

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

Printing date 07.12.2022


Version number 3 (replaces version 2)

Revision: 24.10.2022

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

- **1.1 Product identifier**
- **Trade name:** *Variolink Esthetic LC / Variolink Esthetic LC HV*
- **1.2 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*
- **1.3 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*
- **Further information obtainable from:**  
*Regulatory Affairs  
sds@ivoclarvivadent.com*
- **1.4 Emergency telephone number:** *+423 / 235 33 13 (Ivoclar Vivadent AG, 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.  
Skin Sens. 1 H317 May cause an allergic skin reaction.  
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 GB CLP regulation.*
- **Hazard pictograms**
- 
- **GHS07**
- **Signal word** *Warning*
- **Hazard-determining components of labelling:**  
*urethane dimethacrylate  
ytterbium trifluoride  
aromatic aliphatic urethane dimethacrylate  
1,10-decandiol dimethacrylate*
- **Hazard statements**  
*H315 Causes skin irritation.  
H319 Causes serious eye irritation.  
H317 May cause an allergic skin reaction.  
H335 May cause respiratory irritation.*
- **Precautionary statements**  
*P280 Wear protective gloves/protective clothing/eye protection/face protection.  
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.*

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P337+P313 If eye irritation persists: Get medical advice/attention.

P363 Wash contaminated clothing before reuse.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

**Additional information:**

Medical devices as defined in Regulation (EU) 2017/745 (MDR) 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 (GB CLP/GHS) 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 Mixtures**

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

**Dangerous components:**

CAS: 13760-80-0 EINECS: 237-354-2 Reg.nr.: 17-2119404130-64-XXXX	ytterbium trifluoride Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	10-<25%
CAS: 72869-86-4 EINECS: 276-957-5 Reg.nr.: 01-2120751202-68-XXXX	urethane dimethacrylate Eye Irrit. 2, H319; Skin Sens. 1, H317; Aquatic Chronic 3, H412	3-<10%
CAS: 6701-13-9 EINECS: 229-745-1 Reg.nr.: 01-2120735533-57-XXXX	1,10-decandiol dimethacrylate Eye Irrit. 2, H319; Skin Sens. 1, H317	3-<10%

**Additional information:** For the wording of the listed hazard 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.

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.

**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:**

CO<sub>2</sub>, 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.

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- **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** Wear protective clothing.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).  
Ensure adequate ventilation.
- **6.4 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.

**SECTION 7: Handling and storage**

- **7.1 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.
- **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:**  
Protect from exposure to the light.  
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**
- **Appropriate engineering controls** No further data; see item 7.
- **Individual protection measures, such as 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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· **Hand protection**



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/face protection**



Tightly sealed goggles (EN 166)

**SECTION 9: Physical and chemical properties**

· **9.1 Information on basic physical and chemical properties**

· **General Information**

· **Physical state**

Fluid

· **Colour:**

According to product specification

· **Odour:**

Characteristic

· **Odour threshold:**

Not determined.

· **Melting point/freezing point:**

Undetermined.

· **Boiling point or initial boiling point and boiling range**

Undetermined.

· **Flammability**

Not applicable.

· **Lower and upper explosion limit**

· **Lower:**

Not determined.

· **Upper:**

Not determined.

· **Flash point:**

Not applicable.

· **Decomposition temperature:**

Not determined.

· **pH**

Not applicable.

· **Viscosity:**

· **Kinematic viscosity**

Not determined.

· **Dynamic:**

Not determined.

· **Solubility**

· **water:**

Nearly insoluble.

· **Partition coefficient n-octanol/water (log value)**

Not determined.

· **Vapour pressure:**

Not determined.

· **Density and/or relative density**

· **Density:**

Not determined.

· **Relative density**

Not determined.

· **Vapour density**

Not determined.

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- **9.2 Other information**
- **Appearance:**
- **Form:** Pasty
- **Important information on protection of health and environment, and on safety.**
- **Auto-ignition temperature:** Product is not selfigniting.
- **Explosive properties:** Product does not present an explosion hazard.
- **Change in condition**
- **Evaporation rate** Not determined.

- **Information with regard to physical hazard classes**
- **Explosives** Void
- **Flammable gases** Void
- **Aerosols** Void
- **Oxidising gases** Void
- **Gases under pressure** Void
- **Flammable liquids** Void
- **Flammable solids** Void
- **Self-reactive substances and mixtures** Void
- **Pyrophoric liquids** Void
- **Pyrophoric solids** Void
- **Self-heating substances and mixtures** Void
- **Substances and mixtures, which emit flammable gases in contact with water** Void
- **Oxidising liquids** Void
- **Oxidising solids** Void
- **Organic peroxides** Void
- **Corrosive to metals** Void
- **Desensitised explosives** Void

### **SECTION 10: Stability and reactivity**

- **10.1 Reactivity** No further relevant information available.
- **10.2 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.
- **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 hazard classes as defined in Regulation (EC) No 1272/2008**
- **Skin corrosion/irritation** Causes skin irritation.
- **Serious eye damage/irritation** Causes serious eye irritation.
- **Respiratory or skin sensitisation** May cause an allergic skin reaction.
- **STOT-single exposure** May cause respiratory irritation.
- **Additional toxicological information:** No further relevant information available.

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· **11.2 Information on other hazards**

· **Endocrine disrupting properties**

None of the ingredients is listed.

**SECTION 12: Ecological information**

· **12.1 Toxicity**

· **Aquatic toxicity:** No further relevant information available.

· **12.2 Persistence and degradability** No further relevant information available.

· **12.3 Bioaccumulative potential** No further relevant information available.

· **12.4 Mobility in soil** No further relevant information available.

· **12.5 Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **12.6 Endocrine disrupting properties**

The product does not contain substances with endocrine disrupting properties.

· **12.7 Other adverse effects**

· **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.

**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 or ID number**

· **ADR/RID/ADN, ADN, IMDG, IATA** Void

· **14.2 UN proper shipping name**

· **ADR/RID/ADN, ADN, IMDG, IATA** Void

· **14.3 Transport hazard class(es)**

· **ADR/RID/ADN, ADN, IMDG, IATA**

· **Class** Void

· **14.4 Packing group**

· **ADR/RID/ADN, IMDG, IATA** Void

· **14.5 Environmental hazards:**

· **Marine pollutant:** No

· **14.6 Special precautions for user**

Not applicable.

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- |   |  |
|---|--|
| · <b>14.7 Maritime transport in bulk according to IMO instruments</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   |

**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 Regulation 2017/745 on Medical Devices (MDR).
- **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.  
H317 May cause an allergic skin reaction.  
H319 Causes serious eye irritation.  
H335 May cause respiratory irritation.  
H412 Harmful to aquatic life with long lasting effects.
- **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  
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)  
PBT: Persistent, Bioaccumulative and Toxic  
vPvB: very Persistent and very Bioaccumulative  
Skin Irrit. 2: Skin corrosion/irritation – Category 2  
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2  
Skin Sens. 1: Skin sensitisation – Category 1  
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3  
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3
- **\* Data compared to the previous version altered.**

GB