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

*Printing date 07.05.2015* *Version number 7* *Revision: 16.03.2015*

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

· **1.1 Product identifier**

· **Trade name:** **Variolink II (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/light-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)

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## 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:**
Bis-GMA
ytterbium trifluoride
urethane dimethacrylate
triethylene glycol dimethacrylate
· **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.
P363 Wash contaminated clothing before reuse.

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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.
· **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.

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## 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<br>EINECS: 237-354-2 | ytterbium trifluoride<br>Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335 | ≤25% |
| CAS: 1565-94-2 | Bis-GMA<br>Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317 | 10-<25% |
| CAS: 72869-86-4<br>EINECS: 276-957-5 | urethane dimethacrylate<br>Eye Irrit. 2, H319; Skin Sens. 1, H317; Aquatic Chronic 3, H412 | 3-<10% |
| CAS: 109-16-0 | triethylene glycol dimethacrylate<br>Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335 | 3-<10% |

· **Additional information:** For the wording of the listed risk 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.
· **After eye contact:**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
· **After swallowing:** If symptoms persist consult doctor.
· **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
· **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.



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## 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.

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## 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.
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
Keep away from foodstuffs, beverages and feed.
· **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.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

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*Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation*

· **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.*

· **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:** | *According to product specification* |
| · **Odour:** | *Characteristic* |
| · **Odour 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.* |
| · **Self-igniting:** | *Product is not selfigniting.* |
| · **Danger of explosion:** | *Product does not present an explosion hazard.* |
| · **Explosion limits:** | |
| **Lower:** | *Not determined.* |
| **Upper:** | *Not determined.* |
| · **Vapour pressure:** | *Not applicable.* |
| · **Density at 20 °C:** | *2.23 g/cm³* |
| · **Relative density** | *Not determined.* |
| · **Vapour 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.* |
| · **9.2 Other information** | *No further relevant information available.* |



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## 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.

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## SECTION 11: Toxicological information

· **11.1 Information on toxicological effects**
· **Acute toxicity:**
· **Primary irritant effect:**
· **on the skin:** No irritant effect.
· **on the eye:** Irritating effect.
· **Sensitisation:** Sensitisation possible through skin contact.
· **Additional toxicological information:** No further relevant information available.

## 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.
· **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.



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## SECTION 14: Transport information

| | |
|---|---|
| · **14.1 UN-Number** · **ADR, ADN, IMDG, IATA** | Void |
| · **14.2 UN proper shipping name** · **ADR, ADN, IMDG, IATA** | Void |
| · **14.3 Transport hazard class(es)** · **ADR, ADN, IMDG, IATA** · **Class** | Void |
| · **14.4 Packing group** · **ADR, 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 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":** | - |

## SECTION 15: Regulatory information

· **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **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.

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## 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**
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
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)
Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2
Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2
Skin Sens. 1: Sensitisation - Skin, Hazard Category 1
STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

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*Aquatic Chronic 3: Hazardous to the aquatic environment - Chronic Hazard, Category 3*
· *** Data compared to the previous version altered.**