

Safety Data Sheet
according to HPR, Schedule 1

Printing date 04/24/2018

Version number 2.1

Reviewed on 04/24/2018

1 Identification

- **Product identifier**
- **Trade name:** ***Variolink Esthetic DC (Catalyst)***
- **Application of the substance / the mixture** *Dual-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**

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.
Specific Target Organ Toxicity - Single Exposure - Category 3	H335 May cause respiratory irritation.
Specific Target Organ Toxicity - Repeated Exposure - Category 2	H373 May cause damage to organs through prolonged or repeated exposure.
- **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

(Contd. on page 2)

Safety Data Sheet

according to HPR, Schedule 1

Printing date 04/24/2018

Version number 2.1

Reviewed on 04/24/2018

Trade name: Variolink Esthetic DC (Catalyst)

(Contd. of page 1)

ytterbium trifluoride
α,α-dimethylbenzyl hydroperoxide
 1,10-decandiol dimethacrylate

· **Hazard statements**

Causes skin irritation.
 Causes serious eye irritation.
 May cause an allergic skin reaction.
 May cause respiratory irritation.
 May cause damage to organs through prolonged or repeated exposure.

· **Precautionary statements**

Do not breathe dust/fume/gas/mist/vapours/spray.
 Wash thoroughly after handling.
 Use only outdoors or in a well-ventilated area.
 Contaminated work clothing should not be allowed out of the workplace.
 Wear protective gloves/protective clothing/eye protection/face protection.
 IF ON SKIN: Wash with plenty of water.
 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 Call a POISON CENTER/doctor if you feel unwell.
 Get medical advice/attention if you feel unwell.
 Specific treatment (see on this label).
 If skin irritation or rash occurs: Get medical advice/attention.
 If eye irritation persists: Get medical advice/attention.
 Take off contaminated clothing and wash it before reuse.
 Store in a well-ventilated place. Keep container tightly closed.
 Store locked up.
 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Additional information:**

Medical devices are exempt from the labeling provisions of GHS according to the Hazard Communication Standard (HCS).

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



· **HMIS-ratings (scale 0 - 4)**



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	3-7% w/w
CAS: 6701-13-9	1,10-decandiol dimethacrylate	3-7% w/w

(Contd. on page 3)

CA

Safety Data Sheet

according to HPR, Schedule 1

Printing date 04/24/2018

Version number 2.1

Reviewed on 04/24/2018

Trade name: Variolink Esthetic DC (Catalyst)

CAS: 80-15-9

 α,α -dimethylbenzyl hydroperoxide

(Contd. of page 2)

I-<2.5% w/w

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.

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 Firefighting 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** Not required.

· **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.

(Contd. on page 4)

CA

Safety Data Sheet according to HPR, Schedule 1

Printing date 04/24/2018

Version number 2.1

Reviewed on 04/24/2018

Trade name: Variolink Esthetic DC (Catalyst)

(Contd. of page 3)

- **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 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.
 - 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:** Safety glasses

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.

(Contd. on page 5)

CA

Safety Data Sheet

according to HPR, Schedule 1

Printing date 04/24/2018

Version number 2.1

Reviewed on 04/24/2018

Trade name: Variolink Esthetic DC (Catalyst)

(Contd. of page 4)

· 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 determined.
· Auto igniting:	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:	1.8705 g/cm ³
· 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.
- **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:**

· **LD/LC50 values that are relevant for classification:**

CAS: 80-15-9 α,α -dimethylbenzyl hydroperoxide

Oral	LD50	382 mg/kg (rat)
Dermal	LD50	500 mg/kg (rat)
Inhalative	LC50/4 h	220 mg/l (rat)

(Contd. on page 6)

CA

Safety Data Sheet

according to HPR, Schedule 1

Printing date 04/24/2018

Version number 2.1

Reviewed on 04/24/2018

Trade name: Variolink Esthetic DC (Catalyst)

(Contd. of page 5)

- **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
CAS: 128-37-0	2,6-di-tert-butyl-p-cresol	3

· **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, ADN, IMDG, IATA | Void |
| · UN proper shipping name | |
| · DOT, TDG, ADN, IMDG, IATA | Void |
| · Transport hazard class(es) | |
| · DOT, TDG, ADN, IMDG, IATA | |
| · Class | Void |

(Contd. on page 7)

CA

Safety Data Sheet

according to HPR, Schedule 1

Printing date 04/24/2018

Version number 2.1

Reviewed on 04/24/2018

Trade name: Variolink Esthetic DC (Catalyst)

(Contd. of page 6)

· Packing group · DOT, TDG, IMDG, IATA	Void
· Environmental hazards: · Marine pollutant:	No
· Special precautions for user	Not applicable.
· Transport in bulk according to Annex II of MARPOL 73/78 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):**

CAS: 80-15-9 α, α -dimethylbenzyl hydroperoxide

· **TSCA (Toxic Substances Control Act):**

All ingredients are listed.

· **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

α, α -dimethylbenzyl hydroperoxide

1,10-decandiol dimethacrylate

· **Hazard statements**

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

May cause respiratory irritation.

May cause damage to organs through prolonged or repeated exposure.

· **Precautionary statements**

Do not breathe dust/fume/gas/mist/vapours/spray.

Wash thoroughly after handling.

Use only outdoors or in a well-ventilated area.

Contaminated work clothing should not be allowed out of the workplace.

Wear protective gloves/protective clothing/eye protection/face protection.

(Contd. on page 8)

CA

Safety Data Sheet

according to HPR, Schedule 1

Printing date 04/24/2018

Version number 2.1

Reviewed on 04/24/2018

Trade name: Variolink Esthetic DC (Catalyst)

(Contd. of page 7)

IF ON SKIN: Wash with plenty of water.

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Call a POISON CENTER/doctor if you feel unwell.

Get medical advice/attention if you feel unwell.

Specific treatment (see on this label).

If skin irritation or rash occurs: Get medical advice/attention.

If eye irritation persists: Get medical advice/attention.

Take off contaminated clothing and wash it before reuse.

Store in a well-ventilated place. Keep container tightly closed.

Store locked up.

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 the Directive 93/42/EEC.

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.

· **Date of preparation / last revision** 04/24/2018 / 2

· **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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

· *** Data compared to the previous version altered.**

CA