

# Safety Data Sheet

## according to WHS Regulations

Printing date 16.07.2024

Version number 14

Revision: 16.07.2024

Hazardous according to criteria of Australian Safety and Compensation Council.

### SECTION 1: Identification

- **1.1 Product identifier**
- **Trade name: GrandioSO Heavy Flow**
- **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** Dental filling material
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
VOCO Australia Pty Ltd  
Level 19, 133-145 Castlereagh Street  
Sydney, NSW 2000  
Email: info@voco.com
- **Further information obtainable from:** Australia 02 9369 1770
- **1.4 Emergency telephone number:** Australia: 131126

### SECTION 2: Hazard(s) Identification

- **2.2 Label elements**
- **Classification according to Regulation (EC) No 1272/2008**  
Skin Sens. 1 H317 May cause an allergic skin reaction.
- **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**  
May cause an allergic skin reaction.
- **Precautionary statements**  
Avoid breathing dust/fume/gas/mist/vapours/spray.  
Wear protective gloves.  
Take off contaminated clothing and wash it before reuse.  
If skin irritation or rash occurs: Get medical advice/attention.  
Specific treatment (see on this label).  
Dispose of contents/container in accordance with local/regional/national/international regulations.
- **Additional information:**  
Contains BIS GMA, Triethylene glycol dimethacrylate. May produce an allergic reaction.
- **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:**

CAS: 1565-94-2	BIS GMA Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	2.5-5%
CAS: 109-16-0	Triethylene glycol dimethacrylate Skin Sens. 1, H317	2.5-5%

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### SECTION 4: First Aid Measures

- **4.1 Description of first aid measures**
- **After inhalation:** Seek medical treatment 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.
- **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:** Use fire extinguishing methods suitable to surrounding conditions.
- **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:** No special measures required.
- **6.3 Methods and material for containment and cleaning up:** Pick up mechanically.
- **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.  
No special precautions are necessary if used correctly.  
Follow the instructions for use.
- **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:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** See storage instructions on package
- **7.3 Specific end use(s)** No further relevant information available.

### SECTION 8: Exposure controls and personal protection

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

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- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
The usual precautionary measures are to be adhered to when handling chemicals.
- **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.

### SECTION 9: Physical and Chemical Properties

- |  |   |
|--|---|
| · <b>9.1 Information on basic physical and chemical properties</b> |   |
| · <b>General Information</b>                                       |   |
| · <b>Appearance:</b>   |   |
| Form:  | Fluid   |
| Colour:  | According to product specification            |
| Odour:   | Characteristic                                |
| · <b>pH-value:</b>   | Not determined.                               |
| · <b>Change in condition</b>                                       |   |
| Melting point/freezing point:                                      | Undetermined.                                 |
| Initial boiling point and boiling range:                           | Undetermined.                                 |
| · <b>Flash point:</b>  | Not applicable.                               |
| · <b>Auto-ignition temperature:</b>                                | Product is not selfigniting.                  |
| · <b>Explosive properties:</b>                                     | Product does not present an explosion hazard. |
| · <b>Density:</b>  | Not determined.                               |
| · <b>Solubility in / Miscibility with water:</b>                   | Not miscible or difficult to mix.             |
| · <b>Viscosity:</b>  |   |
| Dynamic:   | Not determined.                               |
| Kinematic:   | Not determined.                               |
| · <b>9.2 Other information</b>                                     | 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.

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### 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
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation**  
May cause an allergic skin reaction.
- **Additional toxicological information:**
- **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:** Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
- **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.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

### SECTION 14: Transport information

- |   |      |
|---|------|
| <ul style="list-style-type: none"> <li>· <b>14.1 UN-Number</b></li> <li>· <b>ADG, ADN, IMDG, IATA</b></li> </ul>  | Void |
| <ul style="list-style-type: none"> <li>· <b>14.2 UN proper shipping name</b></li> <li>· <b>ADG, ADN, IMDG, IATA</b></li> </ul>                            | Void |
| <ul style="list-style-type: none"> <li>· <b>14.3 Transport hazard class(es)</b></li> <li>· <b>ADG, ADN, IMDG, IATA</b></li> <li>· <b>Class</b></li> </ul> | Void |

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· <b>14.4 Packing group</b> · <b>ADG, IMDG, IATA</b>	Void
· <b>14.5 Environmental hazards:</b> · <b>Marine pollutant:</b>	No
· <b>14.6 Special precautions for user</b>	Not applicable.
· <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b>	Not applicable.
· <b>UN "Model Regulation":</b>	Void

### SECTION 15: Regulatory information

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

· **Australian Inventory of Industrial Chemicals**

All ingredients are listed.

· **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.

### SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing SDS:** Scientific department

· **Contact:** Tel.: +49 (0)4721-719-0

· **Abbreviations and acronyms:**

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

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