

## Safety Data Sheet according to WHS Regulations

Date of issue: 17.02.2025

Version number 7


Revision: 11.12.2023

Hazardous according to criteria of Australian Safety and Compensation Council.

### 1 Identification

- **Other means of identification**
- **Trade name:** **SR Ivocron Opaquer**
- **Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** PMMA veneering material
- **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**  
Skin sensitisation – Category 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 statements**  
May cause an allergic skin reaction.
- **Precautionary statements**  
Avoid breathing dust/fume/gas/mist/vapours/spray.  
Do not get in eyes, on skin, or on clothing.  
Wear protective gloves/protective clothing/eye protection/face protection.  
Dispose of contents/container in accordance with local/regional/national/international regulations.
- **Other hazards**  
Dust generation  
Particular danger of slipping on leaked/spilled product.

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

### 3 Composition and Information on Ingredients

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

- **Dangerous components:**

|                |  |        |
|----------------|--|--------|
| CAS: 7727-43-7 | barium sulphate, natural   | 25-50% |
| CAS: 1344-28-1 | aluminium oxide  | 25-50% |
| CAS: 94-36-0   | dibenzoyl peroxide<br>Self-reactive substances and mixtures – Type B, H241; Organic peroxides – Type B, H241; Eye damage/irritation – Category 2A, H319; Skin sensitisation – Category 1, H317 | <2.5%  |

- **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 complaints.  
In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:**  
Rinse with water.  
If skin irritation continues, consult a doctor.
- **After eye contact:**  
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing:**  
Rinse out mouth and then drink plenty of water.  
If symptoms persist consult doctor.
- **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:** Use fire extinguishing methods suitable to surrounding conditions.
- **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**  
Avoid formation of dust.  
Particular danger of slipping on leaked/spilled product.
- **Environmental precautions:**  
No special measures required.  
Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:** Pick up mechanically.

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- **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.

### 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:** Store only in the original receptacle.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Protect from heat and direct sunlight.
- **Specific end use(s)** No further relevant information available.

### 8 Exposure controls and personal protection

- **Appropriate engineering controls** No further data; see section 7.

- **Ingredients with limit values that require monitoring at the workplace:**

**CAS: 7727-43-7 barium sulphate, natural**

NES Long-term value: 10 mg/m<sup>3</sup>

WES Long-term value: 10 mg/m<sup>3</sup>

**CAS: 1344-28-1 aluminium oxide**

NES Long-term value: 10 mg/m<sup>3</sup>

WES Long-term value: 10 mg/m<sup>3</sup>

**CAS: 94-36-0 dibenzoyl peroxide**

NES Long-term value: 5 mg/m<sup>3</sup>

Sen

WES Long-term value: 5 mg/m<sup>3</sup>

Sen

- **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.  
Immediately remove all soiled and contaminated clothing  
Wash hands before breaks and at the end of work.  
Avoid contact with the skin.
- **Respiratory protection:** Use respiratory protective device against the effects of dust.
- **Protection of hands:**



Protective gloves (EN 374)

After use of gloves apply skin-cleaning agents and skin cosmetics.

- **Material of gloves**  
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

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- **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:** Safety glasses

## 9 Physical and Chemical Properties

- **General Information**
- **Appearance:**
- **Form:** Powder
- **Colour:** According to product specification
- **Odour:** Odourless
- **Odour threshold:** Not determined.
- **pH-value:** Not applicable.
- **Change in condition**
- **Melting point/freezing point:** Undetermined.
- **Initial boiling point and boiling range:** Undetermined.
- **Flash point:** Not applicable.
- **Flammability** Not determined.
- **Ignition temperature:** Product is not selfigniting.
- **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:** Nearly insoluble.
- **Partition coefficient: n-octanol/water:** Not determined.
- **Viscosity:**
- **Dynamic:** Not applicable.
- **Kinematic:** Not applicable.
- **Other information** No further relevant information available.
- **Particle characteristics** Not determined.

## 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.

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### 11 Toxicological Information

- **Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Specific symptoms in biological assay:**
- **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**  
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.
- **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.
- **Additional toxicological information:** No further relevant information available.

### 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:**  
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.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

### 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>               |      |
| · <b>ADG, ADN, IMDG, IATA</b>    | Void |
| · <b>UN proper shipping name</b> |      |
| · <b>ADG, ADN, IMDG, IATA</b>    | Void |

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|   |  |
|---|--|
| · <b>Transport hazard class(es)</b>   |  |
| · <b>ADG, ADN, IMDG, IATA</b>   |  |
| · <b>Class</b>  | Void   |
| · <b>Packing group</b>  |  |
| · <b>ADG, IMDG, IATA</b>  | Void   |
| · <b>Environmental hazards:</b>   |  |
| · <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**

|                |                          |
|----------------|--------------------------|
| CAS: 7727-43-7 | barium sulphate, natural |
|----------------|--------------------------|

|                |                 |
|----------------|-----------------|
| CAS: 1344-28-1 | aluminium oxide |
|----------------|-----------------|

|              |                    |
|--------------|--------------------|
| CAS: 94-36-0 | dibenzoyl peroxide |
|--------------|--------------------|

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

|              |                    |            |
|--------------|--------------------|------------|
| CAS: 94-36-0 | dibenzoyl peroxide | S2, S4, S5 |
|--------------|--------------------|------------|

· **GHS label elements**

The product is classified and labelled according to the Globally Harmonised System (GHS).

· **Hazard pictograms**



GHS07

· **Signal word** Warning

· **Hazard statements**

May cause an allergic skin reaction.

· **Precautionary statements**

Avoid breathing dust/fume/gas/mist/vapours/spray.

Do not get in eyes, on skin, or on clothing.

Wear protective gloves/protective clothing/eye protection/face protection.

Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Directive 2012/18/EU**

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

· **National regulations:**

· **Other regulations, limitations and prohibitive regulations**

The product is a medical device according to Regulation 2017/745 on Medical Devices (MDR).

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· **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.*

· **Relevant phrases**

*H241 Heating may cause a fire or explosion.*

*H317 May cause an allergic skin reaction.*

*H319 Causes serious eye irritation.*

· **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*

*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*

*Self-reactive substances and mixtures – Type B: Self-reactive substances and mixtures – Type B*

*Organic peroxides – Type B: Organic peroxides – Type B*

*Eye damage/irritation – Category 2A: Serious eye damage/eye irritation – Category 2A*

*Skin sensitisation – Category 1: Skin sensitisation – Category 1*

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

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