

**Safety Data Sheet**  
according to WHS Regulations

Printing date 13.05.2024

Version number 9

Revision: 13.05.2024

Not classified as hazardous according to criteria of Australian Safety and Compensation Council.

**1 Identification**

- **Product identifier**
- **Trade name:** ***SR Vivodent, SR Orthotyp***
- **CAS Number:**  
9011-14-7
- **Relevant identified uses of the substance or mixture and uses advised against**  
*No further relevant information available.*
- **Application of the substance / the mixture** *Manufacture of dental prosthesis*
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
*Ivoclar Vivadent AG  
Bendererstrasse 2  
9494 Schaan  
PRINCIPALITY OF LIECHTENSTEIN  
Tel: +423 235 35 35 / Fax: +423 235 33 60*
- **Importer:**  
*Ivoclar Vivadent Pty. Ltd.  
1- 5 Overseas Drive  
Noble Park North VIC 3174  
Tel: + 61 3 9795 9599 / Fax: + 61 3 9795 9645*
- **Further information obtainable from:**  
*Regulatory Affairs  
sds@ivoclar.com*
- **Emergency telephone number:** *131 126 (Poisons Information Centre - 24 hours / 7 days)*

**2 Hazard(s) Identification**

- **Classification of the substance or mixture**  
*The substance is not classified, according to the Globally Harmonised System (GHS).*
- **Label elements**
- **GHS label elements** *Void*
- **Hazard pictograms** *Void*
- **Signal word** *Void*
- **Hazard statements** *Void*
- **Other hazards** *Avoid breathing sanding dust /swarf.*
- **Results of PBT and vPvB assessment**
- **PBT:** *Not applicable.*
- **vPvB:** *Not applicable.*

**3 Composition and Information on Ingredients**

- **Chemical characterisation:** *Substances*
- **CAS No. Description**  
*CAS: 9011-14-7 polymethylmethacrylate*
- **Description:** *Resin teeth based on polymethylmethacrylate*

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#### 4 First Aid Measures

- **General information:** No special measures required.
- **After inhalation:**  
Grinding dust: Supply fresh air; consult doctor in case of complaints.  
In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:**  
Rinse opened eye for several minutes under running water. Then consult a doctor.  
Mechanical effects only.
- **After swallowing:**  
Grinding dust: Rinse out mouth and then drink plenty of water.  
Seek medical treatment.
- **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

- **Suitable extinguishing agents:**  
CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Protective equipment:** No special measures required.

#### 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:** Pick up mechanically.
- **Reference to other sections**  
No dangerous substances are released.  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

#### 7 Handling and Storage

- **Handling:**
- **Precautions for safe handling**  
Only adequately trained personnel should handle this product.  
For use in dentistry only.
- **Information about fire - and explosion protection:** No special measures required.
- **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:** None.
- **Specific end use(s)** No further relevant information available.

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### 8 Exposure controls and personal protection

- **Additional information about design of technical facilities:** No further data; see section 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.
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
Usual hygienic measures for dental practice and dental laboratories.  
Keep away from foodstuffs, beverages and feed.  
Wash hands before breaks and at the end of work.
- **Respiratory protection:** Use respiratory protective device against the effects of dust.
- **Protection of hands:**  
Protective gloves should always be worn during mechanical and thermal processing.  
After use of gloves apply skin-cleaning agents and skin cosmetics.
- **Material of gloves**  
Mechanical processing:  
Leather gloves  
Strong material gloves
- **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.
- **Eye protection:**  
Always wear safety goggles during mechanical processing (grinding, sawing /cutting, drilling, milling).

### 9 Physical and Chemical Properties

- **General Information**
- **Appearance:**
- **Form:** Solid
- **Colour:** According to product specification
- **Odour:** Odourless
- **Odour threshold:** Not determined.
- **pH-value:** Not applicable.
- **Change in condition**
- **Melting point/freezing point:** 150 °C
- **Initial boiling point and boiling range:** Undetermined.
- **Flash point:** 250 °C
- **Flammability (solid, gas):** Product is not flammable.
- **Decomposition temperature:** Not determined.
- **Ignition temperature:** Not determined.
- **Explosive properties:** Product does not present an explosion hazard.
- **Explosion limits:**
- **Lower:** Not determined.
- **Upper:** Not determined.
- **Vapour pressure:** Not applicable.
- **Density:** Not determined.
- **Relative density** Not determined.
- **Vapour density** Not applicable.
- **Evaporation rate** Not applicable.
- **Solubility in / Miscibility with**
- **water:** Insoluble.

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- |  |  |
|--|--|
| · <b>Partition coefficient: n-octanol/water:</b> | Not determined.                            |
| · <b>Viscosity:</b>                              |  |
| · <b>Dynamic:</b>                                | Not applicable.                            |
| · <b>Kinematic:</b>                              | Not applicable.                            |
| · <b>Solids content:</b>                         | 100.0 %                                    |
| · <b>Other information</b>                       | No further relevant information available. |

### 10 Stability and Reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability** Stable under normal handling and storage conditions.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used 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 under normal conditions of storage and use.

### 11 Toxicological Information

- **Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **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.

### 12 Ecological Information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:** Not hazardous for water.
- **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**  
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

### 14 Transport information

- |  |  |
|--|--|
| · <b>UN-Number</b><br>· <b>ADG, ADN, IMDG, IATA</b>                                    | Void   |
| · <b>UN proper shipping name</b><br>· <b>ADG, ADN, IMDG, IATA</b>                      | Void   |
| · <b>Transport hazard class(es)</b><br>· <b>ADG, ADN, IMDG, IATA</b><br>· <b>Class</b> | Void   |
| · <b>Packing group</b><br>· <b>ADG, IMDG, IATA</b>                                     | Void   |
| · <b>Environmental hazards:</b><br>· <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>   | Product is not classified as a dangerous good for transport (ADR, IMDG, IATA). |
| · <b>UN "Model Regulation":</b>  | Void   |

### 15 Regulatory information

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

- **Australian Inventory of Industrial Chemicals**

Substance is listed.

- **Standard for the Uniform Scheduling of Medicines and Poisons**

Substance is not listed.

- **Australia: Priority Existing Chemicals**

Substance is not listed.

- **GHS label elements** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void

- **Directive 2012/18/EU**

- **Named dangerous substances - ANNEX I** None of the ingredients is listed.

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- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**  
The product is a medical device according to Regulation 2017/745 on Medical Devices (MDR).
- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

### 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.

- **Contact:**
- **Abbreviations and acronyms:**  
IMO: International Maritime Organization  
ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)  
RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)  
IMDG: International Maritime Code for Dangerous Goods  
IATA: International Air Transport Association  
CAS: Chemical Abstracts Service (division of the American Chemical Society)  
PBT: Persistent, Bioaccumulative and Toxic  
vPvB: very Persistent and very Bioaccumulative
- **\* Data compared to the previous version altered.**

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