 2 H315 Causes skin irritation.

Eye Irritation 2A H319 Causes serious eye irritation.

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:**

7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate

· **Hazard statements**

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

· **Precautionary statements**

Wear protective gloves/protective clothing/eye protection/face protection.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Specific treatment (see on this label).

If skin irritation occurs: Get medical advice/attention.

If eye irritation persists: Get medical advice/attention.

Take off contaminated clothing and wash before reuse.

· **Other hazards -**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

(Contd. on page 2)

AU



**Safety Data Sheet  
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Version number 4

Revision: 16.11.2022

**Trade name: Venus Bulk Fill**

· **vPvB:** Not applicable.

(Contd. of page 1)

### 3 Composition and Information on Ingredients

· **Chemical characterisation: Mixtures**

· **Description:** -

· **Dangerous components:**

13760-80-0	ytterbium trifluoride Skin Irrit. 2, H315; Eye Irritation 2A, H319; STOT SE 3, H335	≥10-<20%
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	10-25%
21245-02-3	2-ethylhexyl 4-(dimethylamino)benzoate Repr. 1B, H360	<0.3%

### 4 First Aid Measures

· **Description of first aid measures**

· **General information** No special measures required.

· **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.

· **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**

CO<sub>2</sub>, extinguishing powder or water jet. Fight larger fires with water jet or alcohol-resistant foam.

Use fire fighting measures that suit the environment.

· **Special hazards arising from the substance or mixture** No further relevant information available.

· **Advice for firefighters**

· **Protective equipment:** No special measures required.

· **Additional information** -

### 6 Accidental Release Measures

· **Personal precautions, protective equipment and emergency procedures** Not required.

· **Environmental precautions:** No special measures required.

· **Methods and material for containment and cleaning up:** Collect mechanically.

· **Reference to other sections**

See Section 13 for information on disposal.

See Section 8 for information on personal protection equipment.

(Contd. on page 3)

AU



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Revision: 16.11.2022

Trade name: **Venus Bulk Fill**

(Contd. of page 2)

## 7 Handling and Storage

- **Handling**
  - **Precautions for safe handling** No special measures required.
  - **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 containers:** No special requirements.
    - **Information about storage in one common storage facility:** Not required.
    - **Further information about storage conditions:**  
Store under dry conditions.  
Store cool (not above 25 °C).
  - **Specific end use(s)** No further relevant information available.

## 8 Exposure controls and personal protection

- **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

**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)

### · 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)

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

- **Exposure controls**
  - **Personal protective equipment**
    - **General protective and hygienic measures**  
Wash hands during breaks and at the end of the work.
    - **Breathing equipment:** Not required.

(Contd. on page 4)



**Safety Data Sheet  
according to WHS Regulations**

Printing date 16.11.2022

Version number 4

Revision: 16.11.2022

**Trade name: Venus Bulk Fill**

(Contd. of page 3)

- **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  
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:** Safety glasses
- **Body protection:** Light weight protective clothing

**9 Physical and Chemical Properties**

· **Information on basic physical and 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:** 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** 1.9 g/cm<sup>3</sup>
  - **Relative density** Not determined.
  - **Vapour density** Not determined.

(Contd. on page 5)



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

Printing date 16.11.2022

Version number 4

Revision: 16.11.2022

**Trade name: Venus Bulk Fill**

(Contd. of page 4)

· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with</b> · <b>Water:</b>	Not miscible or difficult to mix
· <b>Partition coefficient: n-octanol/water:</b>	Not determined.
· <b>Viscosity:</b> · <b>dynamic:</b> · <b>kinematic:</b>	Not determined. Not determined.
· <b>Other information</b>	No further relevant information available.

### 10 Stability and Reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
  - **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**

· <b>LD/LC50 values that are relevant for classification:</b>		
<b>56744-60-6 Bisphenol-A-ethoxylat(4)dimethacrylat</b>		
Oral	LD50	>2000 mg/kg (rat)
<b>72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazaheptadecane-1,16-diyl bismethacrylate</b>		
Oral	LD50	>5000 mg/kg (rat) (OECD 401)
Dermal	LD50	>2000 mg/kg (rat) (OECD 402)
<b>21245-02-3 2-ethylhexyl 4-(dimethylamino)benzoate</b>		
Oral	LD50	14900 mg/kg (rat)

- **Primary irritant effect:**
  - **Skin corrosion/irritation** No irritant effect.
  - **Serious eye damage/irritation** No irritant effect.
  - **Respiratory or skin sensitisation** No sensitizing effect known.
- **Additional toxicological information:**

The product is not subject to classification according to the calculation method of the General EC Classification Guidelines for Preparations as issued in the latest version.  
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

(Contd. on page 6)



**Safety Data Sheet  
according to WHS Regulations**

Printing date 16.11.2022

Version number 4

Revision: 16.11.2022

**Trade name: Venus Bulk Fill**

(Contd. of page 5)

**· CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)**

<b>· Reproductive toxicity</b>	
<b>21245-02-3 2-ethylhexyl 4-(dimethylamino)benzoate</b>	
Oral	NOAEL (Fertility) 50 mg/kg/d /64 d (rat) (OECD 421)

**12 Ecological Information**

**· Toxicity**

<b>· Aquatic toxicity:</b>	
<b>72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate</b>	
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)

**· Persistence and degradability**

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

**· Behaviour in environmental systems:**

- **Bioaccumulative potential** No further relevant information available.
- **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** Smaller quantities can be disposed with household garbage.
- **Uncleaned packagings:**
  - **Recommendation:** Disposal must be made according to official regulations.

**14 Transport information**

<b>· UN-Number</b>	Void
<b>· ADG, ADN, IMDG, IATA</b>	Void
<b>· UN proper shipping name</b>	Void
<b>· ADG</b>	Void
<b>· ADN, IMDG, IATA</b>	Void
<b>· Transport hazard class(es)</b>	Void
<b>· ADG, ADN, IMDG, IATA</b>	Void
<b>· Class</b>	Void

(Contd. on page 7)



**Safety Data Sheet  
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**Trade name: Venus Bulk Fill**

(Contd. of page 6)

· <b>Packing group</b> · <b>ADG, IMDG, IATA</b>	Void
· <b>Environmental hazards:</b> · <b>Marine pollutant:</b>	No
· <b>Special precautions for user</b>	Not applicable.
· <b>Transport in bulk according to Annex II of Marpol and the IBC Code</b>	Not applicable.
· <b>Transport/Additional information:</b>	-
· <b>UN "Model Regulation":</b>	Void

### 15 Regulatory information

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

· <b>Australian Inventory of Industrial Chemicals</b>	
56744-60-6	Bisphenol-A-ethoxylat(4)dimethacrylat
41137-60-4	diurethandimethacrylate
7631-86-9	silicon dioxide, chemically prepared
131-57-7	Oxybenzone
109-16-0	triethylen glycol dimethacrylate
21245-02-3	2-ethylhexyl 4-(dimethylamino)benzoate
10373-78-1	dl-bornane-2,3-dione
128-37-0	2,6-di-tert-butyl-p-cresol
5870-38-2	Diethyl-(2,5-dihydroxyterephthalat)

· **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**

- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.
- H335 May cause respiratory irritation.
- H360 May damage fertility or the unborn child.

· **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

(Contd. on page 8)



**Safety Data Sheet  
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**Trade name: Venus Bulk Fill**

(Contd. of page 7)

*Skin Irrit. 2: Skin corrosion/irritation – Category 2*  
*Eye Irritation 2A: Serious eye damage/eye irritation – Category 2A*  
*Skin Sens. 1: Skin sensitisation – Category 1*  
*Skin Sens. 1B: Skin sensitisation – Category 1B*  
*Repr. 1B: Reproductive toxicity – Category 1B*  
*STOT SE 3: Specific target organ toxicity (single exposure) – Category 3*  
**\* Data compared to the previous version altered.**

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