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

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

· **1.1 Product identifier**

· **Trade name:** **Variolink Esthetic Try-In**

· **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** Water-soluble glycerine try-in paste

· **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**
The product is not classified according to the CLP regulation.

· **2.2 Label elements**
· **Labelling according to Regulation (EC) No 1272/2008** Void

· **Hazard pictograms** Void
· **Signal word** Void
· **Hazard statements** Void
· **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: 56-81-5 EINECS: 200-289-5	glycerol	substance with a Community workplace exposure limit	50-100%

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

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SECTION 4: First aid measures

· **4.1 Description of first aid measures**
· **General information:** No special measures required.
· **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:**
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.
· **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:**
CO_2, 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.
Ensure adequate ventilation.
· **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:** Store away from oxidising agents.
· **Further information about storage conditions:**
This product is hygroscopic.
Keep container tightly sealed.
Protect from heat and direct sunlight.

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· **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:**	
56-81-5 glycerol	
WEL	Long-term value: 10 mg/m³

· **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.
Keep away from foodstuffs, beverages and feed.
Avoid contact with the skin.
· **Respiratory protection:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
· **Recommended filter device for short term use:**
Combination filter A-P2
Combination filter A-P3
· **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**
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
· **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:**

Tightly sealed goggles

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

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· **Odour threshold:**	Not determined.
· **pH-value:**	Not determined.
· **Change in condition**	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
· **Flash point:**	Not applicable.
· **Flammability (solid, gaseous):**	Not applicable.
· **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 determined.
· **Density:**	Not determined.
· **Relative density**	Not determined.
· **Vapour density**	Not determined.
· **Evaporation rate**	Not determined.
· **Solubility in / Miscibility with water:**	Partly soluble.
· **Partition coefficient (n-octanol/water):**	Not determined.
· **Viscosity:**	
Dynamic:	Not determined.
Kinematic:	Not determined.
· **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.
· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
· **10.3 Possibility of hazardous reactions** Reacts with strong oxidising agents.
· **10.4 Conditions to avoid** 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:** No irritating effect.
· **Sensitisation:** No sensitising effects known.
· **Additional toxicological information:** No further relevant information available.

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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.

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":**	-

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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.

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