

**Safety Data Sheet**  
according to WHS Regulations

Printing date 28.04.2023

Version number 3

Revision: 28.04.2023

Hazardous according to criteria of Australian Safety and Compensation Council.

**1 Identification**

- **Product identifier**
- **Trade name:** *Variolink Esthetic LC / Variolink Esthetic LC HV*
- **Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** Light-curing resin-based dental luting material
- **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. 2 H315 Causes skin irritation.  
Serious eye damage/irritation – Category 2A H319 Causes serious eye irritation.  
Skin Sens. 1 H317 May cause an allergic skin reaction.  
STOT SE 3 H335 May cause respiratory irritation.
- **Label elements**
- **GHS label elements**  
The product is classified and labelled according to the Globally Harmonised System (GHS).
- **Hazard pictograms**  
  
GHS07
- **Signal word** Warning
- **Hazard-determining components of labelling:**  
urethane dimethacrylate  
ytterbium trifluoride  
aromatic aliphatic urethane dimethacrylate  
1,10-decandiol dimethacrylate

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- **Hazard statements**

- Causes skin irritation.
- Causes serious eye irritation.
- May cause an allergic skin reaction.
- May cause respiratory irritation.

- **Precautionary statements**

- Wear protective gloves/protective clothing/eye protection/face protection.
- If skin irritation or rash occurs: Get medical advice/attention.
- If eye irritation persists: Get medical advice/attention.
- Wash contaminated clothing before reuse.
- Dispose of contents/container in accordance with local/regional/national/international regulations.

- **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: 13760-80-0	ytterbium trifluoride Skin Irrit. 2, H315; Serious eye damage/irritation – Category 2A, H319; STOT SE 3, H335	10-25%
CAS: 72869-86-4	urethane dimethacrylate Serious eye damage/irritation – Category 2A, H319; Skin Sens. 1, H317	2.5-10%
CAS: 1219495-43-8	aromatic aliphatic urethane dimethacrylate Skin Sens. 1, H317	2.5-10%
CAS: 6701-13-9	1,10-decandiol dimethacrylate Serious eye damage/irritation – Category 2A, H319; Skin Sens. 1, H317	2.5-10%

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

### 4 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.
- If skin irritation continues, consult a doctor.

- **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.

- **After swallowing:** Rinse out mouth and then drink plenty of water.

- **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

- **Suitable extinguishing agents:**

- CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

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- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Protective equipment:** No special measures required.

### 6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures** Wear protective clothing.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).  
Ensure adequate ventilation.
- **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.  
Prevent formation of aerosols.
- **Information about fire - and explosion protection:** No special measures required.
- **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:**  
Protect from exposure to the light.  
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.
- **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.
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
Usual hygienic measures for dental practice and dental laboratories.  
Keep away from foodstuffs, beverages and feed.  
Wash hands before breaks and at the end of work.  
Do not inhale gases / fumes / aerosols.  
Avoid contact with the eyes and skin.
- **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.

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· **Protection of hands:**



Protective gloves (EN 374)

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

· **Material of gloves**

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.

· **Not suitable are gloves made of the following materials:**

Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates.

· **Eye protection:**



Tightly sealed goggles (EN 166)

### 9 Physical and Chemical Properties

· **General Information**

· **Appearance:**

· **Form:**

Pasty

· **Colour:**

According to product specification

· **Odour:**

Characteristic

· **Odour threshold:**

Not determined.

· **pH-value:**

Not applicable.

· **Change in condition**

· **Melting point/freezing point:**

Undetermined.

· **Initial boiling point and boiling range:**

Undetermined.

· **Flash point:**

Not applicable.

· **Flammability (solid, gas):**

Not applicable.

· **Decomposition temperature:**

Not determined.

· **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:**

Not determined.

· **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.

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· **Other information**

No further relevant information available.

### 10 Stability and Reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**  
Photoreactive (Danger of polymerization).  
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.
- **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** Based on available data, the classification criteria are not met.
- **Skin corrosion/irritation** Causes skin irritation.
- **Serious eye damage/irritation** Causes serious eye irritation.
- **Respiratory or skin sensitisation** May cause an allergic skin reaction.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** May cause respiratory irritation.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.
- **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 system.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

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### 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

- |   |  |
|---|--|
| · <b>UN-Number</b>  | Void   |
| · <b>ADG, ADN, IMDG, IATA</b>   | Void   |
| · <b>UN proper shipping name</b>  | Void   |
| · <b>ADG, ADN, IMDG, IATA</b>   | Void   |
| · <b>Transport hazard class(es)</b>   |  |
| · <b>ADG, ADN, IMDG, IATA</b>   |  |
| · <b>Class</b>  | Void   |
| · <b>Packing group</b>  |  |
| · <b>ADG, 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 Marpol and the IBC Code</b> | Not applicable.  |
| · <b>Transport/Additional information:</b>                                  | Product is not classified as a dangerous good for transport (ADR, IMDG, IATA). |
| · <b>UN "Model Regulation":</b>   | Void   |

### 15 Regulatory information

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

- **Australian Inventory of Industrial Chemicals**

CAS: 72869-86-4 | urethane dimethacrylate

- **Standard for the Uniform Scheduling of Medicines and Poisons**

None of the ingredients is listed.

- **Australia: Priority Existing Chemicals**

None of the ingredients is listed.

- **GHS label elements**

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

- **Hazard pictograms**



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- **Signal word** *Warning*
- **Hazard-determining components of labelling:**  
*urethane dimethacrylate*  
*ytterbium trifluoride*  
*aromatic aliphatic urethane dimethacrylate*  
*1,10-decandiol dimethacrylate*
- **Hazard statements**  
*Causes skin irritation.*  
*Causes serious eye irritation.*  
*May cause an allergic skin reaction.*  
*May cause respiratory irritation.*
- **Precautionary statements**  
*Wear protective gloves/protective clothing/eye protection/face protection.*  
*If skin irritation or rash occurs: Get medical advice/attention.*  
*If eye irritation persists: Get medical advice/attention.*  
*Wash contaminated clothing before reuse.*  
*Dispose of contents/container in accordance with local/regional/national/international regulations.*
- **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 Regulation 2017/745 on Medical Devices (MDR).*
- **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.*  
*H317 May cause an allergic skin reaction.*  
*H319 Causes serious eye irritation.*  
*H335 May cause respiratory irritation.*
- **Contact:**
- **Abbreviations and acronyms:**  
*ADR: Accord relatif au transport international 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*  
*Serious eye damage/irritation – Category 2A: Serious eye damage/eye irritation – Category 2A*  
*Skin Sens. 1: Skin sensitisation – Category 1*  
*STOT SE 3: Specific target organ toxicity (single exposure) – Category 3*

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