

**Safety Data Sheet**  
according to HPR, Schedule 1

Printing date 12/07/2022

Version number 3

Reviewed on 10/24/2022

**1 Identification**

- **Product identifier**
- **Trade name:** *Variolink Esthetic LC / Variolink Esthetic LC HV*
- **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 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 identification**

- **Classification of the substance or mixture**

<i>Skin Irritation - Category 2</i>	<i>H315 Causes skin irritation.</i>
<i>Eye Irritation - Category 2A</i>	<i>H319 Causes serious eye irritation.</i>
<i>Skin Sensitizer - Category 1</i>	<i>H317 May cause an allergic skin reaction.</i>
<i>Specific Target Organ Toxicity - Single Exposure - Category 3</i>	<i>H335 May cause respiratory irritation.</i>

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- **Label elements**
- **GHS label elements**  
*The product is classified and labeled according to the Globally Harmonized System (GHS).*
- **Hazard pictograms**



GHS07

- **Signal word** *Warning*
- **Hazard-determining components of labeling:**  
*urethane dimethacrylate*  
*ytterbium trifluoride*  
*aromatic aliphatic urethane dimethacrylate*

(Contd. on page 2)

## Safety Data Sheet

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Printing date 12/07/2022

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**Trade name: Variolink Esthetic LC / Variolink Esthetic LC HV**

(Contd. of page 1)

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.

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



Health = 2

Fire = 0

Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**



Health = 2

Fire = 0

Reactivity = 0

### 3 Composition/Information on ingredients

· **Chemical characterization: Mixtures**

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

· **Dangerous components:**

CAS: 13760-80-0	ytterbium trifluoride	20-<25% w/w *
CAS: 72869-86-4	urethane dimethacrylate	5-<10% w/w *
CAS: 1830-78-0	glycerin-1.3-dimethacrylate	5-<10% w/w *
CAS: 6701-13-9	1,10-decandiol dimethacrylate	3-7% w/w *

\* Actual concentration ranges are withheld as a trade secret.

### 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.

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.

(Contd. on page 3)

CA

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Reviewed on 10/24/2022

**Trade name: Variolink Esthetic LC / Variolink Esthetic LC HV**

(Contd. of page 2)

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

### 5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**  
CO<sub>2</sub>, 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** 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 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:**  
Protect from exposure to the light.  
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.

(Contd. on page 4)

CA

## Safety Data Sheet

### according to HPR, Schedule 1

Printing date 12/07/2022

Version number 3

Reviewed on 10/24/2022

**Trade name: Variolink Esthetic LC / Variolink Esthetic LC HV**

(Contd. of page 3)

- **Exposure controls**

- **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.

- **Breathing equipment:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

- **Protection of hands:**



Protective gloves

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

## 9 Physical and chemical properties

- **Information on basic physical and chemical properties**

- **General Information**

- **Appearance:**

**Form:** Pasty

**Color:** According to product specification

- **Odor:** Characteristic

- **Odor threshold:** Not determined.

- **pH-value:** Not applicable.

- **Change in condition**

**Melting point/Melting range:** Undetermined.

**Boiling point/Boiling range:** Undetermined.

- **Flash point:** Not applicable.

- **Flammability (solid, gaseous):** Not applicable.

- **Decomposition temperature:** Not determined.

- **Auto igniting:** Product is not selfigniting.

(Contd. on page 5)

CA

## Safety Data Sheet

### according to HPR, Schedule 1

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Version number 3

Reviewed on 10/24/2022

**Trade name: Variolink Esthetic LC / Variolink Esthetic LC HV**

(Contd. of page 4)

· <b>Danger of explosion:</b>	<i>Product does not present an explosion hazard.</i>
· <b>Explosion limits:</b>	
<b>Lower:</b>	<i>Not determined.</i>
<b>Upper:</b>	<i>Not determined.</i>
· <b>Vapor pressure:</b>	<i>Not determined.</i>
· <b>Density:</b>	<i>Not determined.</i>
· <b>Relative density</b>	<i>Not determined.</i>
· <b>Vapor density</b>	<i>Not determined.</i>
· <b>Evaporation rate</b>	<i>Not determined.</i>
· <b>Solubility in / Miscibility with Water:</b>	<i>Nearly insoluble.</i>
· <b>Partition coefficient (n-octanol/water):</b>	<i>Not determined.</i>
· <b>Viscosity:</b>	
<b>Dynamic:</b>	<i>Not determined.</i>
<b>Kinematic:</b>	<i>Not determined.</i>
· <b>Other information</b>	<i>No further relevant information available.</i>

### 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:**
- **Specific symptoms in biological assay:**
- **on the skin:** *Irritant to skin and mucous membranes.*
- **on the eye:** *Irritating effect.*
- **Sensitization:** *Sensitization possible through skin contact.*
- **Additional toxicological information:** *No further relevant information available.*
- **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

CAS: 13760-80-0 *ytterbium trifluoride*

3

(Contd. on page 6)

## Safety Data Sheet

### according to HPR, Schedule 1

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Version number 3

Reviewed on 10/24/2022

Trade name: **Variolink Esthetic LC / Variolink Esthetic LC HV**

(Contd. of page 5)

### 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.
- **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.

### 14 Transport information

- |  |  |
|--|--|
| · <b>UN-Number</b>   | Void   |
| · <b>DOT/TDG, ADR, ADN, IMDG, IATA</b>   | Void   |
| · <b>UN proper shipping name</b>   | Void   |
| · <b>DOT/TDG, ADR, ADN, IMDG, IATA</b>   | Void   |
| · <b>Transport hazard class(es)</b>  | Void   |
| · <b>DOT, ADR, ADN, IMDG, IATA</b>   | Void   |
| · <b>Class</b>   | Void   |
| · <b>Packing group</b>   | Void   |
| · <b>DOT/TDG, ADR, IMDG, IATA</b>  | Void   |
| · <b>Environmental hazards:</b>  | No   |
| · <b>Marine pollutant:</b>   | No   |
| · <b>Special precautions for user</b>  | Not applicable.  |
| · <b>Transport in bulk according to Annex II of MARPOL73/78 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   |

(Contd. on page 7)

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Version number 3

Reviewed on 10/24/2022

**Trade name: Variolink Esthetic LC / Variolink Esthetic LC HV**

(Contd. of page 6)

### 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):**

All components have the value ACTIVE.

· **GHS label elements**

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

· **Hazard pictograms**



GHS07

· **Signal word** Warning

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

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.

· **National regulations:**

· **Other regulations, limitations and prohibitive regulations**

The product is a medical device according to Regulation 2017/745 on Medical Devices (MDR).

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.

· **Contact:**

· **Date of the latest revision of the safety data sheet** 12/07/2022

· **Abbreviations and acronyms:**

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

(Contd. on page 8)

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**Trade name: Variolink Esthetic LC / Variolink Esthetic LC HV**

(Contd. of page 7)

*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)*  
*NFPA: National Fire Protection Association (USA)*  
*HMIS: Hazardous Materials Identification System (USA)*  
*PBT: Persistent, Bioaccumulative and Toxic*  
*vPvB: very Persistent and very Bioaccumulative*  
· **\* Data compared to the previous version altered.**

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