

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 29.11.2018

Version number 1

Revision: 29.11.2018

SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **1.1 Product identifier**
- **Trade name:** **Variolink 100 (Base)**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** Dual-curing resin-based dental luting material
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Ivoclar Vivadent AG
Bendererstrasse 2
FL-9494 Schaan
PRINCIPALITY OF LIECHTENSTEIN
- **Tel:** +423 235 35 35
Fax: +423 235 33 60
- **Further information obtainable from:**
Regulatory Affairs
sds@ivoclarvivadent.com
- **1.4 Emergency telephone number:** +423 / 235 33 13 (Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein)

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
Skin Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2 H319 Causes serious eye irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.
STOT SE 3 H335 May cause respiratory irritation.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**



GHS07

- **Signal word** Warning
- **Hazard-determining components of labelling:**
urethane dimethacrylate
ytterbium trifluoride
Aromatic aliphatic urethane dimethacrylate
1,10-decandiol dimethacrylate
2-(2-Hydroxy-5-methylphenyl)-benzotriazol; 2-(2H-Benzotriazol-2-yl)-p-kresol
- **Hazard statements**
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.
H335 May cause respiratory irritation.
- **Precautionary statements**
P280 Wear protective gloves/protective clothing/eye protection/face protection.

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P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P337+P313 If eye irritation persists: Get medical advice/attention.

P363 Wash contaminated clothing before reuse.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Additional information:**

Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

· **2.3 Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

· **3.2 Chemical characterisation: Mixtures**

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

· **Dangerous components:**

CAS: 13760-80-0 EINECS: 237-354-2	ytterbium trifluoride Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	10-25%
CAS: 72869-86-4 EINECS: 276-957-5	urethane dimethacrylate Eye Irrit. 2, H319; Skin Sens. 1, H317; Aquatic Chronic 3, H412	2.5-<10%
CAS: 1219495-43-8	Aromatic aliphatic urethane dimethacrylate Skin Sens. 1, H317	2.5-<10%
CAS: 6701-13-9 EINECS: 229-745-1	1,10-decandiol dimethacrylate Eye Irrit. 2, H319; Skin Sens. 1, H317	2.5-<10%
CAS: 591-08-2 EINECS: 209-699-9	acetyl-2-thiourea Acute Tox. 2, H300	0.1-<2.5%
CAS: 2440-22-4 EINECS: 219-470-5	2-(2-Hydroxy-5-methylphenyl)-benzotriazol; 2-(2H-Benzotriazol-2-yl)-p-kresol Aquatic Chronic 1, H410; Skin Sens. 1, H317	0.1-<0.25%

· **Additional information:** For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

· **4.1 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.

· **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.

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

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:** Pick up mechanically.
- **6.4 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.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
Only adequately trained personnel should handle this product.
For use in dentistry only.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 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 container tightly sealed.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **8.1 Control parameters**
- **Ingredients 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 valid during the making were used as basis.
- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Usual hygienic measures for dental practice and dental laboratories.

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Keep away from foodstuffs, beverages and feed.
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.

· **Respiratory protection:** 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

SECTION 9: Physical and chemical properties

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

· **General Information**

· **Appearance:**

Form: Pasty
Colour: Different according to colouring

· **Odour:** Characteristic

· **Odour threshold:** Not determined.

· **pH-value:** Not applicable.

· **Change in condition**

Melting point/freezing point: Undetermined.

Initial boiling point and boiling range: Undetermined.

· **Flash point:** Not applicable.

· **Flammability (solid, gas):** Not determined.

· **Auto-ignition temperature:** Product is not selfigniting.

· **Explosive properties:** Product does not present an explosion hazard.

· **Explosion limits:**

Lower: Not determined.

Upper: Not determined.

· **Vapour pressure:** Not applicable.

· **Density at 20 °C:** 1.8567 g/cm³

· **Relative density** Not determined.

· **Vapour density** Not applicable.

· **Evaporation rate** Not applicable.

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- | | |
|--|--|
| · Solubility in / Miscibility with water: | Nearly insoluble. |
| · Partition coefficient: n-octanol/water: | Not determined. |
| · Viscosity: | |
| Dynamic: | Not applicable. |
| Kinematic: | Not applicable. |
| · 9.2 Other information | No further relevant information available. |

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 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.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid**
Protect from exposure to the light.
Keep away from heat and direct sunlight.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** None under normal conditions of storage and use.

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Skin corrosion/irritation**
Causes skin irritation.
- **Serious eye damage/irritation**
Causes serious eye irritation.
- **Respiratory or skin sensitisation**
May cause an allergic skin reaction.
- **Additional toxicological information:** No further relevant information available.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure**
May cause respiratory irritation.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.

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- **Additional ecological information:**
- **General notes:**
*Water hazard class 1 (German Regulation) (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.*
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- | | |
|--|--|
| · 14.1 UN-Number | |
| · ADR/RID/ADN, ADN, IMDG, IATA | Void |
| · 14.2 UN proper shipping name | |
| · ADR/RID/ADN, ADN, IMDG, IATA | Void |
| · 14.3 Transport hazard class(es) | |
| · ADR/RID/ADN, ADN, IMDG, IATA | |
| · Class | Void |
| · 14.4 Packing group | |
| · ADR/RID/ADN, IMDG, IATA | Void |
| · 14.5 Environmental hazards: | |
| · Marine pollutant: | No |
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 Transport in bulk according to Annex II of Marpol 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 |

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3

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- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**
The product is a medical device according to the Directive 93/42/EEC.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 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.

- **Relevant phrases**

- H300 Fatal if swallowed.
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.
- H335 May cause respiratory irritation.
- H410 Very toxic to aquatic life with long lasting effects.
- H412 Harmful to aquatic life with long lasting effects.

- **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
- IATA: International Air Transport Association
- GHS: Globally Harmonised System of Classification and Labelling of Chemicals
- 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)
- PBT: Persistent, Bioaccumulative and Toxic
- vPvB: very Persistent and very Bioaccumulative
- Acute Tox. 2: Acute toxicity – Category 2
- Skin Irrit. 2: Skin corrosion/irritation – Category 2
- Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
- Skin Sens. 1: Skin sensitisation – Category 1
- STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
- Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1
- Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

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