

## Safety data sheet according to 1907/2006/EC, Article 31

Printing date 19.05.2015

Version number 2

Revision: 10.04.2015

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

- **1.1 Product identifier**
- **Trade name:** **Telio CS Cem Implant (Catalyst)**
- **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.
- **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
- **Signal word** Warning
- **Hazard-determining components of labelling:**  
1,10-decandiol dimethacrylate  
dibenzoyl peroxide
- **Hazard statements**  
H315 Causes skin irritation.  
H319 Causes serious eye irritation.  
H317 May cause an allergic skin reaction.
- **Precautionary statements**  
P280 Wear protective gloves/protective clothing/eye protection/face protection.  
P363 Wash contaminated clothing before reuse.  
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.  
P337+P313 If eye irritation persists: Get medical advice/attention.

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· **Additional information:**

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 Regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

· **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.

· **Dangerous components:**

|                   |                                                             |         |
|-------------------|-------------------------------------------------------------|---------|
| CAS: 6701-13-9    | 1,10-decandiol dimethacrylate                               | 10-<25% |
| EINECS: 229-745-1 | Eye Irrit. 2, H319; Skin Sens. 1, H317                      |         |
| CAS: 13760-80-0   | ytterbium trifluoride                                       | 10-<25% |
| EINECS: 237-354-2 | Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335    |         |
| CAS: 94-36-0      | dibenzoyl peroxide                                          | 1-<2.5% |
| EINECS: 202-327-6 | Org. Perox. B, H241; Eye Irrit. 2, H319; Skin Sens. 1, H317 |         |

· **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:**

CO<sub>2</sub>, 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.

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· **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

· **Additional information about design of technical facilities:** No further data; see item 7.

· **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 eyes and skin.

· **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**

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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

### 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:** 1.46 g/cm<sup>3</sup>

• **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.

• **9.2 Other information** No further relevant information available.

### SECTION 10: Stability and reactivity

• **10.1 Reactivity** No further relevant information available.

• **10.2 Chemical stability** Stable under normal handling and storage conditions.

• **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.

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- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **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:** 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.
- **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.
- **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

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|                                                                                             |                                                                                |
|---------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| · <b>14.2 UN proper shipping name</b><br>· <b>ADR, ADN, IMDG, IATA</b>                      | Void                                                                           |
| · <b>14.3 Transport hazard class(es)</b><br>· <b>ADR, ADN, IMDG, IATA</b><br>· <b>Class</b> | Void                                                                           |
| · <b>14.4 Packing group</b><br>· <b>ADR, IMDG, IATA</b>                                     | Void                                                                           |
| · <b>14.5 Environmental hazards:</b><br>· <b>Marine pollutant:</b>                          | No                                                                             |
| · <b>14.6 Special precautions for user</b>                                                  | Not applicable.                                                                |
| · <b>14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>       | Not applicable.                                                                |
| · <b>Transport/Additional information:</b>                                                  | Product is not classified as a dangerous good for transport (ADR, IMDG, IATA). |
| · <b>UN "Model Regulation":</b>                                                             | -                                                                              |

### 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**  
H241 Heating may cause a fire or explosion.  
H315 Causes skin irritation.  
H317 May cause an allergic skin reaction.  
H319 Causes serious eye irritation.  
H335 May cause respiratory irritation.
- **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)  
Org. Perox. B: Organic Peroxides, Type B  
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
- **\* Data compared to the previous version altered.**

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