



**Safety Data Sheet
according to WHS Regulations**

Printing date 21.09.2023

Version number 1

Revision: 21.09.2023

Hazardous according to criteria of Australian Safety and Compensation Council.

1 Identification

· **Product identifier**

· **Trade name:** **Venus Bulk Flow ONE**

· **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.

Serious eye damage/irritation – Category 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-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate

· **Hazard statements**

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

· **Precautionary statements**

Avoid release to the environment.

Wear protective gloves / eye protection.

Wear protective clothing.

IF ON SKIN: Wash with plenty of soap and water.

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

If skin irritation or rash occurs: Get medical advice/attention.

If eye irritation persists: Get medical advice/attention.

Take off contaminated clothing and wash it before reuse.

· **Other hazards** -

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

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3 Composition and Information on Ingredients

- **Chemical characterisation: Mixtures**
 - **Description:** -

- **Dangerous components:**

72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazaheptadecane-1,16-diyl bismethacrylate Skin Sens. 1B, H317	10-25%
13760-80-0	ytterbium trifluoride Skin Irrit. 2, H315; Serious eye damage/irritation – Category 2A, H319; STOT SE 3, H335	≥10-<20%
109-16-0	triethylen glycol dimethacrylate Skin Sens. 1B, H317	≥0.1-<1%
21245-02-3	2-ethylhexyl 4-(dimethylamino)benzoate Repr. 1B, H360	<0.3%

- **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** 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** Allergic reactions
 - **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire Fighting Measures

- **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.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Protective equipment:** No special measures required.
- **Additional information** -

6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Prevent material from reaching sewage system, holes and cellars.
- **Methods and material for containment and cleaning up:** Collect mechanically.
- **Reference to other sections**
See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.

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See Section 13 for information on disposal.

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7 Handling and Storage

· Handling

· **Precautions for safe handling**

No special measures required.

Ensure good ventilation/exhaustion at the workplace.

· **Information about protection against explosions and fires:**

Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

· 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.

· **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.

· DNELs

41637-38-1 bisphenol A polyethnylene glycol diether dimethacrylate

Oral	general population, long term, systemic	5 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	140 mg/Kg/d (not defined)
	general population, long term, systemic	50 mg/Kg/d (not defined)
Inhalative	worker industrial, long term, systemic	98.7 mg/m3 (not defined)
	general population, long term, systemic	17.4 mg/m3 (not defined)

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)

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)

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)

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Inhalative	general population, long term, systemic	8.33 mg/Kg/d (not defined)
	worker industrial, long term, systemic	48.5 mg/m3 (not defined)
	general population, long term, systemic	14.5 mg/m3 (not defined)

· PNECs

72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-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)

131-57-7 Oxybenzone

freshwater	0.00067 mg/l (not defined)
marine water	0.00067 mg/l (not defined)
sewage treatment plant	10 mg/l (not defined)
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)

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)

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

· **Personal protective equipment**

· **General protective and hygienic measures**

Wash hands during breaks and at the end of the work.

· **Breathing equipment:** Not necessary if room is well-ventilated.

· **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 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

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Nitrile rubber, NBR

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- **Eye protection:** Tightly sealed safety glasses.
- **Body protection:** Light weight protective clothing

9 Physical and Chemical Properties

· General Information

- **Appearance:**
 - **Form:** Pasty
 - **Colour:** Whitish
- **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:** 140 °C
- **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.
Not determined.
- **Critical values for explosion:**
 - **Lower:** Not determined.
 - **Upper:** Not determined.
- **Steam pressure:** Not determined.
- **Density at 20 °C** 1.9 g/cm³
 - **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.

- **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:** -

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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:**

41637-38-1 bisphenol A polyethnylene glycol diether dimethacrylate

Oral LD50 >2,000 mg/kg (rat) (OECD 423)

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

72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahehexadecane-1,16-diyl bismethacrylate

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

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

131-57-7 Oxybenzone

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

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

109-16-0 triethylen glycol dimethacrylate

Oral LD50 8,300 mg/kg (rat)

Dermal LD50 >2,000 mg/kg (mouse)

21245-02-3 2-ethylhexyl 4-(dimethylamino)benzoate

Oral LD50 14,900 mg/kg (rat)

· **Skin corrosion/irritation** Causes skin irritation.

· **Serious eye damage/irritation** Causes serious eye irritation.

· **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.

21245-02-3 2-ethylhexyl 4-(dimethylamino)benzoate

Oral NOAEL (Fertility) 50 mg/kg/d /64 d (rat) (OECD 421)

· **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.

12 Ecological Information

· **Toxicity**

· **Aquatic toxicity:**

41637-38-1 bisphenol A polyethnylene glycol diether dimethacrylate

EC50/72h >100 mg/l (algae) (OECD 201)

LL50/96h >100 mg/L (fish) (OECD 203)

EL50/48h >100 mg/L (daphnia) (OECD 202)

EL50/72h >100 mg/L (algae) (OECD 201)

NOEC / 21d ≥22.4 mg/l (daphnia) (OECD 211)

NOEC 28d 14.3 mg/l (bacteria)

NOELR 100 mg/L /48h (daphnia) (OECD 202)

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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)

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)

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)

· Persistence and degradability

41637-38-1 bisphenol A polyethnylene glycol diether dimethacrylate

Biodegradation 24 % /28d (not defined) (OECD 301D)

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)

131-57-7 Oxybenzone

Biodegradation 60-70 % /28d (not defined)

109-16-0 triethylen glycol dimethacrylate

Biodegradation 85 % /28d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)

· 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.

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13 Disposal considerations

· **Waste treatment methods**

· **Recommendation**

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

Disposal must be made according to official regulations.

· **Uncleaned packagings:**

· **Recommendation:**

Disposal must be made according to official regulations.

Non contaminated packagings can be used for recycling.

14 Transport information

· **UN-Number**

· **ADG, IMDG, IATA**

Void

· **UN proper shipping name**

· **ADG, 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:**

-

· **UN "Model Regulation":**

Void

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **Australian Inventory of Industrial Chemicals**

41637-38-1	bisphenol A polyethnylene glycol diether dimethacrylate
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate
1343-98-2	silicic acid
7732-18-5	water, distilled, conductivity or of similar purity
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

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128-37-0	2,6-di-tert-butyl-p-cresol
579-07-7	1-phenylpropane-1,2-dione
80-62-6	methyl methacrylate
2530-85-0	3-trimethoxysilylpropyl methacrylate
7732-18-5	water, distilled, conductivity or of similar purity
77-99-6	propylidynetrimethanol
4948-15-6	C.I. Pigment Red 149
64-19-7	acetic acid

· Australia: Priority Existing Chemicals

None of the ingredients is listed.

· Directive 2012/18/EU

· **Named dangerous substances - ANNEX I** 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

72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate
1343-98-2	silicic acid
7732-18-5	water, distilled, conductivity or of similar purity
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
579-07-7	1-phenylpropane-1,2-dione
	Diethyl-(2,5-dihydroxyterephthalat)
80-62-6	methyl methacrylate
2530-85-0	3-trimethoxysilylpropyl methacrylate
7732-18-5	water, distilled, conductivity or of similar purity
77-99-6	propylidynetrimethanol
4948-15-6	C.I. Pigment Red 149
64-19-7	acetic acid

· **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.

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· **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 Irrit. 2: Skin corrosion/irritation – Category 2

Serious eye damage/irritation – Category 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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