### **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



Printing date 05/19/2015 Version number 2

Reviewed on 04/10/2015

#### 1 Identification

- · Product identifier
- · Trade name: Telio CS Cem Implant (Base)
- · 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

- · 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 SDS Assistance: US: 1-800-533-6825 Canada: 1-800-263-8182

#### 2 Hazard(s) identification

· Classification of the substance or mixture

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2A H319 Causes serious eye irritation.

Skin Sens. 1 H317 May cause an allergic skin reaction.

Carc. 2 H351 Suspected of causing cancer.

- · Label elements
- · GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

· Hazard pictograms





GHS07

GHS08

· Signal word Warning

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Printing date 05/19/2015 Version number 2 Reviewed on 04/10/2015

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

(Contd. of page 1)

#### · Hazard-determining components of labeling:

1,10-decandiol dimethacrylate

titanium dioxide

urethane dimethacrylate

#### · Hazard statements

Causes skin irritation.

Causes serious eve irritation.

May cause an allergic skin reaction.

Suspected of causing cancer.

#### · Precautionary statements

Wear protective gloves/protective clothing/eye protection/face protection.

Avoid release to the environment.

Wash contaminated clothing before reuse.

If skin irritation or rash occurs: Get medical advice/attention.

If eye irritation persists: Get medical advice/attention.

Collect spillage.

### · Additional information:

Medical devices are exempt from the labeling provisions of GHS according to the Hazard Communication Standard (HCS).

- · Classification system:
- · NFPA ratings (scale 0 4)



Health = 1 Fire = 0Reactivity = 0

#### · HMIS-ratings (scale 0 - 4)



- · 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 o	components:	
13760-80-0	ytterbium trifluoride	10-<20%
6701-13-9	1,10-decandiol dimethacrylate	10-<20%
72869-86-4	urethane dimethacrylate	1-<2.5%
13463-67-7	titanium dioxide	1-<2.5%
3380-34-5	triclosan	0.25-<1%

#### 4 First-aid measures

- · Description of first aid measures
- · After inhalation:

Supply fresh air and to be sure call for a doctor.

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# Trade name: Telio CS Cem Implant (Base)

(Contd. of page 2)

*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:

CO2, 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.
- · 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.

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Printing date 05/19/2015 Version number 2 Reviewed on 04/10/2015

Trade name: Telio CS Cem Implant (Base)

(Contd. of page 3)

- · 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.

Keep away from foodstuffs, beverages and feed.

Avoid contact with the skin.

- · Breathing equipment: 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

### 9 Physical and chemical properties

· Information on l	hacie ni	nucieal	and c	homical	nron	orting
· IIIIOI IIIUUUUII OII I	iusic iii	uvsicui	unu ci	uemucui	171 (717)	eittes

· General Information

· Appearance:

Form: Pasty

Color: According to product specification

Odor: CharacteristicOdour 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.

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Printing date 05/19/2015 Version number 2 Reviewed on 04/10/2015

Trade name: Telio CS Cem Implant (Base)

		(Contd. of page
· 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):	1.47 g/cm³ (12.267 lbs/gal)	
· Relative density	Not determined.	
· Vapour density	Not determined.	
· Evaporation rate	Not determined.	
· Solubility in / Miscibility with		
Water:	Nearly insoluble.	
· Partition coefficient (n-octanol/wa	ter): 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.

- $\cdot \textbf{Incompatible materials:} \ No \ further \ relevant \ information \ available.$
- · 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.
- $\cdot \textbf{\textit{Additional toxicological information:}} \ \textit{No further relevant information available.}$
- · Carcinogenic categories

· IARC (Inter	· IARC (International Agency for Research on Cancer)	
7631-86-9	silicon dioxide, chemically prepared	3
13463-67-7	titanium dioxide	2B
128-37-0	2,6-di-tert-butyl-p-cresol	3

### · NTP (National Toxicology Program)

None of the ingredients is listed.

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Trade name: Telio CS Cem Implant (Base)

(Contd. of page 5)

· OSHA-Ca (Occupational Safety & Health Administration)

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:
- $\cdot \textbf{\it Bioaccumulative potential} \ No \ further \ relevant \ information \ available.$
- · Mobility in soil No further relevant information available.
- · Ecotoxical effects:
- · Remark: Very toxic for fish
- · 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.

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.

- · Uncleaned packagings:
- · Recommendation: Disposal must be made according to official regulations.

· UN-Number		
· DOT, ADR, ADN, IMDG, IATA	Void	
· UN proper shipping name · DOT, ADR, ADN, IMDG, IATA	Void	
· Transport hazard class(es)		
DOT, ADR, ADN, IMDG, IATA		
· Class	Void	
· Packing group		
· DOT, ADR, IMDG, IATA	Void	
Environmental hazards:		
· Marine pollutant:	No	

Printing date 05/19/2015 Version number 2 Reviewed on 04/10/2015

Trade name: Telio CS Cem Implant (Base)

· Special precautions for user	Not applicable.
<ul> <li>Transport in bulk according to Annex II of         MARPOL73/78 and the IBC Code         <ul> <li>Transport/Additional information:</li> <li>Product is not classified as a dangerous good for tran (ADR, IMDG, IATA).</li> </ul> </li> </ul>	
· Transport/Additional information:	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).
· UN ''Model Regulation'':	-

# 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.

- · TSCA (Toxic Substances Control Act):
- 13760-80-0 ytterbium trifluoride
- 6701-13-9 1,10-decandiol dimethacrylate
- 7631-86-9 silicon dioxide, chemically prepared
- 72869-86-4 urethane dimethacrylate
- 13463-67-7 titanium dioxide
- 10287-53-3 ethyl p-dimethylaminobenzoate
- 3380-34-5 triclosan
- 41637-38-1 ethyoxylated bisphenol A dimethacrylate
- 10373-78-1 camphorquinone
  - 128-37-0 2,6-di-tert-butyl-p-cresol
- · 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
13463-67-7	titanium dioxide	A4
128-37-0	2,6-di-tert-butyl-p-cresol	A4

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Trade name: Telio CS Cem Implant (Base)

(Contd. of page 7)

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

13463-67-7 titanium dioxide

#### · GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

· Hazard pictograms





GHS07 GHS08

### · Signal word Warning

#### · Hazard-determining components of labeling:

1,10-decandiol dimethacrylate titanium dioxide urethane dimethacrylate

#### · Hazard statements

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

Suspected of causing cancer.

### · Precautionary statements

Wear protective gloves/protective clothing/eye protection/face protection.

Avoid release to the environment.

Wash contaminated clothing before reuse.

If skin irritation or rash occurs: Get medical advice/attention.

If eye irritation persists: Get medical advice/attention.

Collect spillage.

#### · 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.

#### · Date of preparation / last revision 05/19/2015 / 1

#### · 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

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Eye Irrit. 2A: Serious eye damage/eye irritation, Hazard Category 2A

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

Carc. 2: Carcinogenicity, Hazard Category 2

#### \* Data compared to the previous version altered.



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 (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/EWG 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.

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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 compone	ents:	
		10-25%
	Xi R36; Xi R43	
CAS: 94-36-0	dibenzoyl peroxide	≤ 2.5%
EINECS: 202-327-6	🗙 Xi R36; 🗙 Xi R43; 🎇 E R3; 🔥 O R7	

· 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:

CO2, 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.

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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

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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	l chemi	ical propei	ties
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· Information on bo	asic ph	vsical and	chemical	properties
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· 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/cm³
 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.

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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

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

GB

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Printing date 27.01.2012 Version number 1 Revision: 27.01.2012

Trade name: Telio CS Cem Implant (Catalyst)

(Contd. of page 5)

· 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	x 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

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.

an.



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

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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 = 1Fire = 0Reactivity = 0

· HMIS-ratings (scale 0 - 4)



1 Health = 1o Fire = 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:

CO2, 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

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

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

Information on basic physical and	chemical properties
General Information	
Appearance:	D
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/cm³ (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)

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)

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.

UN-Number	
DOT, ADR, ADN, IMDG, IATA	Void
UN proper shipping name	****
DOT, ADR, ADN, IMDG, IATA	Void
Transport hazard class(es)	
DOT, ADR, ADN, IMDG, IATA	
Class	Void
Packing group	
DOT, ADR, IMDG, IATA	Void
Environmental hazards:	
Marine pollutant:	No
Special precautions for user	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)

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



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)

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 = 1Fire = 0Reactivity = 0

· HMIS-ratings (scale 0 - 4)



1 Health = 1o Fire = 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:

CO2, 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

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

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

Information on basic physical and	chemical properties
General Information	
Appearance:	D
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/cm³ (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)

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)

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.

· UN-Number · DOT, ADR, ADN, IMDG, IATA	Void	
· UN proper shipping name · DOT, ADR, ADN, IMDG, IATA	Void	
· Transport hazard class(es)		
· DOT, ADR, ADN, IMDG, IATA		
· Class	Void	
· Packing group		
· DOT, ADR, IMDG, IATA	Void	
· Environmental hazards:		
· Marine pollutant:	No	
· Special precautions for user	Not applicable.	
· Transport in bulk according to Annex	x 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
- · 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)

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