

SAFETY DATA SHEETS

This SDS packet was issued with item:

077122567

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

070434456 077122476 077122500

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

077106503 077106511 077106529 077106537 077122534 077122542 077122559 077122575 077124068 077124076
077124084 077124092 077124100

Material Safety Data Sheet

Multilink



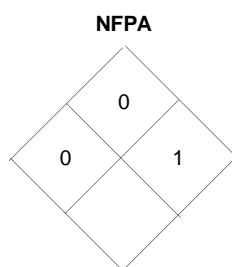
Date of issue / Reference 01.10.2007 lise / Version 3
Replaces version of 11.04.2005 hot
Date of printing 01.10.2007 **Sheet No. 1529**

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Company Ivoclar Vivadent AG, Bendererstrasse 2, FL - 9494 Schaan
Principality of Liechtenstein

1 Commercial product name and supplier

1.1 Commercial product name / Designation **Multilink**



HMIS	
H	0
F	0
R	1
C	

1.2 Application / Use Resin based dental luting material

1.3 Producer Ivoclar Vivadent AG, Bendererstrasse 2, 9494 Schaan
Principality of Liechtenstein (FL)

1.4 Supplier Ivoclar Vivadent, Inc.
175 Pineview Drive, Amherst NY 14228, USA
2785 Skymark Ave., Unit 1 Mississauga, ON L4W4Y3, Canada
MSDS prepared by Andejeet Gulati. Tel. No. 716 691-0010

1.5 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 Composition

2.1 Chemical characterization Base and Catalyst
Pastes of dimethacrylates, hydroxyethyl methacrylate (HEMA),
inorganic fillers, ytterbiumtrifluoride, initiators, stabilizers and
pigments

2.2 Hazardous components

24-26 % Dimethacrylates (CAS No. 1565-94-2, 72869-86-4, 41637-38-1)
R36/38: Irritating to eyes and skin.

CAS No. 868-77-9 6-7 % HEMA
Xi: Irritant. R43: May cause sensitisation by skin contact. R36/38: Irritating to eyes and skin.

CAS No. 94-36-0 < 1 % Benzoylperoxide
Xi: Irritant. E: Explosive. R2: Risk of explosion by shock, friction, fire or other sources of ignition. R36: Irritating to eyes. R43: May cause sensitisation by skin contact.

2.3 Further information None.

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3 Hazards identification

Uncured material: May cause sensitization by skin contact. Direct contact may cause eye and skin irritation. The material is contraindicated if a person is known to be allergic to any of the ingredients of the product.

4 First aid measures

- | | | |
|-----|---------------------|---|
| 4.1 | Eye contact | Flush with plenty of water. Consult a physician if irritation persists. |
| 4.2 | Skin contact | Wash thoroughly with water. |
| 4.3 | Ingestion | Give large amounts of water. No hazards anticipated from swallowing small amounts incidentally to normal handling. If you feel unwell, seek medical advice (show this safety data sheet). |
| 4.4 | Inhalation | Remove to fresh air. |
| 4.5 | Further information | None. |

5 Fire-fighting measures

- | | | |
|-----|------------------------------|---|
| 5.1 | Suitable extinguishing media | Water fog, carbon dioxide, foam, dry chemicals. |
| 5.2 | Extinguishing media to avoid | None known |
| 5.3 | Flash point | |
| 5.4 | Ignition temperature | not determined |
| 5.5 | Explosion limits | Lower:
Upper:
not determined |
| 5.6 | Further information | None. |

Test method:

6 Accidental release measures

Clean up mechanically.
Dispose of according to local and national regulations.

7 Handling and storage

- | | | |
|-----|--------------------|--|
| 7.1 | Handling | Only adequately trained personnel should handle this product.
Keep out of reach of children. |
| 7.2 | Industrial hygiene | Usual hygienic measures for dental practice.
When using, do not eat, drink or smoke. |
| 7.3 | Storage | Store at 2-28 °C / 36-82 °F (Base)
Store catalyst paste in the refrigerator (2-8 °C / 36-46 °F) ! |
| 7.4 | Place of storage | Avoid exposure to direct sunlight. |

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7.5	Fire- and explosion-protection	Not required.
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8 Exposure controls / Personal protection

8.1	Technical measures	Good general ventilation should be sufficient.
8.2	Control of threshold limits	None established.
8.3	Personal protective equipment	
8.3.1	Respiratory protection	Not required.
8.3.2	Hand protection	Gloves. Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates.
8.3.3	Eye protection	Safety goggles.
8.3.4	Other	None.

9 Physical and chemical properties

9.1	Appearance	Paste
9.2	Colour	off-white to cream
9.3	Odour	practically odourless
9.4	Change of physical state	Test method: not applicable
9.5	Density	not determined
9.6	Vapour pressure	not applicable
9.7	Viscosity	not determined
9.8	Solubility	
	Solubility in water	< 0.1 %
9.9	pH	not determined

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9.10 Further information None.

10 Stability and reactivity

10.1 Thermal decomposition None, if used in accordance to instructions.
10.2 Hazardous decomposition products None under normal conditions of storage and use.
10.3 Hazardous reactions None.
10.4 Further information Avoid heat.

11 Toxicological information

11.1 Acute toxicity This product possesses no cytotoxic potential.
non-mutagenic
11.2 Subacute / Chronic toxicity Uncured material: prolonged or frequently repeated skin contact
may cause allergic skin reactions.
11.3 Further information No hazards anticipated from swallowing small amounts incidentally
to normal handling.

12 Ecological information

No ecological problems to be anticipated if properly handled and
used.
nearly insoluble

13 Disposal considerations

Take to a waste incineration plant, under conditions approved by the
local authority.

14 Transport information

14.1 Transport at land ADR --- RID ---

UN Number --- Kemler Number ---
Packing Group ---
Proper shipping name ---
14.2 Transport at sea ADN --- IMDG ---

UN Number ---
EMS --- MFAG ---
Packing Group ---
Proper shipping name ---

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14.3	Air transport	ICAO / IATA-DGR	---
		UN Number	---
		Proper shipping name	---
		Subsidiary Risk	---
		Labels	---
		Packing Group	---
	Passenger airplane	Packing Instructions	---
		max.	---
	Cargo Airplane	Packing Instructions	---
		max.	---

14.4 Further information Product is not classified as a dangerous good for transport.

15 Regulatory information

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.
This product does not require classification as Dangerous Goods.

15.1 National regulations

15.2 NFPA Storage

15.3 Further information None.

16 Other information

Version: 3
Changes: 1.5

The above mentioned data correspond to our present state of knowledge and experience. The safety data sheet serves as description of the products in regard to necessary safety measures. The indications do not have the meaning of guarantees on properties.

This safety data sheet has been generated with the safety database 'ChemManager',
© ASSiST Applied Software Solutions in Science and Technology AG, Weiherweg 3, CH-4104 Oberwil, Switzerland

91/155/EEC

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

- **Product identifier**
- **Trade name:** **Multilink Automix (Base)**
- **Relevant identified uses of the substance or mixture and uses advised against**
- **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.
2785 Skymark Avenue, Unit 1, Mississauga, Ontario L4W4Y3
CANADA
Tel. +1 800 263 8182
Fax +1 905 238 5711

- **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 Composition/information on ingredients

- **Chemical characterization:** Mixtures
- **Description:** Mixture of the substances listed below with nonhazardous additions.

· **Dangerous components:**

868-77-9	2-hydroxyethyl methacrylate	⚠ H315; H319; H317	2.5-10%
1565-94-2	Bis-GMA	⚠ H315; H319	2.5-10%
72869-86-4	urethane dimethacrylate	⚠ H319; H317; H402; H412	2.5-10%

3 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/EC usually if they are in the finished state and intended for the final user.

(Contd. on page 2)

USA

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

(Contd. of page 1)

· **Code letter and hazard designation of product:**

Irritant

· **Hazard-determining components of labelling:**

2-hydroxyethyl methacrylate
urethane dimethacrylate

· **Risk phrases:**

May cause sensitisation by skin contact.

· **Safety phrases:**

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 Health = 0

FIRE 0 Fire = 0

REACTIVITY 0 Reactivity = 0

· **Other hazards**· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

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:** 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.

(Contd. on page 3)

USA

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

(Contd. of page 2)

- **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.
- **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.
Avoid contact with the eyes and skin.
Keep away from foodstuffs, beverages and feed.
- **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.

(Contd. on page 4)

USA

Trade name: Multilink Automix (Base)

(Contd. of page 3)

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

- **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

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.

- **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:**

Not determined.

- **Relative density**

Not determined.

- **Vapour density**

Not determined.

- **Evaporation rate**

Not determined.

- **Solubility in / Miscibility with**

Water:

Nearly insoluble.

- **Segregation 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.

(Contd. on page 5)

USA

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

(Contd. of page 4)

- **Chemical stability**
Stable under normal handling and storage conditions.
Photoreactive (Danger of polymerization).
- **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

12 Ecological information

- **Toxicity**
- **Acquatic 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.

USA

(Contd. on page 6)

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

(Contd. of page 5)

14 Transport information

- DOT regulations:
- Hazard class: -
- Land transport ADR/RID (cross-border):
- ADR/RID class: -
- Maritime transport IMDG:
- IMDG Class: -
- Marine pollutant: No
- Air transport ICAO-TI and IATA-DGR:
- ICAO/IATA Class: -
- 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):

None of the ingredients is listed.

· 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.

· NTP (National Toxicology Program)

None of the ingredients is listed.

· TLV (Threshold Limit Value established by ACGIH)

13760-80-0 ytterbium trifluoride

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.

(Contd. on page 7)

USA

Trade name: Multilink Automix (Base)

(Contd. of page 6)

· 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/EC usually if they are in the finished state and intended for the final user.

· Hazard symbols:

Irritant

· Hazard-determining components of labelling:

2-hydroxyethyl methacrylate
urethane dimethacrylate

· Risk phrases:

May cause sensitisation by skin contact.

· Safety phrases:

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.

· 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.

USA