

**Safety Data Sheet**  
in accordance with HSNO

Printing date 26.11.2020

Version number 1

Revision: 26.11.2020

### 1 Identification of the substance or mixture and of the supplier

- **Product identifier**
- **Trade name:** ***Telio Onlay***
- **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 Ltd.  
12 Omega St, Rosedale, Auckland  
New Zealand  
Tel: + 64 9 914 9999 / Fax: + 64 9 914 9990*
- **Further information obtainable from:**  
*Regulatory Affairs  
sds@ivoclarvivadent.com*
- **Emergency telephone number:** 0800 764 766 (*National Poison Centre - 24 hours / 7 days*)

### 2 Hazards identification

- **Classification of the substance or mixture**  
*Skin Corr. 3 H316 Causes mild skin irritation.*

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- **Label elements**
- **GHS label elements**  
*The product is classified and labelled according to the Globally Harmonised System (GHS).*
- **Hazard pictograms** *Void*
- **Signal word** *Warning*
- **Hazard statements**  
*Causes mild skin irritation.*
- **Precautionary statements**  
*If skin irritation occurs: Get medical advice/attention.*
- **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 Regulation (EC) No 1272/2008 (CLP/GHS) 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/Information on ingredients

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

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**· Dangerous components:**

|                                      |  |         |
|--------------------------------------|--|---------|
| CAS: 39670-09-2<br>EINECS: 254-588-0 | ethyltriglycol methacrylate<br>Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335   | 2.5-10% |
| CAS: 16919-27-0<br>EINECS: 240-969-9 | dipotassium hexafluorotitanate<br>Eye Dam. 1, H318; Acute Tox. 4, H302; Skin Sens. 1, H317 | <2.5%   |

**· 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:**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.**· Advice for firefighters****· Protective equipment:** No special measures required.**6 Accidental release measures****· Personal precautions, protective equipment and emergency procedures** Wear protective clothing.**· 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.

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- **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.
- **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/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:**
  - Form:** Pasty
  - Colour:** According to product specification
  - Odour:** Characteristic
  - Odour threshold:** Not determined.

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|  |  |
|--|--|
| · <b>pH-value:</b>   | <i>Not determined.</i>                               |
| · <b>Change in condition</b><br><b>Melting point/freezing point:</b> | <i>Undetermined.</i>                                 |
| <b>Initial boiling point and boiling range:</b>                      | <i>Undetermined.</i>                                 |
| · <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><br><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><br><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**
- **Respiratory or skin sensitisation** *Sensitisation possible through skin contact.*

### 12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** *No further relevant information available.*

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- **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

- |  |  |
|--|--|
| <ul style="list-style-type: none"> <li>· <b>UN-Number</b></li> <li>· <b>ADR/RID/ADN, ADN, IMDG, IATA</b></li> </ul>  | Void   |
| <ul style="list-style-type: none"> <li>· <b>UN proper shipping name</b></li> <li>· <b>ADR/RID/ADN, ADN, IMDG, IATA</b></li> </ul>                            | Void   |
| <ul style="list-style-type: none"> <li>· <b>Transport hazard class(es)</b></li> <li>· <b>ADR/RID/ADN, ADN, IMDG, IATA</b></li> <li>· <b>Class</b></li> </ul> | Void   |
| <ul style="list-style-type: none"> <li>· <b>Packing group</b></li> <li>· <b>ADR/RID/ADN, IMDG, IATA</b></li> </ul>   | Void   |
| <ul style="list-style-type: none"> <li>· <b>Environmental hazards:</b></li> <li>· <b>Marine pollutant:</b></li> </ul>  | No   |
| <ul style="list-style-type: none"> <li>· <b>Special precautions for user</b></li> </ul>  | Not applicable.  |
| <ul style="list-style-type: none"> <li>· <b>Transport in bulk according to Annex II of Marpol and the IBC Code</b></li> </ul>                                | Not applicable.  |
| <ul style="list-style-type: none"> <li>· <b>Transport/Additional information:</b></li> </ul>   | Product is not classified as a dangerous good for transport (ADR, IMDG, IATA). |
| <ul style="list-style-type: none"> <li>· <b>UN "Model Regulation":</b></li> </ul>  | Void   |

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### 15 Regulatory information

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

· **New Zealand Inventory of Chemicals**

|                 |                             |
|-----------------|-----------------------------|
| CAS: 39670-09-2 | ethyltriglycol methacrylate |
|-----------------|-----------------------------|

· **GHS label elements**

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

· **Hazard pictograms** Void

· **Signal word** Warning

· **Hazard statements**

Causes mild skin irritation.

· **Precautionary statements**

If skin irritation occurs: Get medical advice/attention.

· **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.

· **Relevant phrases**

H302 Harmful if swallowed.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

· **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

Acute Tox. 4: Acute toxicity - oral - Category 4

Skin Irrit. 2: Skin corrosion/irritation - Category 2

Skin Corr. 3: Skin corrosion/irritation - Category 3

Eye Dam. 1: Serious eye damage/eye irritation - Category 1

Eye Irrit. 2A: Serious eye damage/eye irritation - Category 2A

Skin Sens. 1: Skin sensitisation - Category 1

STOT SE 3: Specific target organ toxicity (single exposure) - Category 3