

**Safety Data Sheet**  
according to WHS Regulations

Printing date 18.01.2021

Version number 1

Revision: 18.01.2021

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

## 1 Identification

- **Product identifier**
- **Trade name:** **Telio Inlay**
- **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 temporary restorative 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@ivoclarvivadent.com
- **Emergency telephone number:** 131 126 (Poisons Information Centre - 24 hours / 7 days)

## 2 Hazard(s) Identification

- **Classification of the substance or mixture**  
The product 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
- **Precautionary statements**  
Avoid release to the environment.
- **Additional information:**  
Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Dangerous Preparations Directive 1999/45/EC usually if they are in the finished state and intended for the final user.
- **Other hazards**
- **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.

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- **Dangerous components:** *Void*
- **Additional information:** *For the wording of the listed hazard phrases refer to section 16.*

### 4 First Aid Measures

- **Description of 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.*
- **After eye contact:** *Rinse opened eye for several minutes under running water. Then 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

- **Extinguishing media**
- **Suitable extinguishing agents:**  
*CO2, 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.*
- **Advice for firefighters**
- **Protective equipment:** *No special measures required.*

### 6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures**  
*Wear protective equipment. Keep unprotected persons away.*
- **Environmental precautions:** *Do not allow to enter sewers/ surface or ground water.*
- **Methods and material for containment and cleaning up:** *Pick up mechanically.*
- **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.*
- **Conditions for safe storage, including any incompatibilities**
- **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.*

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- **Further information about storage conditions:**
  - Protect from exposure to the light.
  - Protect from heat and direct sunlight.
  - Keep container tightly sealed.
- **Specific end use(s)** No further relevant information available.

### 8 Exposure controls and personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **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.
- **Exposure controls**
- **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.
  - Avoid contact with the skin.
- **Respiratory protection:** Not required.
- **Protection of hands:**



Protective gloves (EN 374)

- After use of gloves apply skin-cleaning agents and skin cosmetics.
- **Material of gloves**
  - Butyl rubber, BR
  - Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
- **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:** Goggles recommended during refilling

### 9 Physical and Chemical Properties

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

<b>Form:</b>	Pasty
<b>Colour:</b>	According to product specification
- **Odour:** Characteristic
- **Odour threshold:** Not determined.
- **pH-value:** Not determined.
- **Change in condition**

<b>Melting point/freezing point:</b>	Undetermined.
<b>Initial boiling point and boiling range:</b>	Undetermined.

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· <b>Flash point:</b>	<i>Not applicable.</i>
· <b>Flammability (solid, gas):</b>	<i>Not applicable.</i>
· <b>Auto-ignition temperature:</b>	<i>Product is not selfigniting.</i>
· <b>Explosive properties:</b>	<i>Product does not present an explosion hazard.</i>
· <b>Explosion limits:</b>	
<b>Lower:</b>	<i>Not determined.</i>
<b>Upper:</b>	<i>Not determined.</i>
· <b>Vapour pressure:</b>	<i>Not determined.</i>
· <b>Density at 20 °C:</b>	<i>1.358 - 1.392 g/cm<sup>3</sup></i>
· <b>Relative density</b>	<i>Not determined.</i>
· <b>Vapour density</b>	<i>Not determined.</i>
· <b>Evaporation rate</b>	<i>Not determined.</i>
· <b>Solubility in / Miscibility with water:</b>	<i>Nearly insoluble.</i>
· <b>Partition coefficient: n-octanol/water:</b>	<i>Not determined.</i>
· <b>Viscosity:</b>	
<b>Dynamic:</b>	<i>Not determined.</i>
<b>Kinematic:</b>	<i>Not determined.</i>
· <b>Other information</b>	<i>No further relevant information available.</i>

### 10 Stability and Reactivity

- **Reactivity** *No further relevant information available.*
- **Chemical stability**  
*Stable under normal handling and storage conditions.*  
*Photoreactive (Danger of polymerization).*
- **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**
- **Skin corrosion/irritation** *No irritant effect.*
- **Serious eye damage/irritation** *No irritating effect.*
- **Respiratory or skin sensitisation** *No sensitising effects known.*

### 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.*

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

All ingredients are listed.

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

None of the ingredients is listed.

· **Australia: Priority Existing Chemicals**

None of the ingredients is listed.

· **GHS label elements** Void

· **Hazard pictograms** Void

· **Signal word** Void

· **Hazard statements** Void

· **Precautionary statements**

Avoid release to the environment.

· **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 the Directive 93/42/EEC.

· **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.*

· **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

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