

SAFETY DATA SHEETS

This SDS packet was issued with item:

077122492

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).

077106677 077106685 077122468 077122484 077122609 077122617 077122625 077122633 077122641

Safety Data Sheet in accordance with HSNO

Printing date 12.12.2019

Version number 6

Revision: 12.12.2019

1 Identification of the substance or mixture and of the supplier

- **Product identifier**
- **Trade name:** ***Multilink Primer A***
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** Self-curing and self-etching primer
- **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
- **Importer:**
Ivoclar Vivadent Ltd
12 Omega St, Rosedale, Auckland
New Zealand
Tel: + 64 9 914 9999 / Fax: + 64 9 914 9990
- **Further information obtainable from:**
Regulatory Affairs
sds@ivoclarvivadent.com
- **Emergency telephone number:** 0800 764 766 (National Poison Centre - 24 hours / 7 days)

2 Hazards identification

- **Classification of the substance or mixture**
Eye Dam. 1 H318 Causes serious eye damage.
- **Label elements**
- **GHS label elements**
The product is classified and labelled according to the Globally Harmonised System (GHS).
- **Hazard pictograms**



GHS05

- **Signal word** *Danger*
- **Hazard-determining components of labelling:**
2,2'-[(4-methylphenyl)imino]bisethanol
- **Hazard statements**
Causes serious eye damage.
- **Precautionary statements**
Wear eye protection / face protection.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- **Additional information:**
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 Regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

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Trade name: **Multilink Primer A**

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- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/Information on ingredients

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

- **Dangerous components:**

CAS: 3077-12-1	2,2'-[(4-methylphenyl)imino]bisethanol	2.5-10%
EINECS: 221-359-1	Eye Dam. 1, H318; Acute Tox. 4, H302	

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

4 First aid measures

- **Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:**
Rinse with water.
Generally the product does not irritate the skin.
- **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 Fire fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.
- **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:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **Reference to other sections**
No dangerous substances are released.
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.

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See Section 13 for disposal information.

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7 Handling and storage

- **Handling:**
- **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.
- **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:**
Store in a cool place.
Keep container tightly sealed.
Protect from heat and direct sunlight.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **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.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Usual hygienic measures for dental practice and dental laboratories.
- **Respiratory protection:** Not required.
- **Protection of hands:**
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
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

NZ

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9 Physical and chemical properties

- **Information on basic physical and chemical properties**

- **General Information**

- **Appearance:**

Form:	Fluid
Colour:	Colourless
Odour:	Characteristic
Odour threshold:	Not determined.

- **pH-value:** Not determined.

- **Change in condition**

Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	Undetermined.

- **Flash point:** Not applicable.

- **Auto-ignition temperature:** Product is not selfigniting.

- **Explosive properties:** Product does not present an explosion hazard.

- **Explosion limits:**

Lower:	Not determined.
Upper:	Not determined.

- **Vapour pressure:** Not determined.

Density:	Not determined.
Relative density	Not determined.
Vapour density	Not determined.
Evaporation rate	Not determined.

- **Solubility in / Miscibility with water:**

Soluble.

- **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** No further relevant information available.
- **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**
- **Skin corrosion/irritation** No irritant effect.
- **Serious eye damage/irritation** No irritating effect.

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- **Respiratory or skin sensitisation** No sensitising effects known.
- **Additional toxicological information:** No further relevant information available.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour 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 (German Regulation) (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 packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
|--|--|
| <ul style="list-style-type: none"> · UN-Number · ADR/RID/ADN, ADN, IMDG, IATA | Void |
| <ul style="list-style-type: none"> · UN proper shipping name · ADR/RID/ADN, ADN, IMDG, IATA | Void |
| <ul style="list-style-type: none"> · Transport hazard class(es) · ADR/RID/ADN, ADN, IMDG, IATA · Class | Void |
| <ul style="list-style-type: none"> · Packing group · ADR/RID/ADN, IMDG, IATA | Void |
| <ul style="list-style-type: none"> · Environmental hazards: · Marine pollutant: | No |
| <ul style="list-style-type: none"> · Special precautions for user | Not applicable. |
| <ul style="list-style-type: none"> · Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| <ul style="list-style-type: none"> · Transport/Additional information: | Product is not classified as a dangerous good for transport (ADR, IMDG, IATA). |

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· UN "Model Regulation":

Void

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**· **New Zealand Inventory of Chemicals**

All ingredients are listed.

· **HSNO Approval numbers**

None of the ingredients is listed.

· **GHS label elements**

The product is classified and labelled according to the Globally Harmonised System (GHS).

· **Hazard pictograms**

GHS05

· **Signal word** Danger· **Hazard-determining components of labelling:**

2,2'-[(4-methylphenyl)imino]bisethanol

· **Hazard statements**

Causes serious eye damage.

· **Precautionary statements**

Wear eye protection / face protection.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

· **Directive 2012/18/EU**· **Named dangerous substances - ANNEX I** None of the ingredients is listed.· **National regulations:**· **Other regulations, limitations and prohibitive regulations**

The product is a medical device according to the Directive 93/42/EEC.

· **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.

· **Relevant phrases**

H302 Harmful if swallowed.

H318 Causes serious eye damage.

· **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

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

Eye Dam. 1: Serious eye damage/eye irritation – Category 1



1 Identification

- **Product identifier**
- **Trade name:** ***Multilink Primer B***
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** Self-curing and self-etching primer
- **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 Corr. 1B H314 Causes severe skin burns and eye damage.
Eye Dam. 1 H318 Causes serious eye damage.
Skin Sens. 1 H317 May cause an allergic skin reaction.
- **Label elements**
- **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**
 
GHS05 GHS07
- **Signal word** Danger
- **Hazard-determining components of labeling:**
phosphonic acid acrylate
2-hydroxyethyl methacrylate

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- **Hazard statements**

Causes severe skin burns and eye damage.

May cause an allergic skin reaction.

- **Precautionary statements**

Wear protective gloves/protective clothing/eye protection/face protection.

Do not breathe dust/fume/gas/mist/vapors/spray.

If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.

Continue rinsing.

If swallowed: Rinse mouth. Do NOT induce vomiting.

If skin irritation or rash occurs: 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)**



Health = 3

Fire = 0

Reactivity = 0

- **HMIS-ratings (scale 0 - 4)**



Health = 3

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.

- **Dangerous components:**

223681-84-3	phosphonic acid acrylate	25-50%
868-77-9	2-hydroxyethyl methacrylate	25-50%

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.

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- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

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:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Ensure adequate ventilation.
- **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**
Ensure good ventilation/exhaustion at the workplace.
Only adequately trained personnel should handle this product.
- **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:**
Store in a cool place.
Keep receptacle tightly sealed.
Protect from heat and direct sunlight.
- **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.

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- **Exposure controls**

- **Personal protective equipment:**

- **General protective and hygienic measures:**

Usual hygienic measures for dental practice.

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

Do not inhale gases / fumes / aerosols.

Avoid contact with the eyes and skin.

- **Breathing equipment:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

- **Protection of hands:**



Protective gloves

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

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: Fluid

Color: Colorless

· **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.

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Upper:	Not determined.
· Vapor pressure:	Not determined.
· Density at 20 °C (68 °F):	1.04 g/cm ³ (8.679 lbs/gal)
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with Water:	Partly miscible.
· 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** No further relevant information available.
- **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:** Irritant to skin and mucous membranes.
- **on the eye:** 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.

· **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.

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Trade name: Multilink Primer B

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· **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 packaging:**

· **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.

· **Transport/Additional information:**

Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).

· **UN "Model Regulation":**

-

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.

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· 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.

· TLV (Threshold Limit Value established by ACGIH)

None of the ingredients is listed.

· 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


GHS05 GHS07

· Signal word Danger
· Hazard-determining components of labeling:

phosphonic acid acrylate

2-hydroxyethyl methacrylate

· Hazard statements

Causes severe skin burns and eye damage.

May cause an allergic skin reaction.

· Precautionary statements

Wear protective gloves/protective clothing/eye protection/face protection.

Do not breathe dust/fume/gas/mist/vapors/spray.

If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.

Continue rinsing.

If swallowed: Rinse mouth. Do NOT induce vomiting.

If skin irritation or rash occurs: 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.

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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 preparation / last revision** 05/07/2015 / 6

· **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)

Skin Corr. 1B: Skin corrosion/irritation, Hazard Category 1B

Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

· *** Data compared to the previous version altered.**

US


1 Identification

- **Product identifier**
- **Trade name:** ***Multilink Automix Try-In***
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** Water-soluble glycerine try-in paste
- **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 Sens. 1 H317 May cause an allergic skin reaction.
- **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
- **Hazard statements**
May cause an allergic skin reaction.
- **Precautionary statements**
Avoid breathing dust/fume/gas/mist/vapors/spray
Wear protective gloves.

(Contd. on page 2)

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Material Safety Data Sheet

acc. to ISO 11014

Printing date 05/07/2015

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Trade name: **Multilink Automix Try-In**

(Contd. of page 1)

Contaminated work clothing must not be allowed out of the workplace.

Specific treatment (see on this label).

Wash contaminated clothing before reuse.

If skin irritation or rash occurs: Get medical advice/attention.

If on skin: Wash with plenty of water.

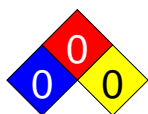
Dispose of contents/container in accordance with local/regional/national/international regulations.

· **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 = 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.

· **Dangerous components:**

56-81-5	glycerol	60-100%
72869-86-4	urethane dimethacrylate	0.1-<0.3%

4 First-aid measures

· **Description of first aid measures**

· **General information:** No special measures required.

· **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.

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Material Safety Data Sheet

acc. to ISO 11014

Printing date 05/07/2015

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Reviewed on 03/20/2015

Trade name: **Multilink Automix Try-In**

(Contd. of page 2)

- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

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.
Ensure adequate ventilation.
- **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:** Store away from oxidizing agents.
- **Further information about storage conditions:**
This product is hygroscopic.
Keep receptacle tightly sealed.
Protect from heat and direct sunlight.
- **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:**

56-81-5 glycerol

EL Long-term value: 10* 3** mg/m³
*mist; **mist, respirable

EV Long-term value: 10 mg/m³

(Contd. on page 4)

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Material Safety Data Sheet

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Trade name: **Multilink Automix Try-In**

(Contd. of page 3)

· **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.

Keep away from foodstuffs, beverages and feed.

Avoid contact with the skin.

· **Breathing equipment:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

· **Recommended filter device for short term use:**

Combination filter A-P2

Combination filter A-P3

· **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:**



Tightly sealed goggles

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.

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Material Safety Data Sheet

acc. to ISO 11014

Printing date 05/07/2015

Version number 2

Reviewed on 03/20/2015

Trade name: **Multilink Automix Try-In**

(Contd. of page 4)

· 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:	1.28 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with Water:	Partly soluble.
· 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** Reacts with strong oxidizing agents.
- **Conditions to avoid** 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:** No sensitizing effects known.
- **Additional toxicological information:** No further relevant information available.

· Carcinogenic categories

· **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.

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Material Safety Data Sheet

acc. to ISO 11014

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Trade name: **Multilink Automix Try-In**

(Contd. of page 5)

- **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": | - |

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Reviewed on 03/20/2015

Trade name: **Multilink Automix Try-In**

(Contd. of page 6)

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):**

1344-28-1 aluminium oxide

· **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)**

1344-28-1 aluminium oxide

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

· **Hazard statements**

May cause an allergic skin reaction.

· **Precautionary statements**

Avoid breathing dust/fume/gas/mist/vapors/spray

Wear protective gloves.

Contaminated work clothing must not be allowed out of the workplace.

Specific treatment (see on this label).

Wash contaminated clothing before reuse.

If skin irritation or rash occurs: Get medical advice/attention.

If on skin: Wash with plenty of water.

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Printing date 05/07/2015

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Trade name: **Multilink Automix Try-In**

(Contd. of page 7)

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 preparation / last revision** 05/07/2015 / 1
- **Abbreviations and acronyms:**
 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)
 Skin Sens. 1: Sensitisation - Skin, Hazard Category 1
- *** Data compared to the previous version altered.**

CA

Safety Data Sheet according to HPR, Schedule 1

Printing date 07/22/2019

Version number 7

Reviewed on 06/03/2019

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

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Safety Data Sheet

according to HPR, Schedule 1

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Reviewed on 06/03/2019

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

(Contd. of page 1)

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	≥0.1-<1% w/w *

* Actual concentration ranges are withheld as a trade secret.

CA
(Contd. on page 3)

Safety Data Sheet according to HPR, Schedule 1

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Reviewed on 06/03/2019

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

(Contd. of page 2)

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.

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Safety Data Sheet according to HPR, Schedule 1

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Reviewed on 06/03/2019

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

(Contd. of page 3)

· **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 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.

(Contd. on page 5)

CA

Safety Data Sheet

according to HPR, Schedule 1

Printing date 07/22/2019

Version number 7

Reviewed on 06/03/2019

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

(Contd. of page 4)

· 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/cm ³
· 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.

CA

(Contd. on page 6)

Safety Data Sheet

according to HPR, Schedule 1

Printing date 07/22/2019

Version number 7

Reviewed on 06/03/2019

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

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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

- | | |
|---|--|
| <ul style="list-style-type: none"> · UN-Number · DOT/TDG, ADR, ADN, IMDG, IATA | Void |
| <ul style="list-style-type: none"> · UN proper shipping name · DOT/TDG, ADR, ADN, IMDG, IATA | Void |
| <ul style="list-style-type: none"> · Transport hazard class(es) · DOT, ADR, ADN, IMDG, IATA · Class | Void |
| <ul style="list-style-type: none"> · Packing group · DOT/TDG, ADR, IMDG, IATA | Void |
| <ul style="list-style-type: none"> · Environmental hazards: · Marine pollutant: | No |
| <ul style="list-style-type: none"> · Special precautions for user | Not applicable. |
| <ul style="list-style-type: none"> · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |
| <ul style="list-style-type: none"> · Transport/Additional information: | Product is not classified as a dangerous good for transport (ADR, IMDG, IATA). |
| <ul style="list-style-type: none"> · UN "Model Regulation": | Void |

CA

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Safety Data Sheet

according to HPR, Schedule 1

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Reviewed on 06/03/2019

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

(Contd. of page 6)

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):**

CAS: 13760-80-0 ytterbium trifluoride

CAS: 1565-94-2 Bis-GMA

CAS: 868-77-9 2-hydroxyethyl methacrylate

CAS: 2867-47-2 2-dimethylaminoethyl methacrylate

· **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

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.

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Safety Data Sheet
according to HPR, Schedule 1

Printing date 07/22/2019

Version number 7

Reviewed on 06/03/2019

Trade name: Multilink Automix (Base)

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- **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** 07/22/2019 / 6
- **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.**

CA

Safety Data Sheet according to HPR, Schedule 1

Printing date 07/22/2019

Version number 6

Reviewed on 06/03/2019

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 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:**
urethane dimethacrylate
ytterbium trifluoride

(Contd. on page 2)

Safety Data Sheet

according to HPR, Schedule 1

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Version number 6

Reviewed on 06/03/2019

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

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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 and 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)**



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-<25% w/w *
CAS: 41637-38-1	Bis-EMA	10-<25% w/w *
CAS: 72869-86-4	urethane dimethacrylate	5-<10% w/w *
CAS: 868-77-9	2-hydroxyethyl methacrylate	3-7% w/w *
CAS: 94-36-0	dibenzoyl peroxide	1-<3% 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.

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

(Contd. of page 2)

- **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.

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Safety Data Sheet

according to HPR, Schedule 1

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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 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.
- **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.
- **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.

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Safety Data Sheet

according to HPR, Schedule 1

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Reviewed on 06/03/2019

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

(Contd. of page 4)

- | | |
|---|--|
| · 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:**
- 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	3

· 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.

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

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- **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 | Void |
| · DOT/TDG, ADR, ADN, IMDG, IATA | Void |
| · UN proper shipping name | |
| · DOT/TDG, ADR, ADN, IMDG, IATA | Void |
| · Transport hazard class(es) | |
| · DOT, ADR, ADN, IMDG, IATA | |
| · Class | Void |
| · Packing group | |
| · DOT/TDG, 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. |
| · 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):**

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

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Trade name: Multilink Automix (Catalyst)

(Contd. of page 6)

CAS: 94-36-0	dibenzoyl peroxide
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· **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

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

· **Precautionary statements**

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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**

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16 Other information

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· **Date of the latest revision of the safety data sheet** 07/22/2019 / 5

· **Abbreviations and acronyms:**

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CA