

## SAFETY DATA SHEETS

**This SDS packet was issued with item:**

077156052

**The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).**

077156946 077156953

**The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).**

077101702 077101710 077101728 077101736 077101785 077101793 077101801 077101819 077156037 077156045  
077156938

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

Printing date 27.01.2012





Version number 1

Revision: 27.01.2012

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

- **Product identifier**
- **Trade name:** ***Telio CS Cem Implant (Base)***
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the preparation**  
Semi-permanent, self-curing dental luting composite with light-curing option for the cementation of restorations on implant abutments
- **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  
msds@ivoclarvivadent.com
- **Emergency telephone number:** +423 / 235 33 13

### 2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**  
 Xi; Sensitising  
R43: May cause sensitisation by skin contact.
-  N; Dangerous for the environment  
R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
- **Classification system:**  
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.
- **Label elements**
- **Labelling according to EU guidelines:**  
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 Dangerous Substance Directive 1999/45/EC usually if they are in the finished state and intended for the final user.
- **Code letter and hazard designation of product:**  
  Xi Irritant  
N Dangerous for the environment
- **Hazard-determining components of labelling:**  
decamethylene dimethacrylate  
urethane dimethacrylate
- **Risk phrases:**  
43 May cause sensitisation by skin contact.

(Contd. on page 2)

GB

## Safety data sheet

### according to 1907/2006/EC, Article 31

Printing date 27.01.2012

Version number 1

Revision: 27.01.2012

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

(Contd. of page 1)

50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

· **Safety phrases:**

24 Avoid contact with skin.

37 Wear suitable gloves.

57 Use appropriate container to avoid environmental contamination.

60 This material and its container must be disposed of as hazardous waste.

· **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 substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 6701-13-9	decamethylene dimethacrylate	 Xi R36;  Xi R43	10-25%
CAS: 72869-86-4 EINECS: 276-957-5	urethane dimethacrylate	 Xi R36;  Xi R43 R52/53	≤ 2.5%
CAS: 3380-34-5 EINECS: 222-182-2	triclosan	 Xi R36/38;  N R50/53	≤ 2.5%

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

### 4 First aid measures

· **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.

· **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 Firefighting measures

· **Extinguishing media**

· **Suitable extinguishing agents:**

CO<sub>2</sub>, 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.

· **Advice for firefighters**

· **Protective equipment:** No special measures required.

### 6 Accidental release measures

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

(Contd. on page 3)

GB

## Safety data sheet

### according to 1907/2006/EC, Article 31

Printing date 27.01.2012

Version number 1

Revision: 27.01.2012

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

(Contd. of page 2)

- **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 fire - and explosion protection:** 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:**  
Store in a cool place.  
Protect from exposure to the light.  
Protect from heat and direct sunlight.  
Keep container tightly sealed.
- **Specific end use(s)** No further relevant information available.

### 8 Exposure controls/personal protection

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

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

(Contd. on page 4)

GB

## Safety data sheet

### according to 1907/2006/EC, Article 31

Printing date 27.01.2012

Version number 1

Revision: 27.01.2012

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

(Contd. of page 3)

· **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
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/cm<sup>3</sup>

· **Relative density** Not determined.

· **Vapour density** Not determined.

· **Evaporation rate** Not determined.

· **Solubility in / Miscibility with water:**

Nearly insoluble.

· **Segregation coefficient (n-octanol/water):** Not determined.

· **Viscosity:**

Dynamic:	Not determined.
Kinematic:	Not determined.

· **Other information** No further relevant information available.

## 10 Stability and reactivity

· **Reactivity** No further relevant information available.

(Contd. on page 5)

GB

## Safety data sheet

### according to 1907/2006/EC, Article 31

Printing date 27.01.2012

Version number 1

Revision: 27.01.2012

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

(Contd. of page 4)

- **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**  
Protect from exposure to the light.  
Keep away from heat and direct sunlight.
- **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:** Sensitization possible through skin contact.
- **Additional toxicological information:**  
The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:  
Irritant

## 12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **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
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

## 13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**  
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

(Contd. on page 6)

GB

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

Printing date 27.01.2012

Version number 1

Revision: 27.01.2012

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

(Contd. of page 5)

· **European waste catalogue**

18 01 06\* chemicals consisting of or containing dangerous substances

· **Uncleaned packaging:**

· **Recommendation:** Disposal must be made according to official regulations.

### 14 Transport information

· **UN-Number**

· **ADR, ADN, IMDG, IATA** Void

· **UN proper shipping name**

· **ADR, ADN, IMDG, IATA** Void

· **Transport hazard class(es)**

· **ADR, ADN, IMDG, IATA**

· **Class** Void

· **Packing group**

· **ADR, IMDG, IATA** Void

· **Environmental hazards:**

· **Marine pollutant:** No

· **Special precautions for user** Not applicable.

· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.

### 15 Regulatory information

· **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 EC-directive 93/42/EEC.

· **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.

· **Relevant phrases**

R36 Irritating to eyes.

R36/38 Irritating to eyes and skin.

R43 May cause sensitisation by skin contact.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

GB



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

- **Product identifier**
- **Trade name:** ***Telio CS Cem Implant (Catalyst)***
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the preparation**  
*Semi-permanent, self-curing dental luting composite with light-curing option for the cementation of restorations on implant abutments*
- **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  
msds@ivoclarvivadent.com*
- **Emergency telephone number:** +423 / 235 33 13

### 2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**  
 **Xi; Irritant**  
*R36: Irritating to eyes.*
-  **Xi; Sensitising**  
*R43: May cause sensitisation by skin contact.*
- **Classification system:**  
*The classification is according to the latest editions of the EU-lists, and extended by company and literature data.*
- **Label elements**
- **Labelling according to EU guidelines:**  
*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 Dangerous Substance Directive 1999/45/EC usually if they are in the finished state and intended for the final user.*
- **Code letter and hazard designation of product:**  
 **Xi Irritant**
- **Hazard-determining components of labelling:**  
*decamethylene dimethacrylate  
dibenzoyl peroxide*
- **Risk phrases:**  
*36 Irritating to eyes.  
43 May cause sensitisation by skin contact.*

(Contd. on page 2)

GB



## Safety data sheet

### according to 1907/2006/EC, Article 31

Printing date 27.01.2012

Version number 1

Revision: 27.01.2012

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

(Contd. of page 1)

**· Safety phrases:**

- 24 Avoid contact with skin.
- 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- 37 Wear suitable gloves.
- 60 This material and its container must be disposed of as hazardous waste.







**· 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 substances listed below with nonhazardous additions.

**· Dangerous components:**

CAS: 6701-13-9	decamethylene dimethacrylate  Xi R36;  Xi R43	10-25%
CAS: 94-36-0 EINECS: 202-327-6	dibenzoyl peroxide  Xi R36;  Xi R43;  E R3;  O R7	≤ 2.5%

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

### 4 First aid measures

**· 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.

**· 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 Firefighting measures

**· Extinguishing media**
**· Suitable extinguishing agents:**

- CO<sub>2</sub>, 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.

**· Advice for firefighters**
**· Protective equipment:** No special measures required.

### 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.

(Contd. on page 3)

GB

## Safety data sheet

### according to 1907/2006/EC, Article 31

Printing date 27.01.2012

Version number 1

Revision: 27.01.2012

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

(Contd. of page 2)

- **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 fire - and explosion protection:** 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:**  
Store in a cool place.  
Protect from exposure to the light.  
Protect from heat and direct sunlight.  
Keep container tightly sealed.
- **Specific end use(s)** No further relevant information available.

## 8 Exposure controls/personal protection

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

(Contd. on page 4)

GB

## Safety data sheet

### according to 1907/2006/EC, Article 31

Printing date 27.01.2012

Version number 1

Revision: 27.01.2012

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

(Contd. of page 3)

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
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.

· **Segregation coefficient (n-octanol/water):** Not determined.

· **Viscosity:**

Dynamic:	Not determined.
Kinematic:	Not determined.

· **Other information** No further relevant information available.

## 10 Stability and reactivity

· **Reactivity** No further relevant information available.

· **Chemical stability** Stable under normal handling and storage conditions.

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

· **Possibility of hazardous reactions** No dangerous reactions known.

(Contd. on page 5)

GB

## Safety data sheet

### according to 1907/2006/EC, Article 31

Printing date 27.01.2012

Version number 1

Revision: 27.01.2012

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

(Contd. of page 4)

- **Conditions to avoid**  
Protect from exposure to the light.  
Keep away from heat and direct sunlight.
- **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:** Irritating effect.
- **Sensitization:** Sensitization possible through skin contact.
- **Additional toxicological information:**  
The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:  
Irritant

## 12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **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.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

## 13 Disposal considerations

- **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
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- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

GB

(Contd. on page 6)

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

Printing date 27.01.2012

Version number 1

Revision: 27.01.2012

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

(Contd. of page 5)

### 14 Transport information

- |  |                 |
|--|-----------------|
| · <b>UN-Number</b>   |                 |
| · <b>ADR, ADN, IMDG, IATA</b>  | Void            |
| · <b>UN proper shipping name</b>   |                 |
| · <b>ADR, ADN, IMDG, IATA</b>  | Void            |
| · <b>Transport hazard class(es)</b>  |                 |
| · <b>ADR, ADN, IMDG, IATA</b>  |                 |
| · <b>Class</b>   | Void            |
| · <b>Packing group</b>   |                 |
| · <b>ADR, IMDG, IATA</b>   | Void            |
| · <b>Environmental hazards:</b>  |                 |
| · <b>Marine pollutant:</b>   | No              |
| · <b>Special precautions for user</b>  | Not applicable. |
| · <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b> | Not applicable. |

### 15 Regulatory information

- **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 EC-directive 93/42/EEC.
- **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.*

- **Relevant phrases**  
R3 Extreme risk of explosion by shock, friction, fire or other sources of ignition.  
R36 Irritating to eyes.  
R43 May cause sensitisation by skin contact.  
R7 May cause fire.

GB

## Safety Data Sheet

acc. to OSHA HCS

Printing date 09/19/2013

Version number 2

Reviewed on 09/19/2013

### 1 Identification

- **Product identifier**
- **Trade name:** ***Telio CS Link (Base)***
- **Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the preparation** Dual-curing resin based temporary cement
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Ivoclar Vivadent Inc.  
175 Pineview Drive, Amherst, N.Y. 14228  
USA  
Tel. +1 800 533 6825  
Fax +1 716 691 2285  
  
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 MSDS Assistance:  
US: 1-800-533-6825  
Canada: 1-800-263-8182

### 2 Hazard(s) identification

- **Classification of the substance or mixture**
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**  
Irritant  
Irritating to eyes, respiratory system and skin.
- **Classification system:**  
The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.
- **Label elements**
- **Labelling according to EU guidelines:**  
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 Dangerous Substance Directive 1999/45/EC usually if they are in the finished state and intended for the final user.
- **Code letter and hazard designation of product:**



Irritant

(Contd. on page 2)

USA

# Safety Data Sheet

## acc. to OSHA HCS

Printing date 09/19/2013

Version number 2

Reviewed on 09/19/2013

Trade name: **Telio CS Link (Base)**

(Contd. of page 1)

- **Risk phrases:**

*Irritating to eyes, respiratory system and skin.*

- **Safety phrases:**

*In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.*

*Wear suitable gloves.*

*This material and its container must be disposed of as hazardous waste.*

- **Classification system:**

- **NFPA ratings (scale 0 - 4)**



Health = 1

Fire = 0

Reactivity = 0

- **HMIS-ratings (scale 0 - 4)**



Health = 1

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:**

25852-47-5	polyethylene glycol dimethacrylate	25-50%
------------	------------------------------------	--------

### 4 First-aid measures

- **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.

- **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:**

*CO<sub>2</sub>, 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.

(Contd. on page 3)

USA



## Safety Data Sheet

### acc. to OSHA HCS

Printing date 09/19/2013

Version number 2

Reviewed on 09/19/2013

**Trade name: Telio CS Link (Base)**

(Contd. of page 2)

- **Advice for firefighters**
- **Protective equipment:** No special measures required.

### 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:**  
 Store in a cool place.  
 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.

(Contd. on page 4)

—USA—

# Safety Data Sheet

## acc. to OSHA HCS

Printing date 09/19/2013

Version number 2

Reviewed on 09/19/2013

Trade name: **Telio CS Link (Base)**

(Contd. of page 3)

· **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):** 1.433 g/cm<sup>3</sup> (11.958 lbs/gal)

· **Relative density** Not determined.

· **Vapour density** Not determined.

· **Evaporation rate** Not determined.

· **Solubility in / Miscibility with**

Water: Nearly insoluble.

(Contd. on page 5)

USA

# Safety Data Sheet

## acc. to OSHA HCS

Printing date 09/19/2013

Version number 2

Reviewed on 09/19/2013

Trade name: **Telio CS Link (Base)**

(Contd. of page 4)

- **Partition coefficient (n-octanol/water):** Not determined.
- **Viscosity:**
  - Dynamic:** Not determined.
  - Kinematic:** Not determined.
- **Other information** No further relevant information available.

### 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**
  - Protect from exposure to the light.
  - Keep away from heat and direct sunlight.
- **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:** Irritant to skin and mucous membranes.
  - on the eye:** Irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**
  - The product shows the following dangers according to internally approved calculation methods for preparations:
  - Irritant
- **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.

### 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.

(Contd. on page 6)

USA

## Safety Data Sheet

### acc. to OSHA HCS

Printing date 09/19/2013

Version number 2

Reviewed on 09/19/2013

**Trade name: Telio CS Link (Base)**

(Contd. of page 5)

- **Additional ecological information:**
- **General notes:**  
*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.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

### 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

- |  |                 |
|--|-----------------|
| · <b>UN-Number</b>   | Void            |
| · <b>DOT, ADR, ADN, IMDG, IATA</b>   | Void            |
| · <b>UN proper shipping name</b>   | Void            |
| · <b>DOT, ADR, ADN, IMDG, IATA</b>   | Void            |
| · <b>Transport hazard class(es)</b>  | Void            |
| · <b>DOT, ADR, ADN, IMDG, IATA</b>   | Void            |
| · <b>Class</b>   | Void            |
| · <b>Packing group</b>   | Void            |
| · <b>DOT, ADR, IMDG, IATA</b>  | Void            |
| · <b>Environmental hazards:</b>  | No              |
| · <b>Marine pollutant:</b>   | No              |
| · <b>Special precautions for user</b>  | Not applicable. |
| · <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b> | Not applicable. |

### 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.*

(Contd. on page 7)

USA

# Safety Data Sheet

## acc. to OSHA HCS

Printing date 09/19/2013

Version number 2

Reviewed on 09/19/2013

Trade name: **Telio CS Link (Base)**

(Contd. of page 6)

· **TSCA (Toxic Substances Control Act):**

All ingredients are listed.

· **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)**

13760-80-0 | ytterbium trifluoride

A4

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

· **Product related hazard informations:**

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 Dangerous Substance Directive 1999/45/EC usually if they are in the finished state and intended for the final user.

· **Hazard symbols:**

Irritant

· **Risk phrases:**

Irritating to eyes, respiratory system and skin.

· **Safety phrases:**

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Wear suitable gloves.

This material and its container must be disposed of as hazardous waste.

· **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.

USA

## Safety Data Sheet

acc. to OSHA HCS

Printing date 09/19/2013

Version number 2

Reviewed on 09/19/2013

### 1 Identification

- **Product identifier**
- **Trade name:** ***Telio CS Link (Base)***
- **Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the preparation** Dual-curing resin based temporary cement
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Ivoclar Vivadent Inc.  
175 Pineview Drive, Amherst, N.Y. 14228  
USA  
Tel. +1 800 533 6825  
Fax +1 716 691 2285  
  
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 MSDS Assistance:  
US: 1-800-533-6825  
Canada: 1-800-263-8182

### 2 Hazard(s) identification

- **Classification of the substance or mixture**
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**  
Irritant  
Irritating to eyes, respiratory system and skin.
- **Classification system:**  
The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.
- **Label elements**
- **Labelling according to EU guidelines:**  
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 Dangerous Substance Directive 1999/45/EC usually if they are in the finished state and intended for the final user.
- **Code letter and hazard designation of product:**



Irritant

(Contd. on page 2)

USA

# Safety Data Sheet

## acc. to OSHA HCS

Printing date 09/19/2013

Version number 2

Reviewed on 09/19/2013

Trade name: **Telio CS Link (Base)**

(Contd. of page 1)

- **Risk phrases:**

*Irritating to eyes, respiratory system and skin.*

- **Safety phrases:**

*In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.*

*Wear suitable gloves.*

*This material and its container must be disposed of as hazardous waste.*

- **Classification system:**

- **NFPA ratings (scale 0 - 4)**



Health = 1

Fire = 0

Reactivity = 0

- **HMIS-ratings (scale 0 - 4)**



Health = 1

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:**

25852-47-5	polyethylene glycol dimethacrylate	25-50%
------------	------------------------------------	--------

### 4 First-aid measures

- **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.

- **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:**

*CO<sub>2</sub>, 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.

(Contd. on page 3)

USA



## Safety Data Sheet

### acc. to OSHA HCS

Printing date 09/19/2013

Version number 2

Reviewed on 09/19/2013

**Trade name: Telio CS Link (Base)**

(Contd. of page 2)

- **Advice for firefighters**
- **Protective equipment:** No special measures required.

### 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:**  
 Store in a cool place.  
 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.

(Contd. on page 4)

—USA—

# Safety Data Sheet

## acc. to OSHA HCS

Printing date 09/19/2013

Version number 2

Reviewed on 09/19/2013

Trade name: **Telio CS Link (Base)**

(Contd. of page 3)

### · 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): 1.433 g/cm<sup>3</sup> (11.958 lbs/gal)

· Relative density: Not determined.

· Vapour density: Not determined.

· Evaporation rate: Not determined.

#### · Solubility in / Miscibility with

Water: Nearly insoluble.

(Contd. on page 5)

USA

# Safety Data Sheet

## acc. to OSHA HCS

Printing date 09/19/2013

Version number 2

Reviewed on 09/19/2013

Trade name: **Telio CS Link (Base)**

(Contd. of page 4)

- **Partition coefficient (n-octanol/water):** Not determined.
- **Viscosity:**
  - Dynamic:** Not determined.
  - Kinematic:** Not determined.
- **Other information** No further relevant information available.

### 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**
  - Protect from exposure to the light.
  - Keep away from heat and direct sunlight.
- **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:** Irritant to skin and mucous membranes.
  - on the eye:** Irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**
  - The product shows the following dangers according to internally approved calculation methods for preparations:
  - Irritant
- **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.

### 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.

(Contd. on page 6)

USA

## Safety Data Sheet

### acc. to OSHA HCS

Printing date 09/19/2013

Version number 2

Reviewed on 09/19/2013

**Trade name: Telio CS Link (Base)**

(Contd. of page 5)

- **Additional ecological information:**
- **General notes:**  
*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.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

### 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

- |   |                 |
|---|-----------------|
| <ul style="list-style-type: none"> <li>· <b>UN-Number</b></li> <li>· <b>DOT, ADR, ADN, IMDG, IATA</b></li> </ul>  | Void            |
| <ul style="list-style-type: none"> <li>· <b>UN proper shipping name</b></li> <li>· <b>DOT, ADR, ADN, IMDG, IATA</b></li> </ul>                            | Void            |
| <ul style="list-style-type: none"> <li>· <b>Transport hazard class(es)</b></li> <li>· <b>DOT, ADR, ADN, IMDG, IATA</b></li> <li>· <b>Class</b></li> </ul> | Void            |
| <ul style="list-style-type: none"> <li>· <b>Packing group</b></li> <li>· <b>DOT, ADR, IMDG, IATA</b></li> </ul>   | Void            |
| <ul style="list-style-type: none"> <li>· <b>Environmental hazards:</b></li> <li>· <b>Marine pollutant:</b></li> </ul>                                     | No              |
| <ul style="list-style-type: none"> <li>· <b>Special precautions for user</b></li> </ul>   | Not applicable. |
| <ul style="list-style-type: none"> <li>· <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b></li> </ul>                        | Not applicable. |

### 15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Sara**

<ul style="list-style-type: none"> <li>· <b>Section 355 (extremely hazardous substances):</b></li> </ul>
--

None of the ingredients is listed.
------------------------------------

<ul style="list-style-type: none"> <li>· <b>Section 313 (Specific toxic chemical listings):</b></li> </ul>
--

None of the ingredients is listed.
------------------------------------

(Contd. on page 7)

USA

# Safety Data Sheet

## acc. to OSHA HCS

Printing date 09/19/2013

Version number 2

Reviewed on 09/19/2013

**Trade name: Telio CS Link (Base)**

(Contd. of page 6)

**· TSCA (Toxic Substances Control Act):**

All ingredients are listed.

**· 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)**

13760-80-0 | ytterbium trifluoride

A4

**· NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

**· OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

**· Product related hazard informations:**

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 Dangerous Substance Directive 1999/45/EC usually if they are in the finished state and intended for the final user.

**· Hazard symbols:**


Irritant

**· Risk phrases:**

Irritating to eyes, respiratory system and skin.

**· Safety phrases:**

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Wear suitable gloves.

This material and its container must be disposed of as hazardous waste.

**· 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.

USA