1 Identification

- **Product identifier**

- **Trade name**: Telio CS 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**

<table>
<thead>
<tr>
<th>Manufacturer/Supplier:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ivoclar Vivadent Inc.</td>
</tr>
<tr>
<td>175 Pineview Drive, Amherst, N.Y. 14228 USA</td>
</tr>
<tr>
<td>Tel. +1 800 533 6825</td>
</tr>
<tr>
<td>Fax +1 716 691 2285</td>
</tr>
</tbody>
</table>

  | 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(s) identification

- **Classification of the substance or mixture**

  Skin Sens. 1 H317 May cause an allergic skin reaction.

- **Label elements**

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

- **Hazard pictograms**

  - GHS07

- **Signal word** Warning

- **Hazard-determining components of labeling:**

  dipotassium hexafluorotitanate

- **Hazard statements**

  May cause an allergic skin reaction.

- **Precautionary statements**

  Avoid release to the environment. Collect spillage.
Trade name: Telio CS Inlay

- **Additional information:**
  Medical devices are exempt from the labeling provisions of GHS according to the Hazard Communication Standard (HCS).
- **Classification system:**
- **NFPA ratings (scale 0 - 4)**
  - Health = 0
  - Fire = 0
  - Reactivity = 0
- **HMIS-ratings (scale 0 - 4)**
  - Health = 0
  - Fire = 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:

<table>
<thead>
<tr>
<th>Component</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>16919-27-0 dipotassium hexafluorotitanate</td>
<td>0.1-&lt;1%</td>
</tr>
<tr>
<td>3380-34-5 triclosan</td>
<td>0.25-&lt;1%</td>
</tr>
</tbody>
</table>

### 4 First-aid measures

- **Description of first aid measures**
  - **After inhalation:**
    Supply fresh air; consult doctor in case of complaints.
  - **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.

### 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.
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.
    - 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/cm³ (11.333 - 11.616 lbs/gal)
  - Relative density: Not determined.
  - Vapour 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.
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.
      - OSHA-Ca (Occupational Safety & Health Administration)
        - 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.
  - Ecotoxic effects:
  - Remark: Very toxic for fish
  - Additional ecological information:
  - General notes:
    - Also poisonous for fish and plankton in water bodies.
    - Very toxic for aquatic organisms
    - 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.
Trade name: Telio CS Inlay

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

- UN-Number
  - DOT, ADR, ADN, IMDG, IATA Void

- UN proper shipping name
  - DOT, ADR, ADN, IMDG, IATA Void

- Transport hazard class(es)
  - DOT, ADR, ADN, IMDG, IATA Void

- Packing group
  - DOT, 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": -

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): All ingredients are listed.

(Contd. on page 7)
Trade name: Telio CS Inlay

- **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.

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

- **Signal word** Warning

- **Hazard-determining components of labeling:**
  - dipotassium hexafluorotitanate
  - **Hazard statements**
    May cause an allergic skin reaction.
  - **Precautionary statements**
    Avoid release to the environment.
    Collect spillage.

- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**
  - The product is a medical device according to the 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.
  - **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.

- **Date of preparation / last revision** 05/19/2015 / 4
- **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
  - DOT: US Department of Transportation

(Contd. on page 8)
Trade name: Telio CS Inlay

IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
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)
Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

* Data compared to the previous version altered.