1 Identification

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

- **Application of the substance / the mixture**
  - 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 SDS Assistance:
    - US: 1-800-533-6825
    - Canada: 1-800-263-8182

2 Hazard(s) identification

- **Classification of the substance or mixture**
  - Skin Irrit. 2 H315 Causes skin irritation.
  - Eye Irrit. 2A H319 Causes serious eye irritation.
  - Skin Sens. 1 H317 May cause an allergic skin reaction.
  - STOT SE 3 H335 May cause respiratory irritation.

- **Label elements**
  - **GHS label elements**
    - The product is classified and labeled according to the Globally Harmonized System (GHS).

- **Hazard pictograms**
  - GHS07

- **Signal word** Warning

- **Hazard-determining components of labeling:**
  - urethane dimethacrylate
  - ytterbium trifluoride
  - 2-hydroxyethyl methacrylate
Trade name: Multilink Automix (Catalyst)

dibenzoyl peroxide

Hazard statements
Causes skin irritation.
Causes serious eye irritation.
May cause an allergic skin reaction.
May cause respiratory irritation.

Precautionary statements
Avoid contact during pregnancy/while nursing.
Wear protective gloves/protective clothing/eye protection/face protection.
If skin irritation or rash occurs: Get medical advice/attention.
If eye irritation persists: Get medical advice/attention.

Additional information:
Medical devices are exempt from the labeling provisions of GHS according to the Hazard Communication Standard (HCS).

Classification system:

NFPA ratings (scale 0 - 4)

<table>
<thead>
<tr>
<th>Health</th>
<th>Fire</th>
<th>Reactivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

HMIS-ratings (scale 0 - 4)

<table>
<thead>
<tr>
<th>HEALTH</th>
<th>FIRE</th>
<th>REACTIVITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>CAS</th>
<th>Description</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>13760-80-0</td>
<td>ytterbium trifluoride</td>
<td>20-&lt;25%</td>
</tr>
<tr>
<td>41637-38-1</td>
<td>Bis-EMA</td>
<td>10-&lt;25%</td>
</tr>
<tr>
<td>72869-86-4</td>
<td>urethane dimethacrylate</td>
<td>2.5-&lt;10%</td>
</tr>
<tr>
<td>868-77-9</td>
<td>2-hydroxyethyl methacrylate</td>
<td>2.5-&lt;10%</td>
</tr>
<tr>
<td>94-36-0</td>
<td>dibenzoyl peroxide</td>
<td>1-&lt;2.5%</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.
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.
  - 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.
9 Physical and chemical properties

- **Information on basic physical and chemical properties**
  - **General Information**
  - **Appearance:**
    - Form: Pasty
    - Color: According to product specification
    - Odor: Characteristic
    - Odor 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.
  - Vapor density Not determined.
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:
    - on the skin: No irritant effect.
    - on the eye: No irritating effect.
  - Sensitization: Sensitization possible through skin contact.
  - Additional toxicological information: No further relevant information available.
- Carcinogenic categories
  - IARC (International Agency for Research on Cancer)
    CAS: 94-36-0 dibenzoyl peroxide
    - NTP (National Toxicology Program)
      None of the ingredients is listed.
    - OSHA-Ca (Occupational Safety & Health Administration)
      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.
Safety Data Sheet
acc. to OSHA HCS

Printing date 07/22/2019
Version number 6
Reviewed on 06/03/2019

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/RID/ADN, ADN, IMDG, IATA Void
- UN proper shipping name
  - DOT, ADR/RID/ADN, ADN, IMDG, IATA Void
- Transport hazard class(es)
  - DOT, ADR/RID/ADN, ADN, IMDG, IATA Void
  - Class
- Packing group
  - DOT, ADR/RID/ADN, 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.
- Transport/Additional information:
  - Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).
- UN "Model Regulation": Void

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.
Safety Data Sheet
acc. to OSHA HCS

Printing date 07/22/2019     Reviewed on 06/03/2019
Version number 6

Trade name: Multilink Automix (Catalyst)

Section 313 (Specific toxic chemical listings):
- CAS: 94-36-0 dibenzoyl peroxide

TSCA (Toxic Substances Control Act):
- CAS: 13760-80-0 ytterbium trifluoride
- CAS: 41637-38-1 Bis-EMA
- CAS: 72869-86-4 urethane dimethacrylate
- CAS: 868-77-9 2-hydroxyethyl methacrylate
- CAS: 94-36-0 dibenzoyl peroxide

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)
- CAS: 13760-80-0 ytterbium trifluoride A4
- CAS: 94-36-0 dibenzoyl peroxide A4

NIOSH-Ca (National Institute for Occupational Safety and Health)
None of the ingredients is listed.

GHS label elements
The product is classified and labeled according to the Globally Harmonized System (GHS).

Hazard pictograms

GHS07

Signal word Warning

Hazard-determining components of labeling:
urethane dimethacrylate
ytterbium trifluoride
2-hydroxyethyl methacrylate
dibenzoyl peroxide

Hazard statements
Causes skin irritation.
Causes serious eye irritation.
May cause an allergic skin reaction.
May cause respiratory irritation.

Precautionary statements
Avoid contact during pregnancy/while nursing.
Wear protective gloves/protective clothing/eye protection/face protection.
If skin irritation or rash occurs: Get medical advice/attention.
If eye irritation persists: Get medical advice/attention.

**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.

**Date of preparation / last revision** 07/22/2019 / 5

**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

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A

Skin Sens. 1: Skin sensitisation – Category 1

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

* Data compared to the previous version altered.