

Safety Data Sheet
acc. to OSHA HCS

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(s) identification

- **Classification of the substance or mixture**

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

- **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
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.

- **Classification system:**

- **NFPA ratings (scale 0 - 4)**



- **HMIS-ratings (scale 0 - 4)**

HEALTH	2	Health = 2
FIRE	0	Fire = 0
REACTIVITY	0	Reactivity = 0

- **Other hazards**

- **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.
· **vPvB:** Not applicable.

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%
CAS: 72869-86-4	urethane dimethacrylate	2.5-<10%
CAS: 1830-78-0	glycerin-1,3-dimethacrylate	2.5-<10%
CAS: 6701-13-9	1,10-decandiol dimethacrylate	2.5-<10%

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.

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- **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, 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.
- **Protective Action Criteria for Chemicals**

· PAC-1:

CAS: 13760-80-0	ytterbium trifluoride	30 mg/m ³
CAS: 72869-86-4	urethane dimethacrylate	120 mg/m ³

· PAC-2:

CAS: 13760-80-0	ytterbium trifluoride	330 mg/m ³
CAS: 72869-86-4	urethane dimethacrylate	1,300 mg/m ³

· PAC-3:

CAS: 13760-80-0	ytterbium trifluoride	2,000 mg/m ³
CAS: 72869-86-4	urethane dimethacrylate	7,900 mg/m ³

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.

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

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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.
- **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.

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· pH-value:	<i>Not applicable.</i>
· Change in condition	
Melting point/Melting range:	<i>Undetermined.</i>
Boiling point/Boiling range:	<i>Undetermined.</i>
· Flash point:	<i>Not applicable.</i>
· Flammability (solid, gaseous):	<i>Not applicable.</i>
· Decomposition temperature:	<i>Not determined.</i>
· Auto igniting:	<i>Product is not selfigniting.</i>
· Danger of explosion:	<i>Product does not present an explosion hazard.</i>
· Explosion limits:	
Lower:	<i>Not determined.</i>
Upper:	<i>Not determined.</i>
· Vapor pressure:	<i>Not determined.</i>
· Density:	<i>Not determined.</i>
· Relative density	<i>Not determined.</i>
· Vapor density	<i>Not determined.</i>
· Evaporation rate	<i>Not determined.</i>
· Solubility in / Miscibility with	
Water:	<i>Nearly insoluble.</i>
· Partition coefficient (n-octanol/water):	<i>Not determined.</i>
· Viscosity:	
Dynamic:	<i>Not determined.</i>
Kinematic:	<i>Not determined.</i>
· Solvent content:	
VOC content:	<i>0.00 %</i>
· Other information	<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.*

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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
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- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

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

- | |
|---|
| <ul style="list-style-type: none"> · UN-Number · DOT, ADR/RID/ADN, ADN, IMDG, IATA Void |
| <ul style="list-style-type: none"> · UN proper shipping name · DOT, ADR/RID/ADN, ADN, IMDG, IATA Void |

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· Transport hazard class(es)	
· DOT, ADR/RID/ADN, ADN, IMDG, IATA	
· Class	Void
· Packing group	
· DOT, ADR/RID/ADN, IMDG, IATA	Void
· Environmental hazards:	
· Marine pollutant:	No
· Special precautions for user	Not applicable.
· 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":	Void

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.

· **Proposition 65**

· **Chemicals known to cause cancer:**

All ingredients are listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value)**

CAS: 13760-80-0 | ytterbium trifluoride

A4

· **GHS label elements**

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

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· **Hazard pictograms**



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· **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 preparation / last revision** 12/07/2022

· **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
 DOT: US Department of Transportation
 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)
 VOC: Volatile Organic Compounds (USA, EU)
 PBT: Persistent, Bioaccumulative and Toxic
 vPvB: very Persistent and very Bioaccumulative
 OSHA: Occupational Safety & Health
 TLV: Threshold Limit Value
 PEL: Permissible Exposure Limit
 REL: Recommended Exposure Limit
 Skin Irritation 2: Skin corrosion/irritation – Category 2
 Eye Irritation 2A: Serious eye damage/eye irritation – Category 2A
 Sensitization - Skin 1: Skin sensitisation – Category 1

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Specific Target Organ Toxicity - Single Exposure 3: Specific target organ toxicity (single exposure) – Category 3
· *** Data compared to the previous version altered.**

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