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

- **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

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· HMIS-ratings (scale 0 - 4)

HEALTH 0
FIRE 0
REACTIVITY 0

· 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:
    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
  - 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.
· **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:** Pasty
  - **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.
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
acc. to OSHA HCS

Printing date 09/19/2013 Reviewed on 09/19/2013
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37.0.5 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
  - 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.

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### 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.