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

1.1 Product identifier

Trade name: Telio CS Cem Implant (Base)

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

No further relevant information available.

Application of the substance / the mixture

Semi-permanent, self-curing dental luting composite with light-curing option for the cementation of restorations on implant abutments

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

Skin Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2 H319 Causes serious eye irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.
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.

Hazard pictograms

GHS07 GHS09

Signal word Warning

Hazard-determining components of labelling:
1,10-decandioldimethacrylate
urethane dimethacrylate

Hazard statements
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements
P280 Wear protective gloves/protective clothing/eye protection/face protection.
**SECTION 3: Composition/information on ingredients**

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

<table>
<thead>
<tr>
<th>CAS</th>
<th>EINECS</th>
<th>Substance</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>13760-80-0</td>
<td>237-354-2</td>
<td>ytterbium trifluoride</td>
<td>10-&lt;25%</td>
</tr>
<tr>
<td>6701-13-9</td>
<td>229-745-1</td>
<td>1,10-decandiol dimethacrylate</td>
<td>10-&lt;25%</td>
</tr>
<tr>
<td>72869-86-4</td>
<td>276-957-5</td>
<td>urethane dimethacrylate</td>
<td>1-&lt;2.5%</td>
</tr>
<tr>
<td>3380-34-5</td>
<td>222-182-2</td>
<td>triclosan</td>
<td>0.3-&lt;1%</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 and to be sure call for a doctor.
    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. 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

Protective equipment: 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.

SECTION 7: Handling and storage

7.1 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.
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:
Store in a cool place.
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.
Keep away from foodstuffs, beverages and feed.
Avoid contact with the skin.
Respiratory protection: Not required.
Protection of hands:
Protective gloves
**SECTION 9: Physical and chemical properties**

- **9.1 Information on basic physical and chemical properties**

- **General Information**
  - **Appearance:**
    - Form: Pasty
    - Colour: According to product specification
  - Odour: 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.

- **Self-igniting:** Product is not selfigniting.

- **Danger of explosion:** Product does not present an explosion hazard.

- **Explosion limits:**
  - Lower: Not determined.
  - Upper: Not determined.

- **Vapour pressure:** Not determined.

- **Density at 20 °C:** 1.47 g/cm³
  - 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.
SECTION 10: Stability and reactivity

- 10.1 Reactivity: No further relevant information available.
- 10.2 Chemical stability
  Stable under normal handling and storage conditions.
  Photoreactive (Danger of polymerization).
- 10.3 Possibility of hazardous reactions: No decomposition if used according to specifications.
- 10.4 Conditions to avoid
  Protect from exposure to the light.
  Keep away from heat and direct sunlight.
- 10.5 Incompatible materials: No further relevant information available.
- 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: Sensitisation possible through skin contact.
  - Additional toxicological information: No further relevant information available.

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.
- Ecotoxicological 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.

European waste catalogue
18 01 06* chemicals consisting of or containing dangerous substances

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

14.3 Transport hazard class(es)
ADR, ADN, IMDG, IATA 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 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": -

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
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
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.
H412 Harmful 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)
Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2
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 - Acute Hazard, Category 1
Aquatic Chronic 1: Hazardous to the aquatic environment - Chronic Hazard, Category 1
Aquatic Chronic 3: Hazardous to the aquatic environment - Chronic Hazard, Category 3

* Data compared to the previous version altered.