

**Safety Data Sheet**  
acc. to OSHA HCS

Printing date 05/23/2013

Version number 4

Reviewed on 05/14/2013

**1 Identification of the substance/mixture and of the company/undertaking**

- **Product identifier**
- **Trade name:** **Telio CS Onlay**
- **Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the preparation** 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 MSDS Assistance:  
US: 1-800-533-6825  
Canada: 1-800-263-8182

**2 Hazards identification**

- **Classification of the substance or mixture**
  - **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**  
Dangerous for the environment  
Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
  - **Classification system:**  
The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.
- 
- **Label elements**
  - **Labelling according to EU guidelines:**  
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 Substance Directive 1999/45/EC usually if they are in the finished state and intended for the final user.
  - **Code letter and hazard designation of product:**



Dangerous for the environment

(Contd. on page 2)

## Safety Data Sheet

### acc. to OSHA HCS

Printing date 05/23/2013

Version number 4

Reviewed on 05/14/2013

**Trade name: Telio CS Onlay**

(Contd. of page 1)

- **Risk phrases:**

*Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.*

- **Safety phrases:**

*Use appropriate container to avoid environmental contamination.*

*This material and its container must be disposed of as hazardous waste.*

- **Special labelling of certain preparations:**

*Contains dipotassium hexafluorotitanate. May produce an allergic reaction.*

- **Classification system:**

- **NFPA ratings (scale 0 - 4)**



- **HMIS-ratings (scale 0 - 4)**

HEALTH	0	Health = 0
FIRE	0	Fire = 0
REACTIVITY	0	Reactivity = 0

- **Other hazards**

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

### 3 Composition/information on ingredients

- **Chemical characterization: Mixtures**

- **Description:** Mixture of the substances listed below with nonhazardous additions.

- **Dangerous components:**

39670-09-2	ethyltriglycol methacrylate	2.5-<10%
16919-27-0	dipotassium hexafluorotitanate	0.1-<1%
3380-34-5	triclosan	0.25-<1%

### 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.*

*Generally the product does not irritate the skin.*

- **After eye contact:**

*Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.*

- **After swallowing:** 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.*

USA

(Contd. on page 3)

## Safety Data Sheet acc. to OSHA HCS

Printing date 05/23/2013

Version number 4

Reviewed on 05/14/2013

Trade name: **Telio CS Onlay**

(Contd. of page 2)

### 5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**  
CO<sub>2</sub>, 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.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **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 item 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.  
Wash hands before breaks and at the end of work.  
Avoid contact with the eyes and skin.

(Contd. on page 4)

## Safety Data Sheet

### acc. to OSHA HCS

Printing date 05/23/2013

Version number 4

Reviewed on 05/14/2013

**Trade name: Telio CS Onlay**

(Contd. of page 3)

Keep away from foodstuffs, beverages and feed.

· **Breathing equipment:** Not required.

· **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· **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

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form:

Pasty

Color:

According to product specification

· **Odor:**

Characteristic

· **Odour 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.

· **Auto igniting:**

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 (68 °F):**

1.358 - 1.392 g/cm<sup>3</sup> (11.333 - 11.616 lbs/gal)

· **Relative density**

Not determined.

· **Vapour density**

Not determined.

· **Evaporation rate**

Not determined.

(Contd. on page 5)

## Safety Data Sheet

acc. to OSHA HCS

Printing date 05/23/2013

Version number 4

Reviewed on 05/14/2013

Trade name: **Telio CS Onlay**

(Contd. of page 4)

- |   |  |
|---|--|
| <b>· Solubility in / Miscibility with Water:</b>  | Nearly insoluble.                          |
| <b>· Partition coefficient (n-octanol/water):</b> | Not determined.                            |
| <b>· Viscosity:</b>                               |  |
| <b>Dynamic:</b>                                   | Not determined.                            |
| <b>Kinematic:</b>                                 | Not determined.                            |
| <b>· Other information</b>                        | No further relevant information available. |

### 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:**
- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**
- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

7631-86-9	silicon dioxide, chemically prepared	3
-----------	--------------------------------------	---

- **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.
- **Ecotoxicological effects:**
- **Remark:** Very toxic for fish

(Contd. on page 6)

USA

## Safety Data Sheet

### acc. to OSHA HCS

Printing date 05/23/2013

Version number 4

Reviewed on 05/14/2013

**Trade name: Telio CS Onlay**

(Contd. of page 5)

- **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.*  
*Also poisonous for fish and plankton in water bodies.*  
*Very toxic for aquatic organisms*
- **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 packagings:**
- **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>DOT, ADR, ADN, IMDG, IATA</b></li> </ul>  | Void            |
| <ul style="list-style-type: none"> <li>· <b>UN proper shipping name</b></li> <li>· <b>DOT, ADR, ADN, IMDG, IATA</b></li> </ul>                            | Void            |
| <ul style="list-style-type: none"> <li>· <b>Transport hazard class(es)</b></li> <li>· <b>DOT, ADR, 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>DOT, ADR, 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 MARPOL73/78 and the IBC Code</b></li> </ul>                        | Not applicable. |

### 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.

(Contd. on page 7)

## Safety Data Sheet

acc. to OSHA HCS

Printing date 05/23/2013

Version number 4

Reviewed on 05/14/2013

**Trade name: *Telio CS Onlay***

(Contd. of page 6)

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

None of the ingredients is listed.

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

All ingredients are listed.

· **Proposition 65**

· **Chemicals known to cause cancer:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**

None of the ingredients is listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

· **Product related hazard informations:**

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 Substance Directive 1999/45/EC usually if they are in the finished state and intended for the final user.

· **Hazard symbols:**



*Dangerous for the environment*

· **Risk phrases:**

Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

· **Safety phrases:**

Use appropriate container to avoid environmental contamination.  
This material and its container must be disposed of as hazardous waste.

· **Special labeling of certain preparations:**

Contains dipotassium hexafluorotitanate. May produce an allergic reaction.

· **National regulations:**

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

The product is a medical device according to the EC-directive 93/42/EEC.  
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.

(Contd. on page 8)

**Safety Data Sheet**  
**acc. to OSHA HCS**

Printing date 05/23/2013

Version number 4

Reviewed on 05/14/2013

**Trade name: *Telio CS Onlay***

· **Chemical safety assessment:** *A Chemical Safety Assessment has not been carried out.*

(Contd. of page 7)

**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.*

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

USA