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

- **Product identifier**
  - **Trade name:** *Multilink Automix (Catalyst)*

- **Relevant identified uses of the substance or mixture and uses advised against**
  - No further relevant information available.

- **Application of the substance / the preparation**
  - Self-curing resin-based dental luting material with light-curing option

- **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 Hazards identification

- **Classification of the substance or mixture**
  - **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
    - Irritant
    - May cause sensitisation by skin contact.

  - **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/EWG usually if they are in the finished state and intended for the final user.

  - **Code letter and hazard designation of product:**
    - *Irritant*
Trade name: Multilink Automix (Catalyst)

- **Hazard-determining components of labelling:**
  - urethane dimethacrylate
  - 2-hydroxyethyl methacrylate
  - dibenzoyl peroxide

- **Risk phrases:**
  May cause sensitisation by skin contact.

- **Safety phrases:**
  - Do not breathe vapour.
  - Avoid contact with skin.
  - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
  - After contact with skin, wash immediately with plenty of water
  - Wear suitable gloves.
  - This material and its container must be disposed of as hazardous waste.

- **Classification system:**
  - NFPA ratings (scale 0 - 4)
    - Health = 0
    - Fire = 0
    - Reactivity = 0
  - 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.

<table>
<thead>
<tr>
<th>Dangerous components</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>72869-86-4</td>
<td>urethane dimethacrylate</td>
</tr>
<tr>
<td>868-77-9</td>
<td>2-hydroxyethyl methacrylate</td>
</tr>
<tr>
<td>94-36-0</td>
<td>dibenzoyl peroxide</td>
</tr>
</tbody>
</table>

### 4 First aid measures

- **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.
Trade name: Multilink Automix (Catalyst)

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 Firefighting 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.
  - 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.
  - Keep receptacle tightly sealed.
  - 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:
    - 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 that were valid during the creation were used as basis.
Safety Data Sheet
acc. to OSHA HCS

Printing date 01/16/2013 Reviewed on 01/16/2013
Version number 4

Trade name: Multilink Automix (Catalyst)

(Contd. of page 3)

- **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.
- **Breathing equipment:** Not required.
- **Protection of hands:**

  ![Protective gloves]

  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

(Contd. on page 5)

**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.
- **Flammability (solid, gaseous):** 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 at 20 °C (68 °F):** 2.05 g/cm³ (17.107 lbs/gal)
- **Relative density** Not determined.
- **Vapour density** Not determined.

(Contd. on page 5)
Trade name: Multilink Automix (Catalyst)

- **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.
- **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: Sensitization possible through skin contact.
  - Additional toxicological information:
    - The product shows the following dangers according to internally approved calculation methods for preparations:
      - Irritant

- **Carcinogenic categories**

```
<table>
<thead>
<tr>
<th>IARC (International Agency for Research on Cancer)</th>
<th>NTP (National Toxicology Program)</th>
</tr>
</thead>
<tbody>
<tr>
<td>7631-86-9 silicon dioxide, chemically prepared</td>
<td>None of the ingredients is listed.</td>
</tr>
<tr>
<td>94-36-0 dibenzoyl peroxide</td>
<td></td>
</tr>
</tbody>
</table>
```

### 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.
Safety Data Sheet
acc. to OSHA HCS

Trade name: Multilink Automix (Catalyst)

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.

- 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):
    - 94-36-0 dibenzoyl peroxide

(Contd. on page 7) USA
### 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)**
  
  13760-80-0 ytterbium trifluoride A4
  94-36-0 dibenzoyl peroxide A4

- **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/EWG usually if they are in the finished state and intended for the final user.

### Hazard symbols:

- **Irritant**

### Hazard-determining components of labelling:

- urethane dimethacrylate
- 2-hydroxyethyl methacrylate
- dibenzoyl peroxide

### Risk phrases:

- May cause sensitisation by skin contact.

### Safety phrases:

- Do not breathe vapour.
- Avoid contact with skin.
- In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- After contact with skin, wash immediately with plenty of water
- Wear suitable gloves.
- This material and its container must be disposed of as hazardous waste.
Trade name: **Multilink Automix (Catalyst)**

- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**
  The product is a medical device according to the EC-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.

* Data compared to the previous version altered.