1 Identification

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

- **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 identification

- **Classification of the substance or mixture**
  - **Skin Irritation - Category 2**: H315  Causes skin irritation.
  - **Eye Irritation - Category 2A**: H319  Causes serious eye irritation.
  - **Skin Sensitizer - Category 1**: H317  May cause an allergic skin reaction.
  - **Specific Target Organ Toxicity - Single Exposure - Category 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**:
  - Bis-GMA
  - ytterbium trifluoride

(Contd. on page 2)
 Trade name: **Multilink Automix (Base)**

2-hydroxyethyl methacrylate
2-dimethylaminoethyl methacrylate

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

**Precautionary statements**
Avoid breathing dust/fume/gas/mist/vapours/spray.
Wash thoroughly after handling.
Use only outdoors or in a well-ventilated area.
Contaminated work clothing should not be allowed out of the workplace.
Wear protective gloves/protective clothing/eye protection/face protection.
If on skin: Wash with plenty of water.
Specific treatment (see on this label).
IF INHALED: Remove person to fresh air and keep comfortable for breathing.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Call a poison center/doctor if you feel unwell.
Take off contaminated clothing and wash it before reuse.
If skin irritation or rash occurs: Get medical advice/attention.
If eye irritation persists: Get medical advice/attention.
Store in a well-ventilated place. Keep container tightly closed.
Store locked up.
Dispose of contents/container in accordance with local/regional/national/international regulations.

**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)**
- Health = 2
- Fire = 0
- Reactivity = 0

**HMIS-ratings (scale 0 - 4)**
- Health = 2
- Fire = 0
- Reactivity = 0

**3 Composition/Information on ingredients**

**Chemical characterization:** Mixtures

**Description:** Mixture of the substances listed below with nonhazardous additions.

**Dangerous components:**
- CAS: 13760-80-0 ytterbium trifluoride ≥20-<30% w/w *
- CAS: 36425-15-7 Bis-GMA ≥10-<13% w/w *
- CAS: 868-77-9 2-hydroxyethyl methacrylate ≥3-7% w/w *
- CAS: 2867-47-2 2-dimethylaminoethyl methacrylate ≥80.1-<1% w/w *

* Actual concentration ranges are withheld as a trade secret.
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.
  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.
### 8 Exposure controls/ Personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **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.

**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.
  - 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.
- **Not suitable are gloves made of the following materials:**
  - Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates.
- **Eye protection:** Safety glasses

### 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.
Safety Data Sheet
according to HPR, Schedule 1

Trade name: Multilink Automix (Base)

- **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:** 2.05 g/cm³
  - **Relative density** Not determined.
  - **Vapor 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**
  - Photoreactive (Danger of polymerization).
  - 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**
- **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.
- Uncleaned packagings:
  - Recommendation: Disposal must be made according to official regulations.

14 Transport information

- UN-Number
  - DOT, TDG, ADN, IMDG, IATA: Void
- UN proper shipping name
  - DOT, TDG, ADN, IMDG, IATA: Void
- Transport hazard class(es)
  - DOT, TDG, ADN, IMDG, IATA
    - Class: Void
- Packing group
  - DOT, TDG, 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.
    - **Section 313 (Specific toxic chemical listings):**
      - None of the ingredients is listed.
    - **TSCA (Toxic Substances Control Act):**
      - All ingredients are 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:**
  - Bis-GMA
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  - 2-hydroxyethyl methacrylate
  - 2-dimethylaminoethyl methacrylate

- **Hazard statements**
  - Causes skin irritation.
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  - May cause an allergic skin reaction.
  - May cause respiratory irritation.

- **Precautionary statements**
  - Avoid breathing dust/fume/gas/mist/vapours/spray.
  - Wash thoroughly after handling.
  - Use only outdoors or in a well-ventilated area.
  - Contaminated work clothing should not be allowed out of the workplace.
  - Wear protective gloves/protective clothing/eye protection/face protection.
  - If on skin: Wash with plenty of water.
  - Specific treatment (see on this label).
  - IF INHALED: Remove person to fresh air and keep comfortable for breathing.
  - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
  - Call a poison center/doctor if you feel unwell.
  - Take off contaminated clothing and wash it before reuse.
  - If skin irritation or rash occurs: Get medical advice/attention.
  - If eye irritation persists: Get medical advice/attention.
  - Store in a well-ventilated place. Keep container tightly closed.
  - Store locked up.
  - Dispose of contents/container in accordance with local/regional/national/international regulations.

- **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.

- **Date of the latest revision of the safety data sheet:** 03/25/2019 / 5

- **Abbreviations and acronyms:**
  - IMDG: International Maritime Code for Dangerous Goods
  - DOT: US Department of Transportation
  - IATA: International Air Transport Association
  - 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

- *Data compared to the previous version altered.*