

SAFETY DATA SHEETS

This SDS packet was issued with item:

070990564

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

070990291 070990341 070990382 070990432 070990523 070990572

Safety Data Sheet according to HPR, Schedule 1

Printing date 10/10/2023

Version number 2

Reviewed on 07/18/2023

1 Identification



- **Product identifier**
- **Trade name:** ***Telio Onlay***
- **Application of the substance / the mixture** *Light-curing temporary restorative material*
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
 Ivoclar Vivadent Inc.
 175 Pineview Drive, Amherst, N.Y. 14228
 USA
 Tel. +1 800 533 6825
 Fax +1 716 691 2285

 Ivoclar Vivadent Inc.
 1-6600 Dixie Road
 Mississauga, Ontario
 L5T 2Y2
 Canada
 Phone: +1 905 670 8499
 Fax: +1 905 670 3102
- **Information department:** *Quality Assurance / Regulatory Affairs*
- **Emergency telephone number:**
 24 Hour Emergency Assistance:
 Emergency-Call USA - Infotrac: 1-800-535-5053
 Emergency-Call Canada - Canutec: 1-613-996-6666

 General SDS Assistance:
 US: 1-800-533-6825
 Canada: 1-800-263-8182

2 Hazard identification

- **Classification of the substance or mixture**
 Skin Sensitizer - Category 1 *H317 May cause an allergic skin reaction.*
 Reproductive Toxicity - Category 1B *H360 May damage fertility or the unborn child.*
- **Label elements**
- **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**

GHS07 GHS08
- **Signal word** *Danger*
- **Hazard-determining components of labeling:**
Hexanedioic acid, polymer with 2,2-dimethyl-1,3-propanediol, 1,6-diisocyanato-2,2,4(or2,4,4)-trimethylhexane, 2-hydroxyethyl methacrylate-blocked ethyl p-dimethylaminobenzoate dipotassium hexafluorotitanate 1,10-decandiol dimethacrylate
- **Hazard statements**
May cause an allergic skin reaction.

(Contd. on page 2)

Safety Data Sheet

according to HPR, Schedule 1

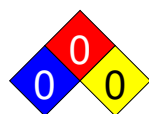
Printing date 10/10/2023

Version number 2

Reviewed on 07/18/2023

Trade name: **Telio Onlay**

(Contd. of page 1)

*May damage fertility or the unborn child.***· Precautionary statements***Avoid breathing dust/fume/gas/mist/vapours/spray.**Wear protective gloves/protective clothing/eye protection/face protection.**If on skin: Wash with plenty of water.**If skin irritation or rash occurs: Get medical advice/attention.**Take off contaminated clothing and wash it before reuse.***· Classification system:****· NFPA ratings (scale 0 - 4)**

Health = 0

Fire = 0

Reactivity = 0

· HMIS-ratings (scale 0 - 4)

Health = 0

Fire = 0

Reactivity = 0

3 Composition/Information on ingredients

· Chemical characterization: Mixtures**· Description:** Mixture of the substances listed below with nonhazardous additions.**· Dangerous components:**

CAS: 39670-09-2	ethyltriglycol methacrylate	3-7% w/w *
CAS: 16919-27-0	dipotassium hexafluorotitanate	0.1-1% w/w *

* Actual concentration ranges are withheld as a trade secret.

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, extinguishing 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.

(Contd. on page 3)

Safety Data Sheet according to HPR, Schedule 1

Printing date 10/10/2023

Version number 2

Reviewed on 07/18/2023

Trade name: **Telio Onlay**

(Contd. of page 2)

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

*

8 Exposure controls/ Personal protection

- **Additional information about design of technical systems:** No further data; see section 7.
- **Control parameters**
- **Components 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 that were valid during the creation 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.
- **Breathing equipment:** Not required.
- **Protection of hands:**



Protective gloves

(Contd. on page 4)

CA

Safety Data Sheet

according to HPR, Schedule 1

Printing date 10/10/2023

Version number 2

Reviewed on 07/18/2023

Trade name: Telio Onlay

(Contd. of page 3)

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

Color:

According to product specification

· **Odor:**

Characteristic

· **Odor threshold:**

Not determined.

· **pH-value:**

Not determined.

· **Change in condition**

Melting point/Melting range:

Undetermined.

Boiling point/Boiling range:

Undetermined.

· **Flash point:**

Not applicable.

· **Flammability (solid, gaseous):**

Not applicable.

· **Ignition temperature:**

Product is not selfigniting.

· **Danger of explosion:**

Product does not present an explosion hazard.

· **Explosion limits:**

Lower:

Not determined.

Upper:

Not determined.

· **Vapor pressure:**

Not determined.

· **Density at 20 °C:**

1.358 - 1.392 g/cm³

· **Relative density**

Not determined.

· **Vapor density**

Not determined.

· **Evaporation rate**

Not determined.

· **Solubility in / Miscibility with**

Water:

Nearly insoluble.

· **Partition coefficient (n-octanol/water):** Not determined.

· **Viscosity:**

Dynamic:

Not determined.

Kinematic:

Not determined.

· **Other information**

No further relevant information available.

10 Stability and reactivity

· **Reactivity** No further relevant information available.

(Contd. on page 5)

CA

Safety Data Sheet

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(Contd. of page 4)

- **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:**
- **Sensitization:** Sensitization possible through skin contact.
- **Additional toxicological information:**

- **Carcinogenic categories**

- **NTP (National Toxicology Program)**

None of the ingredients is listed.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior 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 (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

- **UN-Number**
- **DOT/TDG, ADR, ADN, IMDG, IATA** Void

(Contd. on page 6)

CA

Safety Data Sheet

according to HPR, Schedule 1

Printing date 10/10/2023

Version number 2

Reviewed on 07/18/2023

Trade name: **Telio Onlay**

(Contd. of page 5)

· UN proper shipping name	
· DOT/TDG, ADR, ADN, IMDG, IATA	Void
· Transport hazard class(es)	
· DOT, ADR, ADN, IMDG, IATA	
· Class	Void
· Packing group	
· DOT/TDG, ADR, IMDG, IATA	Void
· Environmental hazards:	
· Marine pollutant:	No
· Special precautions for user	Not applicable.
· Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable.
· Transport/Additional information:	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).
· UN "Model Regulation":	Void

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**· **Sara**· **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

· **Section 313 (Specific toxic chemical listings):**

None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**

CAS: 39670-09-2 ethyltriglycol methacrylate

· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**

GHS07 GHS08

· **Signal word** Danger· **Hazard-determining components of labeling:**

Hexanedioic acid, polymer with 2,2-dimethyl-1,3-propanediol, 1,6-diisocyanato-2,2,4(or2,4,4)-trimethylhexane, 2-hydroxyethyl methacrylate-blocked

ethyl p-dimethylaminobenzoate

dipotassium hexafluorotitanate

1,10-decandiol dimethacrylate

· **Hazard statements**

May cause an allergic skin reaction.

May damage fertility or the unborn child.

· **Precautionary statements**

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

(Contd. on page 7)

CA

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(Contd. of page 6)

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

If on skin: Wash with plenty of water.

If skin irritation or rash occurs: Get medical advice/attention.

Take off contaminated clothing and wash it before reuse.

· **National regulations:**

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

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

This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada.

· **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:**

· **Date of the latest revision of the safety data sheet 10/10/2023**

· **Abbreviations and acronyms:**

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

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

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