SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name: Variolink N (Catalyst)

1.2 Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

Application of the substance / the mixture
Dual-curing/light-curing resin based dental luting material

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:
Ivoclar Vivadent AG
Bendererstrasse 2
9494 Schaan
PRINCIPALITY OF LIECHTENSTEIN

Tel: +423 235 35 35
Fax: +423 235 33 60

Further information obtainable from:
Regulatory Affairs
sds@ivoclarvivadent.com

1.4 Emergency telephone number: +423 / 235 33 13 (Ivoclar Vivadent AG, 9494 Schaan, Liechtenstein)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

Skin Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2 H319 Causes serious eye irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.
STOT SE 3 H335 May cause respiratory irritation.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

Hazard pictograms

GHS07

Signal word Warning

Hazard-determining components of labelling:
Bis-GMA
ytterbium trifluoride
triethylene glycol dimethacrylate
urethane dimethacrylate
dibenzoyl peroxide

Hazard statements

H315 Causes skin irritation.
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.
H335 May cause respiratory irritation.

Precautionary statements
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
Trade name: Variolink N (Catalyst)

P280 Wear protective gloves / eye protection / face protection.
P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Additional information:
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 Regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

2.3 Other hazards
Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

3.2 Chemical characterisation: Mixtures
Description: Mixture of substances listed below with nonhazardous additions.

Dangerous components:

<table>
<thead>
<tr>
<th>CAS</th>
<th>Description</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>36425-15-7</td>
<td>Bis-GMA</td>
<td>50-100%</td>
</tr>
<tr>
<td>500-089-0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13760-80-0</td>
<td>ytterbium trifluoride</td>
<td>≥20-≤25%</td>
</tr>
<tr>
<td>237-354-2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>109-16-0</td>
<td>triethylene glycol dimethacrylate</td>
<td>≥2.5-&lt;10%</td>
</tr>
<tr>
<td>72869-86-4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>276-957-5</td>
<td>urethane dimethacrylate</td>
<td>≥2.5-&lt;10%</td>
</tr>
<tr>
<td>94-36-0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>202-327-6</td>
<td>dibenzoyl peroxide</td>
<td>≥0.1-&lt;1%</td>
</tr>
</tbody>
</table>

Additional information: For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures
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.

4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed No further relevant information available.
SECTION 5: Firefighting measures

5.1 Extinguishing media
- Suitable extinguishing agents:
  CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

5.2 Special hazards arising from the substance or mixture No further relevant information available.

5.3 Advice for firefighters
- Protective equipment: No special measures required.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures Not required.

6.2 Environmental precautions: Do not allow to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up: Pick up mechanically.

6.4 Reference to other sections
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

7.1 Precautions for safe handling
- Only adequately trained personnel should handle this product.
- For use in dentistry only.
- Information about fire - and explosion protection: No special measures required.

7.2 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:
    - Store in a cool place.
    - Protect from exposure to the light.
    - Protect from heat and direct sunlight.
    - Keep container tightly sealed.

7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

Additional information about design of technical facilities: No further data; see item 7.

8.1 Control parameters
- Ingredients with limit values that require monitoring at the workplace:
  The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

8.2 Exposure controls
- Personal protective equipment:
  - General protective and hygienic measures:
    Usual hygienic measures for dental practice and dental laboratories.
    Wash hands before breaks and at the end of work.
    Avoid contact with the eyes and skin.
    Keep away from foodstuffs, beverages and feed.
### SECTION 9: Physical and chemical properties

**9.1 Information on basic physical and chemical properties**

- **General Information**
  - **Form:** Pasty
  - **Colour:** According to product specification
  - **Odour:** Characteristic
  - **Odour threshold:** Not determined.

- **pH-value:** Not applicable.

- **Change in condition**
  - **Melting point/freezing point:** Undetermined.
  - **Initial boiling point and boiling range:** Undetermined.

- **Flash point:** Not applicable.

- **Flammability (solid, gas):** Not determined.

- **Auto-ignition temperature:** Product is not selfigniting.

- **Explosive properties:** Product does not present an explosion hazard.

- **Explosion limits:**
  - **Lower:** Not determined.
  - **Upper:** Not determined.

- **Vapour pressure:** Not applicable.

- **Density at 20 °C:** 2.23 g/cm³
- **Relative density** Not determined.
- **Vapour density** Not determined.
- **Evaporation rate** Not applicable.
SECTION 10: Stability and reactivity

- 10.1 Reactivity No further relevant information available.
- 10.2 Chemical stability Stable under normal handling and storage conditions.
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- 10.3 Possibility of hazardous reactions No dangerous reactions known.
- 10.4 Conditions to avoid
  Protect from exposure to the light.
  Keep away from heat and direct sunlight.
- 10.5 Incompatible materials: No further relevant information available.
- 10.6 Hazardous decomposition products: None under normal conditions of storage and use.

SECTION 11: Toxicological information

- 11.1 Information on toxicological effects
  - Acute toxicity Based on available data, the classification criteria are not met.
  - Skin corrosion/irritation
    Causes skin irritation.
  - Serious eye damage/irritation
    Causes serious eye irritation.
  - Respiratory or skin sensitisation
    May cause an allergic skin reaction.
  - Additional toxicological information: No further relevant information available.
  - Germ cell mutagenicity Based on available data, the classification criteria are not met.
  - Carcinogenicity Based on available data, the classification criteria are not met.
  - Reproductive toxicity Based on available data, the classification criteria are not met.
  - STOT-single exposure
    May cause respiratory irritation.
  - STOT-repeated exposure Based on available data, the classification criteria are not met.
  - Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- 12.1 Toxicity
  - Aquatic toxicity: No further relevant information available.
  - 12.2 Persistence and degradability No further relevant information available.
  - 12.3 Bioaccumulative potential No further relevant information available.
  - 12.4 Mobility in soil No further relevant information available.
  - Additional ecological information:
    - General notes:
      Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
      (Contd. on page 6)
**Trade name:** Variolink N (Catalyst)

(Contd. of page 5)

- 12.5 Results of PBT and vPvB assessment
  - PBT: Not applicable.
  - vPvB: Not applicable.
- 12.6 Other adverse effects No further relevant information available.

### SECTION 13: Disposal considerations

- 13.1 Waste treatment methods
  - Recommendation
  Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
- Uncleaned packaging:
  - Recommendation: Disposal must be made according to official regulations.

### SECTION 14: Transport information

<table>
<thead>
<tr>
<th>14.1 UN-Number</th>
<th>Void</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADR/RID/ADN, ADN, IMDG, IATA</td>
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</tr>
<tr>
<td>14.2 UN proper shipping name</td>
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</tr>
<tr>
<td>ADR/RID/ADN, ADN, IMDG, IATA</td>
<td>Void</td>
</tr>
<tr>
<td>14.3 Transport hazard class(es)</td>
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<tr>
<td>Class</td>
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<td>14.4 Packing group</td>
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<tr>
<td>ADR/RID/ADN, IMDG, IATA</td>
<td>Void</td>
</tr>
<tr>
<td>14.5 Environmental hazards:</td>
<td>No</td>
</tr>
<tr>
<td>Marine pollutant:</td>
<td>No</td>
</tr>
<tr>
<td>14.6 Special precautions for user</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Transport/Additional information:</td>
<td>Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).</td>
</tr>
<tr>
<td>UN &quot;Model Regulation&quot;:</td>
<td>Void</td>
</tr>
</tbody>
</table>

### SECTION 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
  - REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3
- National regulations:
  - Other regulations, limitations and prohibitive regulations
  The product is a medical device according to the Directive 93/42/EEC.
- 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

(Contd. on page 7)
SECTION 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.

Relevant phrases
- H241 Heating may cause a fire or explosion.
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.
- H335 May cause respiratory irritation.
- H412 Harmful to aquatic life with long lasting effects.

Abbreviations and acronyms:
- ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
- IMDG: International Maritime Code for Dangerous Goods
- IATA: International Air Transport Association
- GHS: Globally Harmonised System of Classification and Labelling of Chemicals
- EINECS: European Inventory of Existing Commercial Chemical Substances
- ELINCS: European List of Notified Chemical Substances
- CAS: Chemical Abstracts Service (division of the American Chemical Society)
- PBT: Persistent, Bioaccumulative and Toxic
- vPvB: very Persistent and very Bioaccumulative
- Org. Perox. B: Organic peroxides – Type B
- Skin Irrit. 2: Skin corrosion/irritation – Category 2
- Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
- Skin Sens. 1: Skin sensitisation – Category 1
- STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
- Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

* Data compared to the previous version altered.