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)

<table>
<thead>
<tr>
<th>HEALTH</th>
<th>FIRE</th>
<th>REACTIVITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

  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

<table>
<thead>
<tr>
<th>Components with limit values that require monitoring at the workplace:</th>
</tr>
</thead>
<tbody>
<tr>
<td>56-81-5 glycerol</td>
</tr>
<tr>
<td>PEL 15* 5** mg/m³</td>
</tr>
<tr>
<td>*total dust **respirable fraction</td>
</tr>
<tr>
<td>TLV 10* ppm</td>
</tr>
<tr>
<td>*Mist</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.
Trade name: Variolink Veneer Try-In

· 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: 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 selfigniting.
  · Danger of explosion: Product does not present an explosion hazard.
  · Explosion limits:
    · Lower: Not determined.
    · Upper: Not determined.
  · Vapor pressure: Not determined.
  · Density:
    · 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.
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.

(Contd. on page 6)
14 Transport information

- **UN-Number**
  - DOT, ADR, ADN, IMDG, IATA: Void
- **DOT, ADR, ADN, IMDG, IATA**
- **Transport hazard class(es)**
  - DOT, ADR, ADN, 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):
      - 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.
- **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.

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### 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.