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:**
  
<table>
<thead>
<tr>
<th>Component</th>
<th>PEL</th>
<th>TLV</th>
</tr>
</thead>
<tbody>
<tr>
<td>56-81-5 glycerol</td>
<td>15*</td>
<td>10*</td>
</tr>
<tr>
<td></td>
<td>5**</td>
<td>ppm</td>
</tr>
<tr>
<td></td>
<td>total dust</td>
<td>**respirable fraction</td>
</tr>
</tbody>
</table>

- **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.
### 9 Physical and chemical properties

- **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

#### Physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>General Information</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Appearance</strong></td>
<td>Pasty</td>
</tr>
<tr>
<td><strong>Form</strong></td>
<td>Pasty</td>
</tr>
<tr>
<td><strong>Color</strong></td>
<td>According to product specification</td>
</tr>
<tr>
<td><strong>Odor</strong></td>
<td>Characteristic</td>
</tr>
<tr>
<td><strong>Odour threshold</strong></td>
<td>Not determined</td>
</tr>
<tr>
<td><strong>pH-value</strong></td>
<td>Not determined</td>
</tr>
<tr>
<td><strong>Change in condition</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Melting point/Melting range</strong></td>
<td>Undetermined</td>
</tr>
<tr>
<td><strong>Boiling point/Boiling range</strong></td>
<td>Undetermined</td>
</tr>
<tr>
<td><strong>Flash point</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Auto igniting</strong></td>
<td>Product is not selfigniting.</td>
</tr>
<tr>
<td><strong>Danger of explosion</strong></td>
<td>Product does not present an explosion hazard.</td>
</tr>
<tr>
<td><strong>Explosion limits</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Lower</strong></td>
<td>Not determined</td>
</tr>
<tr>
<td><strong>Upper</strong></td>
<td>Not determined</td>
</tr>
<tr>
<td><strong>Vapor pressure</strong></td>
<td>Not determined</td>
</tr>
<tr>
<td><strong>Density</strong></td>
<td>Not determined</td>
</tr>
<tr>
<td><strong>Relative density</strong></td>
<td>Not determined</td>
</tr>
<tr>
<td><strong>Vapour density</strong></td>
<td>Not determined</td>
</tr>
<tr>
<td><strong>Evaporation rate</strong></td>
<td>Not determined</td>
</tr>
<tr>
<td><strong>Solubility in / Miscibility with</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Water</strong></td>
<td>Nearly insoluble</td>
</tr>
<tr>
<td><strong>Partition coefficient (n-octanol/water)</strong></td>
<td>Not determined</td>
</tr>
<tr>
<td><strong>Viscosity</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Dynamic</strong></td>
<td>Not determined</td>
</tr>
<tr>
<td><strong>Kinematic</strong></td>
<td>Not determined</td>
</tr>
<tr>
<td><strong>Other information</strong></td>
<td>No further relevant information available.</td>
</tr>
</tbody>
</table>

### 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.
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**
  - **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):** None of the ingredients is listed.
    - **Section 313 (Specific toxic chemical listings):** None of the ingredients is listed.
  - **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.

- **Carcinogenic categories**
  - **EPA (Environmental Protection Agency)**
    - None of the ingredients is listed.
### Trade name: Variolink Veneer Try-In

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>37.0.5</strong></td>
<td></td>
</tr>
<tr>
<td>· <strong>TLV (Threshold Limit Value established by ACGIH)</strong></td>
<td>None of the ingredients is listed.</td>
</tr>
<tr>
<td>· <strong>NIOSH-Ca (National Institute for Occupational Safety and Health)</strong></td>
<td>None of the ingredients is listed.</td>
</tr>
<tr>
<td>· <strong>OSHA-Ca (Occupational Safety &amp; Health Administration)</strong></td>
<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.

### 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.