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

1.1 Product identifier

Trade name: Telio CS Link (Base)

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

No further relevant information available.

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:
Ivoclar Vivadent AG
Bendererstrasse 2
FL-9494 Schaan
PRINCIPALITY OF LIECHTENSTEIN

Tel: +423 235 35 35
Fax: +423 235 33 60

Further information obtainable from:
Regulatory Affairs
sds@ivoclarvivadent.com

1.4 Emergency telephone number: +423 / 235 33 13 (Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008
Skin Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2 H319 Causes serious eye irritation.
STOT SE 3 H335 May cause respiratory irritation.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008
The product is classified and labelled according to the CLP regulation.

Hazard pictograms

GHS07

Signal word Warning

Hazard-determining components of labelling:
polyethylene glycol dimethacrylate

Hazard statements
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.

Precautionary statements
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P332+P313 If skin irritation occurs: Get medical advice/attention.
P337+P313 If eye irritation persists: Get medical advice/attention.
Trade name: Telio CS Link (Base)

Additional information:
Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

2.3 Other hazards
Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

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

Dangers components:
- CAS: 25852-47-5 polyethylene glycol dimethacrylate
  Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335
  25-50%

- CAS: 13760-80-0 ytterbium trifluoride
  Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335
  10-<25%

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

SECTION 4: First aid measures

4.1 Description of first aid measures
After inhalation:
Supply fresh air and to be sure call for a doctor.
In case of unconsciousness place patient stably in side position for transportation.
After skin contact: Rinse with water.
After eye contact:
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
After swallowing: If symptoms persist consult doctor.

4.2 Most important symptoms and effects, both acute and delayed
No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed
No further relevant information available.

SECTION 5: Firefighting measures

5.1 Extinguishing media
Suitable extinguishing agents:
CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

5.2 Special hazards arising from the substance or mixture
No further relevant information available.

5.3 Advice for firefighters
Protective equipment: No special measures required.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
Not required.

6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.

6.3 Methods and material for containment and cleaning up:
Pick up mechanically.

6.4 Reference to other sections
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
SECTION 7: Handling and storage

7.1 Precautions for safe handling
Only adequately trained personnel should handle this product.
For use in dentistry only.

7.2 Conditions for safe storage, including any incompatibilities

- Storage:
  - Requirements to be met by storerooms and receptacles: Store only in the original receptacle.
  - Information about storage in one common storage facility: Not required.
  - Further information about storage conditions:
    - Store in a cool place.
    - Protect from exposure to the light.
    - Protect from heat and direct sunlight.
    - Keep container tightly sealed.

7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

- Ingredients with limit values that require monitoring at the workplace:
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- Additional information: The lists valid during the making were used as basis.

8.2 Exposure controls

- Personal protective equipment:
  - General protective and hygienic measures:
    - Usual hygienic measures for dental practice.
    - Wash hands before breaks and at the end of work.
    - Avoid contact with the eyes and skin.
    - Keep away from foodstuffs, beverages and feed.
  - Respiratory protection: Not required.
  - Protection of hands:

Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

- Material of gloves:
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
  - **General Information**
    - **Appearance:** 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:** 1.433 g/cm³
  - **Relative density** Not determined.
  - **Vapour density** Not determined.
  - **Evaporation rate** Not determined.
  - **Solubility in / Miscibility with water:** Nearly insoluble.
  - **Partition coefficient (n-octanol/water):** Not determined.
  - **Viscosity**
    - **Dynamic:** Not determined.
    - **Kinematic:** Not determined.
  - **9.2 Other information**
    - No further relevant information available.

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
  - Stable under normal handling and storage conditions.
  - Photoreactive (Danger of polymerization).
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
10.4 Conditions to avoid

- Protect from exposure to the light.
- Keep away from heat and direct sunlight.

10.5 Incompatible materials: No further relevant information available.

10.6 Hazardous decomposition products: None under normal conditions of storage and use.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

- Acute toxicity:
- Primary irritant effect:
  - on the skin: Irritant to skin and mucous membranes.
  - on the eye: Irritating effect.
- Sensitisation: No sensitising effects known.
- Additional toxicological information: No further relevant information available.

SECTION 12: Ecological information

12.1 Toxicity

- Aquatic toxicity: No further relevant information available.
- Persistence and degradability: No further relevant information available.
- 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.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

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

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

SECTION 14: Transport information

14.1 UN-Number

- ADR, ADN, IMDG, IATA: Void

14.2 UN proper shipping name

- ADR, ADN, IMDG, IATA: Void
Trade name: Telio CS Link (Base)

- 14.3 Transport hazard class(es)
  - ADR, ADN, IMDG, IATA
  - Class Void

- 14.4 Packing group
  - ADR, IMDG, IATA Void

- 14.5 Environmental hazards:
  - Marine pollutant: No

- 14.6 Special precautions for user
  Not applicable.

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

- Transport/Additional information:
  Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).

- UN "Model Regulation": -

SECTION 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
  - National regulations:
    - Other regulations, limitations and prohibitive regulations
      The product is a medical device according to the Directive 93/42/EEC.
  - 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

* SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- Relevant phrases
  H315 Causes skin irritation.
  H319 Causes serious eye irritation.
  H335 May cause respiratory irritation.

- Abbreviations and acronyms:
  ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
  IMDG: International Maritime Code for Dangerous Goods
  IATA: International Air Transport Association
  GHS: Globally Harmonised System of Classification and Labelling of Chemicals
  EINECS: European Inventory of Existing Commercial Chemical Substances
  ELINCS: European List of Notified Chemical Substances
  CAS: Chemical Abstracts Service (division of the American Chemical Society)
  Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2
  Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2
  STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

* Data compared to the previous version altered.