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

1.1 Product identifier

Trade name: **Multilink N (Base)**

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

Self-curing resin-based dental luting material with light-curing option

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

Ivoclar Vivadent AG

Bendererstrasse 2

FL-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, FL-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](image)

Signal word Warning

Hazard-determining components of labelling:

Bis-GMA

ytterbium trifluoride

2-hydroxyethyl methacrylate

2-dimethylaminoethyl methacrylate

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

P280 Wear protective gloves/protective clothing/eye protection/face protection.
40.1.5

P363 Wash contaminated clothing before reuse.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P337+P313 If eye irritation persists: Get medical advice/attention.

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.

<table>
<thead>
<tr>
<th>CAS</th>
<th>Substance</th>
<th>PBT</th>
<th>vPvB</th>
</tr>
</thead>
<tbody>
<tr>
<td>13760-80-0</td>
<td>ytterbium trifluoride</td>
<td></td>
<td></td>
</tr>
<tr>
<td>237-354-2</td>
<td>ethoxylated bisphenol A dimethacrylate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>41637-38-1</td>
<td>2-hydroxyethyl methacrylate</td>
<td>Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335</td>
<td></td>
</tr>
<tr>
<td>1565-94-2</td>
<td>Bis-GMA</td>
<td>Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317</td>
<td></td>
</tr>
<tr>
<td>868-77-9</td>
<td>2-hydroxyethyl methacrylate</td>
<td>Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317</td>
<td></td>
</tr>
<tr>
<td>2867-47-2</td>
<td>2-dimethylaminoethyl methacrylate</td>
<td>Acute Tox. 4, H302; Acute Tox. 4, H312; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317</td>
<td>&lt;1%</td>
</tr>
</tbody>
</table>

Additional information: For the wording of the listed risk 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:
Rinse out mouth and then drink plenty of water. 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.
Trade name: **Multilink N (Base)**

- **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**
    - 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.
  - **Additional information**: The lists valid during the making were used as basis.
- **8.2 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.
      - Keep away from foodstuffs, beverages and feed.
      - Avoid contact with the eyes and skin.
  - **Respiratory protection**: Not required.
  - **Protection of hands**:
    - **Protective gloves**
40.1.5 The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
After use of gloves apply skin-cleaning agents and skin cosmetics.
· Material of gloves
  Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/
the chemical mixture.
· 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

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties
· General Information
  · Appearance:
    Form: Pasty
    Colour: According to product specification
  · Odour:
    Odour: Characteristic
    Odour threshold: Not determined.
  · pH-value:
    pH-value: Not determined.
  · Change in condition
    Melting point/Melting range: Undetermined.
    Boiling point/Boiling range: Undetermined.
  · Flash point:
    Flash point: Not applicable.
  · Flammability (solid, gaseous):
    Flammability (solid, gaseous): Not applicable.
  · Self-igniting:
    Product is not selfigniting.
  · Danger of explosion:
    Product does not present an explosion hazard.
  · Explosion limits:
    Lower: Not determined.
    Upper: Not determined.
  · Vapour pressure:
    Vapour pressure: Not determined.
  · Density at 20 °C:
    2.05 g/cm³
  · Relative density
    Relative density: Not determined.
  · Vapour density
    Vapour density: Not determined.
  · Evaporation rate
    Evaporation rate: Not determined.
  · Solubility in / Miscibility with water:
    Solubility in / Miscibility with water: Nearly insoluble.
  · Partition coefficient (n-octanol/water):
    Partition coefficient (n-octanol/water): Not determined.
  · Viscosity:
    Dynamic: Not determined.
    Kinematic: Not determined.
· 9.2 Other information
  No further relevant information available.

SECTION 10: Stability and reactivity

· 10.1 Reactivity
  No further relevant information available.
10.2 Chemical stability
Photoreactive (Danger of polymerization).
Stable under normal handling and storage conditions.

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:
Primary irritant effect:
- on the skin: Irritant to skin and mucous membranes.
- on the eye: Irritating effect.
Sensitisation: Sensitisation possible through skin contact.
Additional toxicological information: No further relevant information available.

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
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

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.

European waste catalogue
18 01 06* chemicals consisting of or containing dangerous substances

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>ADR, ADN, IMDG, IATA</th>
<th>Void</th>
</tr>
</thead>
<tbody>
<tr>
<td>14.2 UN proper shipping name</td>
<td>ADR, ADN, IMDG, IATA</td>
<td>Void</td>
</tr>
<tr>
<td>14.3 Transport hazard class(es)</td>
<td>ADR, ADN, IMDG, IATA</td>
<td>Void</td>
</tr>
<tr>
<td>Class</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14.4 Packing group</td>
<td>ADR, IMDG, IATA</td>
<td>Void</td>
</tr>
<tr>
<td>14.5 Environmental hazards:</td>
<td>Marine pollutant:</td>
<td>No</td>
</tr>
<tr>
<td>14.6 Special precautions for user</td>
<td></td>
<td>Not applicable.</td>
</tr>
<tr>
<td>14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</td>
<td></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>
<td></td>
</tr>
<tr>
<td>UN &quot;Model Regulation&quot;:</td>
<td>-</td>
<td></td>
</tr>
</tbody>
</table>

### SECTION 15: Regulatory information

| 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture |
| 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. |

### 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**
- H302 Harmful if swallowed.
- H312 Harmful in contact with skin.
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.
- H335 May cause respiratory irritation.
- H413 May cause long lasting harmful effects to aquatic life.

**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)
- Acute Tox. 4: Acute toxicity, Hazard Category 4
- Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2
<table>
<thead>
<tr>
<th>Hazard Classification</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye Irrit. 2: Serious eye damage/eye irritation</td>
<td>2</td>
</tr>
<tr>
<td>Skin Sens. 1: Sensitisation - Skin</td>
<td>1</td>
</tr>
<tr>
<td>STOT SE 3: Specific target organ toxicity - Single exposure</td>
<td>3</td>
</tr>
<tr>
<td>Aquatic Chronic 4: Hazardous to the aquatic environment</td>
<td>4</td>
</tr>
</tbody>
</table>

* Data compared to the previous version altered.