

Safety Data Sheet

according to WHS Regulations

Printing date 01.09.2017

Version number 1

Revision: 01.09.2017

Hazardous according to criteria of Australian Safety and Compensation Council

SECTION 1: Identification

- **1.1 Product identifier**
- **Trade name: *BrackFix Primer***
- **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** *Light-curing bracket bonding system*
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Australien contact and address:
VOCO Australia Pty Ltd.
Suite 406-408, 251 Oxford Street,
Bondi Junction, NSW 2022
- **Further information obtainable from:** *Australia 02 9369 1770*
- **1.4 Emergency telephone number:** *Australia: 131126*

SECTION 2: Hazard(s) Identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
Skin Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2 H319 Causes serious eye irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
As a medical device the product is not subject to labelling regulations under 1272/2008/EC.
- **Hazard pictograms** *GHS07*
- **Hazard statements**
Causes skin irritation.
Causes serious eye irritation.
May cause an allergic skin reaction.
- **Precautionary statements**
Avoid breathing vapours.
Wear protective gloves / face protection.
Wear protective clothing.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If skin irritation occurs: Get medical advice/attention.
Dispose of contents/container in accordance with local/regional/national/international regulations.
- **2.3 Other hazards** *Use only for intended scope of application*
- **Results of PBT and vPvB assessment**
- **PBT:** *Not applicable.*
- **vPvB:** *Not applicable.*

SECTION 3: Composition and Information on Ingredients

- **3.2 Chemical characterisation: Mixtures**
- **Description:** *Mixture of substances listed below with nonhazardous additions.*

- **Dangerous components:**

1565-94-2	BIS GMA Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	25-50%
-----------	--	--------

(Contd. on page 2)

Safety Data Sheet

according to WHS Regulations

Printing date 01.09.2017

Version number 1

Revision: 01.09.2017

Trade name: BrackFix Primer

(Contd. of page 1)

109-16-0	Triethylene glycol dimethacrylate Skin Sens. 1, H317	25-50%
10373-78-1	camphorquinone Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	≤ 2.5%

SECTION 4: First Aid Measures

- **4.1 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.
- **After eye contact:**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing:** If symptoms persist consult doctor.
- **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.

SECTION 5: Fire Fighting Measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

SECTION 6: Accidental Release Measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **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 disposal information.

SECTION 7: Handling and Storage

- **7.1 Precautions for safe handling** For dental use only.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** See storage instructions on package
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Keep container tightly sealed.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls and personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.

(Contd. on page 3)

Safety Data Sheet

according to WHS Regulations


Printing date 01.09.2017

Version number 1

Revision: 01.09.2017

Trade name: BrackFix Primer

(Contd. of page 2)

- **8.1 Control parameters**
 - **Ingredients 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.
 - **Additional information:** The lists valid during the making were used as basis.
 - **8.2 Exposure controls**
 - **Personal protective equipment:**
 - **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
Avoid contact with the eyes and skin.
 - **Respiratory protection:** Not required.
 - **Protection of hands:**
- 
Protective gloves
- **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.
 - **Eye protection:** Safety glasses

SECTION 9: Physical and Chemical Properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

· Form:	Fluid
· Colour:	Yellowish
· Odour:	Characteristic
· Odour threshold:	Not determined.
- **pH-value:** Not determined.
- **Change in condition**

· Melting point/freezing point:	Undetermined.
· Initial boiling point and boiling range:	Undetermined.
- **Flash point:** Not applicable.
- **Flammability (solid, gas):** Not applicable.
- **Decomposition temperature:** Not determined.
- **Auto-ignition temperature:** Product is not selfigniting.
- **Explosive properties:** Product does not present an explosion hazard.
- **Density:** Not determined.
- **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 4)

Safety Data Sheet

according to WHS Regulations

Printing date 01.09.2017

Version number 1

Revision: 01.09.2017

Trade name: **BrackFix Primer**

(Contd. of page 3)

· **9.2 Other information** *No further relevant information available.*

SECTION 10: Stability and Reactivity

- **10.1 Reactivity** *No further relevant information available.*
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:** *No decomposition if used 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:** *No dangerous decomposition products known.*

SECTION 11: Toxicological Information

- **11.1 Information on toxicological effects**
- **Acute toxicity** *Based on available data, the classification criteria are not met.*
- **Primary irritant effect:**
- **Skin corrosion/irritation**
*Testing according to ISO 10993-1/10993-10 showed no skin irritation for this product when fully cured
Causes skin irritation.*
- **Serious eye damage/irritation**
Causes serious eye irritation.
- **Respiratory or skin sensitisation**
May cause an allergic skin reaction.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **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.*

SECTION 12: Ecological Information

- **12.1 Toxicity**
- **Aquatic toxicity:** *No further relevant information available.*
- **12.2 Persistence and degradability** *No further relevant information available.*
- **12.3 Bioaccumulative potential** *No further relevant information available.*
- **12.4 Mobility in soil** *No further relevant information available.*
- **Additional ecological information:**
- **General notes:**
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** *Not applicable.*
- **vPvB:** *Not applicable.*
- **12.6 Other adverse effects** *No further relevant information available.*

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.

(Contd. on page 5)

Safety Data Sheet

according to WHS Regulations

Printing date 01.09.2017

Version number 1

Revision: 01.09.2017

Trade name: **BrackFix Primer**

(Contd. of page 4)

- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- | | |
|--|-----------------|
| · 14.1 UN-Number | Void |
| · ADG, ADN, IMDG, IATA | Void |
| · 14.2 UN proper shipping name | - |
| · ADG, ADN, IMDG, IATA | Void |
| · 14.3 Transport hazard class(es) | - |
| · ADG, ADN, IMDG, IATA | Void |
| · Class | Void |
| · 14.4 Packing group | - |
| · ADG, IMDG, IATA | Void |
| · 14.5 Environmental hazards: | Not applicable. |
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · UN "Model Regulation": | Void |

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- | |
|--|
| · Australian Inventory of Chemical Substances |
| All ingredients are listed. |
- **Directive 2012/18/EU**
 - **Named dangerous substances - ANNEX I** None of the ingredients is listed.

SECTION 16: Other information

- **Department issuing SDS:** Scientific department
- **Contact:** Tel.: +49 (0)4721-719-0
- **Abbreviations and acronyms:**
 - ADR: Accord européen sur le transport 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)
 - PBT: Persistent, Bioaccumulative and Toxic
 - vPvB: very Persistent and very Bioaccumulative
 - Skin Irrit. 2: Skin corrosion/irritation – Category 2
 - Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
 - Skin Sens. 1: Skin sensitisation – Category 1
 - STOT SE 3: Specific target organ toxicity (single exposure) – Category 3