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

- **1.1 Product identifier**
  Trade name: **Multilink Hybrid Abutment (Base)**

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

- **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

- **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](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**
  P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
  P280 Wear protective gloves / eye protection / face protection.

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48.0.6
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.

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:

| CAS: 13760-80-0 | ytterbium trifluoride | Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335 | ≥20-<25% |
| CAS: 237-354-2 | ethyoxylated bisphenol A dimethacrylate | Aquatic Chronic 4, H413 | ≥10-<25% |
| CAS: 41637-38-1 | ethyoxylated bisphenol A dimethacrylate | Aquatic Chronic 4, H413 | ≥10-<25% |
| CAS: 36425-15-7 | Bis-GMA | Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317 | 10-25% |
| NLP: 500-089-0 | 2-hydroxyethyl methacrylate | Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317 | ≥2.5-<10% |
| CAS: 868-77-9 | 2-hydroxyethyl methacrylate | Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317 | ≤2.5-<10% |
| EINECS: 220-688-8 | 2-dimethylaminoethyl methacrylate | Acute Tox. 2, H300; Acute Tox. 4, H302; Acute Tox. 4, H306; Acute Tox. 4, H312; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317 | ≥0.1-<1% |

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. Then 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.

5.2 Special hazards arising from the substance or mixture No further relevant information available.
5.3 Advice for firefighters

Protection 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 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.
Respiratory protection: Not required.
Protection of hands:

Protective gloves
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
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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 breakthrough 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

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: 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 applicable.
  
    **Auto-ignition temperature:**
    - Product is not self-igniting.
  
    **Explosive properties:**
    - Product does not present an explosion hazard.
  
    **Explosion limits:**
    - Lower: Not determined.
    - Upper: Not determined.
  
    **Vapour pressure:**
    - Not determined.
  
    **Density at 20 °C:**
    - ~1.95 g/cm³
  
    **Relative density:**
    - Not determined.
  
    **Vapour 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.
  
    **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: 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.
- Bioaccumulative potential: No further relevant information available.
- Mobility in soil: 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.

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.
SECTION 14: Transport information

14.1 UN-Number
- ADR/RID/ADN, ADN, IMDG, IATA: Void

14.2 UN proper shipping name
- ADR/RID/ADN, ADN, IMDG, IATA: Void

14.3 Transport hazard class(es)
- ADR/RID/ADN, ADN, IMDG, IATA: Void

14.4 Packing group
- ADR/RID/ADN, IMDG, IATA: Void

14.5 Environmental hazards:
- Marine pollutant: No

14.6 Special precautions for user
- Not applicable.

14.7 Transport in bulk according to Annex II of Marpol 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

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.

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.
- H330 Fatal if inhaled.
- H335 May cause respiratory irritation.

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Safety data sheet  
according to 1907/2006/EC, Article 31 

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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)  
PBT: Persistent, Bioaccumulative and Toxic  
vPvB: very Persistent and very Bioaccumulative  
Acute Tox. 4: Acute toxicity – Category 4  
Acute Tox. 2: Acute toxicity – Category 2  
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 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4  
* Data compared to the previous version altered.  

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