Safety Data Sheet
according to HPR, Schedule 1

Printing date 02/23/2024 *Version number 1* *Reviewed on 02/21/2024*

1 Identification

· **Product identifier**

· **Trade name:** **Variolink Esthetic LC (Opaque Shade)**

· **Application of the substance / the mixture** Polymer-based dental luting material (intraoral dual-curing)

· **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**

Skin Irritation - Category 2	H315 Causes skin irritation.
Eye Irritation - Category 2A	H319 Causes serious eye irritation.
Skin Sensitizer - Category 1	H317 May cause an allergic skin reaction.
Carcinogenicity – Category 2	H351 Suspected of causing cancer. Route of exposure: Inhalation.
Specific Target Organ Toxicity - Single Exposure - Category 3	H335 May cause respiratory irritation.

· **Label elements**

· **GHS label elements**

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

· **Hazard pictograms**



GHS07 GHS08

· **Signal word** Warning

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

urethane dimethacrylate

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ytterbium trifluoride
titanium dioxide
aromatic aliphatic urethane dimethacrylate
1,10-decandiol dimethacrylate

· **Hazard statements**
Causes skin irritation.
Causes serious eye irritation.
May cause an allergic skin reaction.
Suspected of causing cancer. Route of exposure: Inhalation.
May cause respiratory irritation.

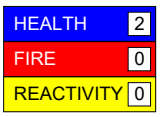
· **Precautionary statements**
Avoid release to the environment.
Wear protective gloves/protective clothing/eye protection/face protection.
If skin irritation or rash occurs: Get medical advice/attention.
If eye irritation persists: Get medical advice/attention.
Wash contaminated clothing before reuse.
And wash it before reuse.

· **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	10-30% w/w *
CAS: 72869-86-4	urethane dimethacrylate	5-10% w/w *
CAS: 1219495-43-8	aromatic aliphatic urethane dimethacrylate	3-7% w/w *
CAS: 6701-13-9	1,10-decandiol dimethacrylate	1-5% w/w *
CAS: 13463-67-7	titanium dioxide	0.1-1% 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.*

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· **After swallowing:**
Rinse out mouth and then drink plenty of water.
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, 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 equipment. Keep unprotected persons away.
· **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.
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 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.
Protect from heat and direct sunlight.
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 section 7.

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· **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.
Avoid contact with the eyes and skin.
· **Breathing equipment:** Not required.
· **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
After use of gloves apply skin-cleaning agents and skin cosmetics.
· **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
· **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.

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· **Flammability (solid, gaseous):**	Not determined.
· **Ignition temperature:**	Product is not selfigniting.
· **Danger of explosion:**	Product does not present an explosion hazard.
· **Explosion limits:**	
Lower:	Not determined.
Upper:	Not determined.
· **Vapor pressure:**	Not applicable.
· **Density at 20 °C:**	1.7924 g/cm³
· **Relative density**	Not determined.
· **Vapor density**	Not applicable.
· **Evaporation rate**	Not applicable.
· **Solubility in / Miscibility with**	
Water:	Nearly insoluble.
· **Partition coefficient (n-octanol/water):**	Not determined.
· **Viscosity:**	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
· **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.
· **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

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· **NTP (National Toxicology Program)**

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

· **UN-Number**	
· **DOT/TDG**	Void
· **ADR, IMDG, IATA**	UN3082
· **UN proper shipping name**	
· **DOT/TDG, ADR**	Void
· **IMDG**	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (1,10-decandiol dimethacrylate), MARINE POLLUTANT
· **IATA**	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (1,10-decandiol dimethacrylate)
· **Transport hazard class(es)**	
· **DOT/TDG (Transport dangerous goods):**	
· **Class**	Void

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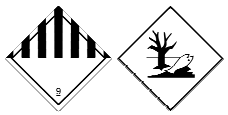
(Contd. of page 6)

· **ADR**



· **Class**	9 (M6) Miscellaneous dangerous substances and articles
· **Label**	9

· **IMDG, IATA**



· **Class**	9 Miscellaneous dangerous substances and articles
· **Label**	9
· **Packing group**	
· **DOT/TDG**	Void
· **ADR, IMDG, IATA**	III
· **Environmental hazards:**	
· **Marine pollutant:**	No Symbol (fish and tree)
· **Special marking (ADR):**	Symbol (fish and tree)
· **Special marking (IATA):**	Symbol (fish and tree)
· **Special precautions for user**	Warning: Miscellaneous dangerous substances and articles
· **Hazard identification number (Kemler code):**	90
· **EMS Number:**	F-A,S-F
· **Stowage Category**	A
· **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).
· **ADR**	
· **Excepted quantities (EQ)**	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· **IMDG**	
· **Limited quantities (LQ)**	5L
· **Excepted quantities (EQ)**	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· **UN "Model Regulation":**	Void

CA

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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):**

CAS: 13760-80-0	ytterbium trifluoride

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

· **Hazard pictograms**



GHS07 GHS08

· **Signal word** Warning

· **Hazard-determining components of labeling:**
urethane dimethacrylate
ytterbium trifluoride
titanium dioxide
aromatic aliphatic urethane dimethacrylate
1,10-decandiol dimethacrylate

· **Hazard statements**
Causes skin irritation.
Causes serious eye irritation.
May cause an allergic skin reaction.
Suspected of causing cancer. Route of exposure: Inhalation.
May cause respiratory irritation.

· **Precautionary statements**
Avoid release to the environment.
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.
And wash it before reuse.

· **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.

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· **Contact:**
· **Date of the latest revision of the safety data sheet** 02/23/2024
· **Abbreviations and acronyms:**
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)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative