

# Safety data sheet

## according to 1907/2006/EC, Article 31

Printing date 24.07.2024

Version number 16

Revision: 24.07.2024

Hazardous according to criteria of Australian Safety and Compensation Council

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **1.1 Product identifier**
- **Trade name:** *x-tra base*
- **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 (Australien sponsor address):**  
*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: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
*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**  
*May cause an allergic skin reaction.*
- **Precautionary statements**  
*Wear protective gloves / 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.*  
*If eye irritation persists: Get medical advice/attention.*  
*IF ON SKIN: Wash with plenty of water.*  
*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/information on ingredients

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

· **Dangerous components:**

<i>aliphatic dimethacrylate</i>	<i>Skin Irrit. 2, H315; Eye Irrit. 2, H319</i>	<i>10-25%</i>
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### SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:** *No special measures required.*
- **After inhalation:** *Supply fresh air; consult doctor in case of complaints.*

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- **After skin contact:**  
Immediately 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.
- **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: Firefighting 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:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:** Pick up mechanically.
- **6.4 Reference to other sections** No dangerous substances are released.

### 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:** 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/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **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.
- **Respiratory protection:** Not required.
- **Protection of hands:**  
Not required.



Protective gloves

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- **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.
- **Eye protection:** Not required.

### SECTION 9: Physical and chemical properties

#### · 9.1 Information on basic physical and chemical properties

##### · General Information

##### · Appearance:

Form: Pasty

Colour: Beige

· Odour: Characteristic

· pH-value: Not determined.

##### · Change in condition

Melting point/Melting range: Undetermined.

Boiling point/Boiling range: Undetermined.

· Flash point: Not applicable.

· Self-igniting: Product is not selfigniting.

· Danger of explosion: Product does not present an explosion hazard.

· Density: Not determined.

· Solubility in / Miscibility with water: Not miscible or difficult to mix.

##### · Viscosity:

Dynamic: Not determined.

Kinematic: Not determined.

· 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

· Serious eye damage/irritation: Based on available data, the classification criteria are not met.

##### · 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.

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

### SECTION 14: Transport information

- |  |                 |
|--|-----------------|
| · <b>14.1 UN-Number</b>  | Void            |
| · <b>ADG, ADN, IMDG, IATA</b>  | Void            |
| · <b>14.2 UN proper shipping name</b>  | Void            |
| · <b>ADG, ADN, IMDG, IATA</b>  | Void            |
| · <b>14.3 Transport hazard class(es)</b>   | Void            |
| · <b>ADG, ADN, IMDG, IATA</b>  | Void            |
| · <b>Class</b>   | Void            |
| · <b>14.4 Packing group</b>  | Void            |
| · <b>ADG, IMDG, IATA</b>   | Void            |
| · <b>14.5 Environmental hazards:</b>   | No              |
| · <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            |

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**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**

*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:**

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

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

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