

Safety Data Sheet
acc. to OSHA HCS

Printing date 11/29/2018

Version number 1

Reviewed on 11/29/2018

1 Identification



- **Product identifier**
- **Trade name:** *Variolink 100 (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(s) identification

- **Classification of the substance or mixture**
Skin Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2A H319 Causes serious eye irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.
STOT SE 3 H335 May cause respiratory irritation.
STOT RE 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
ytterbium trifluoride
α,α -dimethylbenzyl hydroperoxide

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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**

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.

· **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)**



Health = 1

Fire = 0

Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**



Health = *1

Fire = 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	10-25%
CAS: 72869-86-4	urethane dimethacrylate	2.5-<10%
CAS: 6701-13-9	1,10-decandiol dimethacrylate	2.5-<10%
CAS: 80-15-9	α,α -dimethylbenzyl hydroperoxide	1-<2.5%

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.

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- **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 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** 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.
- **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
CAS: 80-15-9	α,α -dimethylbenzyl hydroperoxide	0.15 ppm

· **PAC-2:**

CAS: 13760-80-0	ytterbium trifluoride	330 mg/m ³
CAS: 72869-86-4	urethane dimethacrylate	1,300 mg/m ³
CAS: 80-15-9	α,α -dimethylbenzyl hydroperoxide	1.6 ppm

· **PAC-3:**

CAS: 13760-80-0	ytterbium trifluoride	2,000 mg/m ³
CAS: 72869-86-4	urethane dimethacrylate	7,900 mg/m ³
CAS: 80-15-9	α,α -dimethylbenzyl hydroperoxide	9.7 ppm

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.

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- **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 item 7.
- **Control parameters**

· **Components with limit values that require monitoring at the workplace:**

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

WEEL	Long-term value: 6 mg/m ³ , 1 ppm
	Skin

- **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

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9 Physical and chemical properties

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

· **General Information**

· **Appearance:**

· Form:	Pasty
· Color:	Whitish
· 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 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 (68 °F):** 1.8705 g/cm³ (15.609 lbs/gal)

· **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.

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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)

- **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

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- **NTP (National Toxicology Program)**

None of the ingredients is listed.

- **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.

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14 Transport information

- | | |
|---|--|
| · UN-Number | · DOT, ADR/RID/ADN, ADN, IMDG, IATA Void |
| · UN proper shipping name | · DOT, ADR/RID/ADN, ADN, IMDG, IATA Void |
| · 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):

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

- TSCA (Toxic Substances Control Act):

All ingredients are listed.

· Proposition 65

- Chemicals known to cause cancer:

None of the ingredients is 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.

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· **TLV (Threshold Limit Value established by ACGIH)**

CAS: 13760-80-0 Ytterbium trifluoride

.A4

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is 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**

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 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** 11/29/2018 / -

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport 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

ACGIH: American Conference of Governmental Industrial Hygienists

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)

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*LC50: Lethal concentration, 50 percent**LD50: Lethal dose, 50 percent**PBT: Persistent, Bioaccumulative and Toxic**vPvB: very Persistent and very Bioaccumulative**NIOSH: National Institute for Occupational Safety**OSHA: Occupational Safety & Health**TLV: Threshold Limit Value**PEL: Permissible Exposure Limit**REL: Recommended Exposure Limit**Skin Irrit. 2: Skin corrosion/irritation – Category 2**Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A**Skin Sens. 1: Skin sensitisation – Category 1**STOT SE 3: Specific target organ toxicity (single exposure) – Category 3**STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2*

-US-