

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

Printing date 22.07.2019

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 (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
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, 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-decandiol dimethacrylate
urethane dimethacrylate
Aromatic aliphatic 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.

(Contd. on page 2)

Safety data sheet

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Version number 2

Revision: 10.04.2015

Trade name: Telio CS Cem Implant (Base)

(Contd. of page 1)

· **Precautionary statements**

- P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
 P280 Wear protective gloves / eye protection / face protection.
 P302+P352 IF ON SKIN: Wash with plenty of water.
 P321 Specific treatment (see on this label).
 P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **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: 13760-80-0 EINECS: 237-354-2	ytterbium trifluoride Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	10-<25%
CAS: 6701-13-9 EINECS: 229-745-1	1,10-decandiol dimethacrylate Eye Irrit. 2, H319; Skin Sens. 1, H317	10-<25%
CAS: 72869-86-4 EINECS: 276-957-5	urethane dimethacrylate Eye Irrit. 2, H319; Skin Sens. 1, H317; Aquatic Chronic 3, H412	1-<2.5%
CAS: 3380-34-5 EINECS: 222-182-2	triclosan Aquatic Acute 1, H400; Aquatic Chronic 1, H410; Skin Irrit. 2, H315; Eye Irrit. 2, H319	0.3-<1%

· **Additional information:** For the wording of the listed hazard 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.

GB

(Contd. on page 3)

Safety data sheet
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Version number 2

Revision: 10.04.2015

Trade name: Telio CS Cem Implant (Base)

(Contd. of page 2)

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

- **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 and dental laboratories.
Wash hands before breaks and at the end of work.
Keep away from foodstuffs, beverages and feed.
Avoid contact with the skin.

(Contd. on page 4)

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

Printing date 22.07.2019

Version number 2

Revision: 10.04.2015

Trade name: Telio CS Cem Implant (Base)

(Contd. of page 3)

- **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.

- **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/freezing point:	Undetermined.
Initial boiling point and boiling range:	Undetermined.

- **Flash point:** Not applicable.

- **Flammability (solid, gas):** Not applicable.

- **Auto-ignition temperature:** Product is not selfigniting.

- **Explosive properties:** 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/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.

- **Solubility in / Miscibility with water:** Nearly insoluble.

(Contd. on page 5)

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

Printing date 22.07.2019

Version number 2

Revision: 10.04.2015

Trade name: **Telio CS Cem Implant (Base)**

(Contd. of page 4)

- **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.
Photoreactive (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**
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** Based on available data, the classification criteria are not met.
- **Skin corrosion/irritation**
Causes skin irritation.
- **Serious eye damage/irritation**
Causes serious eye irritation.
- **Respiratory or skin sensitisation**
May cause an allergic skin reaction.
- **Additional toxicological information:** No further relevant information available.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

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

(Contd. on page 6)

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

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Version number 2

Revision: 10.04.2015

Trade name: Telio CS Cem Implant (Base)

(Contd. of page 5)

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/RID/ADN, ADN, IMDG, IATA** Void

· 14.2 UN proper shipping name

· **ADR/RID/ADN, ADN, IMDG, IATA** Void

· 14.3 Transport hazard class(es)

· **ADR/RID/ADN, ADN, IMDG, IATA**

· **Class** Void

· 14.4 Packing group

· **ADR/RID/ADN, 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 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":

Void

SECTION 15: Regulatory information

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

· **Directive 2012/18/EU**

· **Qualifying quantity (tonnes) for the application of lower-tier requirements** 100 t

· **Qualifying quantity (tonnes) for the application of upper-tier requirements** 200 t

(Contd. on page 7)

Safety data sheet
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Revision: 10.04.2015

Trade name: Telio CS Cem Implant (Base)

(Contd. of page 6)

· **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3

· **Regulation (EU) No 649/2012**

CAS: 3380-34-5	triclosan	Annex I Part 1
		Annex I Part 2

· **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)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 1

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

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

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