

1 Identification

- **Product identifier**
- **Trade name:** ***Variolink Esthetic Try-In***
- **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
- **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

- **Manufacturer/Supplier:**
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**
The product is not classified according to the Globally Harmonized System (GHS).

- **Label elements**
- **GHS label elements** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **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 = 0
Fire = 1
Reactivity = 0

(Contd. on page 2)

US

Trade name: Variolink Esthetic Try-In

(Contd. of page 1)

· HMIS-ratings (scale 0 - 4)

| | | |
|------------|---|----------------|
| HEALTH | 0 | Health = 0 |
| FIRE | 1 | Fire = 1 |
| REACTIVITY | 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:

| | | |
|---------|----------|---------|
| 56-81-5 | glycerol | 50-100% |
|---------|----------|---------|

4 First-aid measures

- **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.
- **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.
Ensure adequate ventilation.

(Contd. on page 3)

Trade name: Variolink Esthetic Try-In

(Contd. of page 2)

- **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:** Store away from oxidizing agents.
- **Further information about storage conditions:**
This product is hygroscopic.
Keep receptacle tightly sealed.
Protect from heat and direct sunlight.
- **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:**

56-81-5 glycerol

PEL Long-term value: 15* 5** mg/m³
mist; *total dust **respirable fraction

TLV TLV withdrawn-insufficient data human occup. exp.

- **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.
Wash hands before breaks and at the end of work.
Keep away from foodstuffs, beverages and feed.
Avoid contact with the skin.
- **Breathing equipment:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.
- **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.

(Contd. on page 4)

Trade name: Variolink Esthetic Try-In

(Contd. of page 3)

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

9 Physical and chemical properties

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

· **General Information**

· **Appearance:**

- **Form:** Pasty
- **Color:** According to product specification
- **Odor:** Characteristic
- **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.

· **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 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.

· **Other information** No further relevant information available.

Trade name: Variolink Esthetic Try-In

(Contd. of page 4)

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** Reacts with strong oxidizing agents.
- **Conditions to avoid** 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:**
- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:** No further relevant information available.

· **Carcinogenic categories**· **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.

(Contd. on page 6)

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

(Contd. of page 5)

- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

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

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): | 1344-28-1 aluminium oxide |
| · 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. |

(Contd. on page 7)

US

Trade name: Variolink Esthetic Try-In

(Contd. of page 6)

· **Carcinogenic categories**· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

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

1344-28-1 aluminium oxide

A4

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

None of the ingredients is listed.

· **GHS label elements** Void· **Hazard pictograms** Void· **Signal word** Void· **Hazard statements** Void· **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** 05/07/2015 / 1· **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)

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