Printing date 26.11.2020

vivadent

Version number 4

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Hazardous according to criteria of Australian Safety and Compensation Council.

# **1** Identification

· Product identifier

• Trade name: Telio Link (Base)

• *Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.* 

· Application of the substance / the mixture Dual-curing resin based temporary cement

Details of the supplier of the safety data sheet
Manufacturer/Supplier: Ivoclar Vivadent AG Bendererstrasse 2
9494 Schaan PRINCIPALITY OF LIECHTENSTEIN Tel: +423 235 35 35 / Fax: +423 235 33 60

Importer: Ivoclar Vivadent Pty. Ltd. 1- 5 Overseas Drive Noble Park North VIC 3174 Tel: + 61 3 9795 9599 / Fax: + 61 3 9795 9645

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

*Emergency telephone number: 131 126 (Poisons Information Centre - 24 hours / 7 days)* 

### 2 Hazard(s) Identification

# · Classification of the substance or mixture

Skin Irrit. 2H315Causes skin irritation.Eye Irrit. 2AH319Causes serious eye irritation.STOT SE 3H335May cause respiratory irritation.

· Label elements

• GHS label elements The product is classified and labelled according to the Globally Harmonised System (GHS).

· Hazard pictograms



· Signal word Warning

· Hazard statements

Causes skin irritation.

*Causes serious eye irritation. May cause respiratory irritation.* 

· Precautionary statements

Avoid breathing dust/fume/gas/mist/vapours/spray. Wear protective gloves/protective clothing/eye protection/face protection. If skin irritation occurs: Get medical advice/attention.

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If eye irritation persists: Get medical advice/attention.

• 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.

• Other hazards

· Results of PBT and vPvB assessment

· PBT: Not applicable.

• **vPvB:** Not applicable.

#### **3** Composition and Information on Ingredients

· Chemical characterisation: Mixtures

· Description: Mixture of substances listed below with nonhazardous additions.

· Dangerous components:

| CAS: 25852-47-5 polyethylene glycol dimethacrylate   | 25-50% |  |
|--|--------|--|
| Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335                                  |        |  |
| CAS: 13760-80-0 ytterbium trifluoride  | 10-25% |  |
| Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335                                  | 1      |  |
| • Additional information: For the wording of the listed hazard phrases refer to section 16 |        |  |

• Additional information: For the wording of the listed hazard phrases refer to section

#### 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, powder or water spray. Fight larger fire with 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.

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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 and 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 and dental laboratories.
- 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:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

• Protection of hands:



Protective gloves (EN 374)

After use of gloves apply skin-cleaning agents and skin cosmetics.

#### • Material of gloves

Butyl rubber, BR

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· 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.

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• Eye protection:



Tightly sealed goggles (EN 166)

| Physical and Chemical Properties          |   |
|---|---|
| · Information on basic physical and chem  |   |
| · General Information                     |   |
| · Appearance:                             |   |
| Form:                                     | Pasty   |
| Colour:                                   | According to product specification            |
| · Odour:                                  | Characteristic                                |
| • Odour threshold:                        | Not determined.                               |
| · pH-value:                               | Not determined.                               |
| · Change in condition                     |   |
| Melting point/freezing point:             | Undetermined.                                 |
| Initial boiling point and boiling range:  | Undetermined.                                 |
| · Flash point:                            | Not applicable.                               |
| · Flammability (solid, gas):              | Not applicable.                               |
| • Auto-ignition temperature:              | Product is not selfigniting.                  |
| • Explosive properties:                   | Product does not present an explosion hazard. |
| · Explosion limits:                       |   |
| Lower:                                    | Not determined.                               |
| Upper:                                    | Not determined.                               |
| · Vapour pressure:                        | Not determined.                               |
| · Density at 20 •C:                       | 1.433 g/cm <sup>3</sup>                       |
| · Relative density                        | Not determined.                               |
| · Vapour density                          | Not determined.                               |
| · Evaporation rate                        | Not determined.                               |
| · Solubility in / Miscibility with        |   |
| water:                                    | Nearly insoluble.                             |
| · Partition coefficient: n-octanol/water: | Not determined.                               |
| · Viscosity:                              |   |
| Dynamic:                                  | Not determined.                               |
| Kinematic:                                | Not determined.                               |
| • 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.

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- · 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
- · Skin corrosion/irritation Irritant to skin and mucous membranes.
- · Serious eye damage/irritation Irritating effect.
- **Respiratory or skin sensitisation** No sensitising effects known.
- · Additional toxicological information: No further relevant information available.

# **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 svstem.

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

# **14 Transport information**

- · UN-Number
- · ADG, ADN, IMDG, IATA
- · UN proper shipping name

Void

· ADG, ADN, IMDG, IATA

Void

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|---|--|
| · Transport hazard class(es)                    |  |
| · ADG, ADN, IMDG, IATA                          | 17 . 1   |
| · Class   | Void   |
| · Packing group<br>· ADG, IMDG, IATA            | Void   |
| · Environmental hazards:<br>· Marine pollutant: | No   |
| · Special precautions for user                  | Not applicable.  |
| • Transport in bulk according to Annex II of    | `Marpol  |
| and the IBC Code                                | Not applicable.  |
| • Transport/Additional information:             | Product is not classified as a dangerous good for transport (ADR, IMDG, IATA). |
| · UN ''Model Regulation'':                      | Void   |

#### **15 Regulatory information**

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

· Australian Inventory of Industrial Chemicals

CAS: 25852-47-5 polyethylene glycol dimethacrylate

· Standard for the Uniform Scheduling of Medicines and Poisons

None of the ingredients is listed.

· GHS label elements

The product is classified and labelled according to the Globally Harmonised System (GHS).

• Hazard pictograms



· Signal word Warning

· Hazard statements

Causes skin irritation.

*Causes serious eye irritation. May cause respiratory irritation.* 

· Precautionary statements

Avoid breathing dust/fume/gas/mist/vapours/spray. Wear protective gloves/protective clothing/eye protection/face protection. If skin irritation occurs: Get medical advice/attention. If eye irritation persists: Get medical advice/attention.

· Directive 2012/18/EU

· Named dangerous substances - ANNEX I None of the ingredients is listed.

· National regulations:

• Other regulations, limitations and prohibitive regulations

The product is a medical device according to the Directive 93/42/EEC.

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· 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

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

- EINECS: European Inventory of Existing Commercial Chemical Substances
- ELINCS: European List of Notified Chemical Substances
- CAS: Chemical Abstracts Service (division of the American Chemical Society)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

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

*Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A STOT SE 3: Specific target organ toxicity (single exposure) – Category 3* 

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