1 Identification

1. Product identifier

   Trade name: Variolink Veneer Try-In

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

1. Application of the substance / the preparation
   Water-soluble glycerine try-in paste

1. 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

2. 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.

2. 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.

   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.
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:

    | Component        | Limit Value 1 | Limit Value 2 |
    |------------------|---------------|---------------|
    | 56-81-5 glycerol | 15* 5** mg/m³ | 10* ppm       |
    |                  | *total dust   | **respirable  |
    |                  | fraction      |               |

- 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.
    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.
37.0.5

- Penetration time of glove material
  The exact breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.
- Eye protection: Safety glasses

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.
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.
# Safety Data Sheet

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

## 14 Transport information

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>UN-Number</strong></td>
<td>Void</td>
</tr>
<tr>
<td>DOT, ADR, ADN, IMDG, IATA</td>
<td></td>
</tr>
<tr>
<td><strong>UN proper shipping name</strong></td>
<td>Void</td>
</tr>
<tr>
<td>DOT, ADR, ADN, IMDG, IATA</td>
<td></td>
</tr>
<tr>
<td><strong>Transport hazard class(es)</strong></td>
<td>Void</td>
</tr>
<tr>
<td>DOT, ADR, ADN, IMDG, IATA</td>
<td></td>
</tr>
<tr>
<td><strong>Class</strong></td>
<td>Void</td>
</tr>
<tr>
<td><strong>Packing group</strong></td>
<td>Void</td>
</tr>
<tr>
<td>DOT, ADR, IMDG, IATA</td>
<td></td>
</tr>
<tr>
<td><strong>Environmental hazards:</strong></td>
<td>No</td>
</tr>
<tr>
<td><strong>Marine pollutant:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Special precautions for user</strong></td>
<td>Not applicable.</td>
</tr>
<tr>
<td><strong>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</strong></td>
<td>Not applicable.</td>
</tr>
</tbody>
</table>

## 15 Regulatory information

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Safety, health and environmental regulations/legislation specific for the substance or mixture</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Sara</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Section 355 (extremely hazardous substances):</strong></td>
<td>None of the ingredients is listed.</td>
</tr>
<tr>
<td><strong>Section 313 (Specific toxic chemical listings):</strong></td>
<td>None of the ingredients is listed.</td>
</tr>
<tr>
<td><strong>TSCA (Toxic Substances Control Act):</strong></td>
<td>All ingredients are listed.</td>
</tr>
<tr>
<td><strong>Proposition 65</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Chemicals known to cause cancer:</strong></td>
<td>None of the ingredients is listed.</td>
</tr>
<tr>
<td><strong>Chemicals known to cause reproductive toxicity for females:</strong></td>
<td>None of the ingredients is listed.</td>
</tr>
<tr>
<td><strong>Chemicals known to cause reproductive toxicity for males:</strong></td>
<td>None of the ingredients is listed.</td>
</tr>
<tr>
<td><strong>Chemicals known to cause developmental toxicity:</strong></td>
<td>None of the ingredients is listed.</td>
</tr>
<tr>
<td><strong>Carcinogenic categories</strong></td>
<td></td>
</tr>
<tr>
<td><strong>EPA (Environmental Protection Agency):</strong></td>
<td>None of the ingredients is listed.</td>
</tr>
</tbody>
</table>
Trade name: Variolink Veneer Try-In

<table>
<thead>
<tr>
<th>(Contd. of page 6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>- TLV (Threshold Limit Value established by ACGIH)</td>
</tr>
<tr>
<td>None of the ingredients is listed.</td>
</tr>
<tr>
<td>- NIOSH-Ca (National Institute for Occupational Safety and Health)</td>
</tr>
<tr>
<td>None of the ingredients is listed.</td>
</tr>
<tr>
<td>- OSHA-Ca (Occupational Safety &amp; Health Administration)</td>
</tr>
<tr>
<td>None of the ingredients is listed.</td>
</tr>
</tbody>
</table>

- **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.

<table>
<thead>
<tr>
<th>16 Other information</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
</tr>
</tbody>
</table>