SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name: Telio CS Onlay

1.2 Relevant identified uses of the substance or mixture and uses advised against

Application of the substance / the mixture Light-curing temporary restorative material

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:
Ivoclar Vivadent AG
Bendererstrasse 2
FL-9494 Schaan
PRINCIPALITY OF LIECHTENSTEIN

Tel: +423 235 35 35
Fax: +423 235 33 60

Further information obtainable from:
Regulatory Affairs
sds@ivoclarvivadent.com

1.4 Emergency telephone number: +423 / 235 33 13 (Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008
Aquatic Acute 1  H400 Very toxic to aquatic life.
Aquatic Chronic 1 H410 Very toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008
The product is classified and labelled according to the CLP regulation.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.
**SECTION 3: Composition/information on ingredients**

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

<table>
<thead>
<tr>
<th>Dangerous components</th>
<th>CAS:</th>
<th>EINECS:</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ethyltriglycol methacrylate</td>
<td>39670-09-2</td>
<td>254-588-0</td>
<td>Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335</td>
</tr>
<tr>
<td>ethyltriglycol methacrylate</td>
<td>39670-09-2</td>
<td>254-588-0</td>
<td>Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335</td>
</tr>
<tr>
<td>dipotassium hexafluorotitanate</td>
<td>16919-27-0</td>
<td>240-969-9</td>
<td>Eye Dam. 1, H318; Acute Tox. 4, H302; Skin Sens. 1, H317</td>
</tr>
<tr>
<td>triclosan</td>
<td>3380-34-5</td>
<td>222-182-2</td>
<td>Aquatic Acute 1, H400; Aquatic Chronic 1, H410; Skin Irrit. 2, H315; Eye Irrit. 2, H319</td>
</tr>
</tbody>
</table>

- **Additional information:** For the wording of the listed risk phrases refer to section 16.

**SECTION 4: First aid measures**

- **4.1 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.

- **4.2 Most important symptoms and effects, both acute and delayed**
  No further relevant information available.

- **4.3 Indication of any immediate medical attention and special treatment needed**
  No further relevant information available.

**SECTION 5: Firefighting measures**

- **5.1 Extinguishing media**
  - Suitable extinguishing agents:
    CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

- **5.2 Special hazards arising from the substance or mixture**
  No further relevant information available.

- **5.3 Advice for firefighters**
  No special measures required.

**SECTION 6: Accidental release measures**

- **6.1 Personal precautions, protective equipment and emergency procedures**
  Not required.

- **6.2 Environmental precautions**
  Do not allow to enter sewers/ surface or ground water.

- **6.3 Methods and material for containment and cleaning up**
  Pick up mechanically.

- **6.4 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.

(Contd. on page 3)
SECTION 7: Handling and storage

7.1 Precautions for safe handling
   Only adequately trained personnel should handle this product.
   For use in dentistry only.

7.2 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.

7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

8.1 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.

8.2 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.
   Respiratory protection: 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.
### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

**General Information**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance:</td>
<td>Pasty</td>
</tr>
<tr>
<td>Colour:</td>
<td>According to product specification</td>
</tr>
<tr>
<td>Odour:</td>
<td>Characteristic</td>
</tr>
<tr>
<td>Odour threshold:</td>
<td>Not determined.</td>
</tr>
<tr>
<td>pH-value:</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Change in condition</td>
<td></td>
</tr>
<tr>
<td>Melting point/Melting range:</td>
<td>Undetermined.</td>
</tr>
<tr>
<td>Boiling point/Boiling range:</td>
<td>Undetermined.</td>
</tr>
<tr>
<td>Flash point:</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Flammability (solid, gaseous):</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Self-igniting:</td>
<td>Product is not selfigniting.</td>
</tr>
<tr>
<td>Danger of explosion:</td>
<td>Product does not present an explosion hazard.</td>
</tr>
<tr>
<td>Explosion limits:</td>
<td></td>
</tr>
<tr>
<td>Lower:</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Upper:</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Vapour pressure:</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Density at 20 °C:</td>
<td>1.358 - 1.392 g/cm³</td>
</tr>
<tr>
<td>Relative density</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Vapour density</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Solubility in / Miscibility with water:</td>
<td>Nearly insoluble.</td>
</tr>
<tr>
<td>Partition coefficient (n-octanol/water):</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Viscosity:</td>
<td></td>
</tr>
<tr>
<td>Dynamic:</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Kinematic:</td>
<td>Not determined.</td>
</tr>
<tr>
<td>9.2 Other information</td>
<td>No further relevant information available.</td>
</tr>
</tbody>
</table>

### SECTION 10: Stability and reactivity

#### 10.1 Reactivity

No further relevant information available.

#### 10.2 Chemical stability

Stable under normal handling and storage conditions.

Photo reactive (Danger of polymerization).

#### Thermal decomposition / conditions to be avoided

No decomposition if used according to specifications.

#### 10.3 Possibility of hazardous reactions

No dangerous reactions known.

#### 10.4 Conditions to avoid

No further relevant information available.

#### 10.5 Incompatible materials

No further relevant information available.
Trade name: Telio CS Onlay

- 10.6 Hazardous decomposition products: None under normal conditions of storage and use.

SECTION 11: Toxicological information

- 11.1 Information on toxicological effects
  - Acute toxicity:
  - Primary irritant effect:
    - on the skin: No irritant effect.
    - on the eye: No irritating effect.
  - Sensitisation: No sensitising effects known.

SECTION 12: Ecological information

- 12.1 Toxicity
  - Aquatic toxicity: No further relevant information available.
- 12.2 Persistence and degradability: No further relevant information available.
- 12.3 Bioaccumulative potential: No further relevant information available.
- 12.4 Mobility in soil: No further relevant information available.
- Ecotoxical effects:
  - Remark: Very toxic for fish
  - 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.
      - Also poisonous for fish and plankton in water bodies.
      - Very toxic for aquatic organisms
- 12.5 Results of PBT and vPvB assessment
  - PBT: Not applicable.
  - vPvB: Not applicable.
- 12.6 Other adverse effects: No further relevant information available.

SECTION 13: Disposal considerations

- 13.1 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.

* SECTION 14: Transport information

- 14.1 UN-Number
  - ADR, ADN, IMDG, IATA: Void
- 14.2 UN proper shipping name
  - ADR, ADN, IMDG, IATA: Void
Trade name: Telio CS Onlay

· 14.3 Transport hazard class(es)
  - ADR, ADN, IMDG, IATA
  - Class
  - Void

· 14.4 Packing group
  - ADR, IMDG, IATA
  - Void

· 14.5 Environmental hazards:
  - Marine pollutant:
  - No

· 14.6 Special precautions for user
  - Not applicable.

· 14.7 Transport in bulk according to Annex II of MARPOL73/78 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":
  - -

SECTION 15: Regulatory information

· 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
  - National regulations:

· Other regulations, limitations and prohibitive regulations
  - The product is a medical device according to the Directive 93/42/EEC.

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

SECTION 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.
  - H400 Very toxic to aquatic life.
  - H410 Very toxic to aquatic life with long lasting effects.

· 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
  - GHS: Globally Harmonised System of Classification and Labelling of Chemicals
  - 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)
  - Acute Tox. 4: Acute toxicity, Hazard Category 4
  - Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2
  - Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1
  - Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2
  - Skin Sens. 1: Sensitisation - Skin, Hazard Category 1
  - STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3
  - Aquatic Acute 1: Hazardous to the aquatic environment - AcuteHazard, Category 1

(Contd. on page 7)
Aquatic Chronic 1: Hazardous to the aquatic environment - Chronic Hazard, Category 1

* Data compared to the previous version altered.