1 Identification

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

- **Relevant identified uses of the substance or mixture and uses advised against**
  - No further relevant information available.

- **Application of the substance / the preparation**
  - 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

  - 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 MSDS Assistance:**
    - US: 1-800-533-6825
    - Canada: 1-800-263-8182

2 Hazard(s) identification

- **Classification of the substance or mixture**

- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
  - Not applicable.

- **Classification system:**
  - The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

- **Label elements**

- **Labelling according to EU guidelines:**
  - 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 Dangerous Substance Directive 1999/45/EC usually if they are in the finished state and intended for the final user.

- **Classification system:**

- **NFPA ratings (scale 0 - 4)**
  - Health = 0
  - Fire = 0
  - Reactivity = 0

(Contd. on page 2)
Trade name: Variolink Veneer Try-In

- HMIS-ratings (scale 0 - 4)
  - Health = 0
  - 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:
  - 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: 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.
Trade name: Variolink Veneer Try-In

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: Not required.
    - Further information about storage conditions:
      - Protect from exposure to the light.
      - 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 15* 5** mg/m³
      - total dust **respirable fraction
    - TLV 10* ppm
      - Mist

- Additional information: The lists that were valid during the creation were used as basis.

- Exposure controls
  - 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.
  - Breathing equipment: Not required.
  - Protection of hands:
    - 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.
    - 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.


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.

- **Auto igniting:** Product is not self-igniting.

- **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: Nearly insoluble.

- **Partition coefficient (n-octanol/water):** Not determined.

- **Viscosity:**
  - Dynamic: Not determined.
  - Kinematic: Not determined.

- **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.
  - Photoreactive (Danger of polymerization).

- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.

- **Possibility of hazardous reactions** No dangerous reactions known.

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

- **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.

### 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:**
  - The product is not subject to classification according to internally approved calculation methods for preparations:
  - When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.
- **Carcinogenic categories**
  - **NTP (National Toxicology Program)**
  - 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.
Trade name: Variolink Veneer Try-In

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

14 Transport information

- UN-Number
  - DOT, ADR, ADN, IMDG, IATA: Void

- UN proper shipping name
  - DOT, ADR, ADN, IMDG, IATA: Void

- Transport hazard class(es)
  - DOT, ADR, ADN, IMDG, IATA: Void

- Class
  - DOT, ADR, IMDG, IATA: Void

- Packing group
  - 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.

15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
  - Sara
    - Section 355 (extremely hazardous substances):
      No of the ingredients is listed.

    - Section 313 (Specific toxic chemical listings):
      No of the ingredients is listed.

    - TSCA (Toxic Substances Control Act):
      All ingredients are listed.

- Proposition 65
  - Chemicals known to cause cancer:
    No of the ingredients is listed.

  - Chemicals known to cause reproductive toxicity for females:
    No of the ingredients is listed.

  - Chemicals known to cause reproductive toxicity for males:
    No of the ingredients is listed.

  - Chemicals known to cause developmental toxicity:
    No of the ingredients is listed.

- Carcinogenic categories
  - EPA (Environmental Protection Agency):
    No of the ingredients is listed.
### Safety Data Sheet

**acc. to OSHA HCS**

**Printing date 09/19/2013**

**Version number 3**

**Reviewed on 09/19/2013**

### Trade name: Variolink Veneer Try-In

- **TLV (Threshold Limit Value established by ACGIH)**
  
  None of the ingredients is listed.

- **NIOSH-Ca (National Institute for Occupational Safety and Health)**
  
  None of the ingredients is listed.

- **OSHA-Ca (Occupational Safety & Health Administration)**
  
  None of the ingredients is listed.

- **Product related hazard informations:**
  
  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 Dangerous Substance Directive 1999/45/EC usually if they are in the finished state and intended for the final user.

- **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.