

Safety Data Sheet
according to WHS Regulations

Printing date 26.11.2020

Version number 1

Revision: 26.11.2020

Hazardous according to criteria of Australian Safety and Compensation Council.

1 Identification

- **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 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*
- **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 and 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	ethyltriglycol methacrylate Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335	2.5-10%
CAS: 16919-27-0	dipotassium hexafluorotitanate 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:**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 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 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:**

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

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· pH-value:	<i>Not determined.</i>
· Change in condition Melting point/freezing point:	<i>Undetermined.</i>
Initial boiling point and boiling range:	<i>Undetermined.</i>
· Flash point:	<i>Not applicable.</i>
· Flammability (solid, gas):	<i>Not applicable.</i>
· Auto-ignition temperature:	<i>Product is not selfigniting.</i>
· Explosive properties:	<i>Product does not present an explosion hazard.</i>
· Explosion limits: Lower:	<i>Not determined.</i>
Upper:	<i>Not determined.</i>
· Vapour pressure:	<i>Not determined.</i>
· Density at 20 °C:	<i>1.358 - 1.392 g/cm³</i>
· Relative density	<i>Not determined.</i>
· Vapour density	<i>Not determined.</i>
· Evaporation rate	<i>Not determined.</i>
· Solubility in / Miscibility with water:	<i>Nearly insoluble.</i>
· Partition coefficient: n-octanol/water:	<i>Not determined.</i>
· Viscosity: Dynamic:	<i>Not determined.</i>
Kinematic:	<i>Not determined.</i>
· Other information	<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"> · UN-Number · ADG, ADN, IMDG, IATA | <i>Void</i> |
| <ul style="list-style-type: none"> · UN proper shipping name · ADG, ADN, IMDG, IATA | <i>Void</i> |
| <ul style="list-style-type: none"> · Transport hazard class(es) · ADG, ADN, IMDG, IATA · Class | <i>Void</i> |
| <ul style="list-style-type: none"> · Packing group · ADG, IMDG, IATA | <i>Void</i> |
| <ul style="list-style-type: none"> · Environmental hazards: · Marine pollutant: | <i>No</i> |
| <ul style="list-style-type: none"> · Special precautions for user | <i>Not applicable.</i> |
| <ul style="list-style-type: none"> · Transport in bulk according to Annex II of Marpol and the IBC Code | <i>Not applicable.</i> |
| <ul style="list-style-type: none"> · Transport/Additional information: | <i>Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).</i> |
| <ul style="list-style-type: none"> · UN "Model Regulation": | <i>Void</i> |

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15 Regulatory information

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

· **Australian Inventory of Industrial Chemicals**

CAS: 39670-09-2	ethyltriglycol methacrylate
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CAS: 16919-27-0	dipotassium hexafluorotitanate
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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

· **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

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