

SAFETY DATA SHEETS

This SDS packet was issued with item:


077106677

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).

077081102 077106503 077106511 077106529 077106537 077106685 077122468 077122484 077122492 077122617

077175425

3610-ba2

 <p>175 Pineview Drive, AMHERST NY 14228 2785 Skymark Ave. Unit 1, Mississauga, Ontario L4W 4Y3</p>	<h1>M S D S</h1> <p>Material Safety Data Sheet</p> <p>For emergency only call INFOTRAC: 1-800-535-5053 In Canada, call CANUTEC: 613-996-6666</p>	<p>Multilink Metal Primer</p> <p>Page 1</p>
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FOR PROFESSIONAL DENTAL USE ONLY

Section 1: Product Identification & Use **Primer**

Product **Multilink Metal Primer**

Product # 576827

Section 2.1: Hazardous Ingredients

Component	% Range	CAS#	PEL*	TLV*	LD50/LC50/TDL _o
Tert. butyl alcohol	< 70	75-65-0	n.av.	n.av.	LD50 for rat is 3500 mg/kg
Methyl isobutyl ketone	< 25	108-10-1	n.av.	n.av.	LD50 for rat is 2080 mg/kg
Phosphonic acid acrylate	< 6	223681-84-3	n.av.	n.av.	
Benzoylperoxide	< 2	94-36-0		n.av.	LD50 for rat is > 7710 mg/kg
Ethoxylated Bis-EMA	0-5	41637-38-1		200 ppm	

Section 2.2: Other Ingredients *All Exposure limits are in milligram per cubic meter of air (mg/m3)

Component	% Range	CAS#	PEL*	TLV*	LD50/LC50/TDL _o
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Section 3: Physical Data

Boiling Point °C:	n. ap.	Melting Point °C:	n. ap.	pH:	n. det.
Vapor Pressure mm Hg:	n. ap.	Vapor Density air 1:	n. det.		
Odor Threshold:	characteristic	Specific Gravity H ₂ O—1g/cm ³ :	n. ap.		
Appearance / Odor:	Clear liquid				

Section 4: Fire or Explosion Data

Flash Point °C:	11	Autoignition °C:	> 400	Solubility in water:	partially miscible
Flammable Limits % In Air / Upper:	9 val.%	Lower:	1.2 val %		
Extinguisher Media:	Not required.				
Other Fire and Explosion Hazards:	Highly flammable				
Hazardous Combustion Products:	Avoid ignition sources such as flames or spark producing equipment.				

ivoclar
vivadent

175 Pineview Drive, AMHERST NY 14228
2785 Skymark Ave. Unit 1, Mississauga, Ontario L4W 4Y3

M S D S

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Multilink Metal Primer

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Section 5: Reactivity Data

Chemical Stability: No **If No...Under What Conditions:** n. ap.
Incompatibility with other Substances: Not required.
If So...Which Ones: n. ap.
Reactivity and Under What Conditions: Polymerization with heat buildup may occur.
Hazardous Polymerization: Avoid ignition sources such as flames or spark producing equipment.

Section 6: Toxicological Properties

Primary Routes of Entry: Ingestion, inhalation, eyes, skin
Symptoms of Acute Exposure: Do not breathe vapor. Signs and symptoms of excessive exposure may be narcotic effects.
Symptoms of Chronic Exposure: Prolonged or repeated skin contact may cause allergic skin reactions in some individuals.

Medical Conditions Generally Aggravated by Exposure: Excessive exposure may cause eye and respiratory irritation.

Carcinogen/Potential Carcinogen: No **NTP:** No **IARC:** No **OSHA Reg.:** No
Teratogenicity: No **Reproductive Toxicity:** No
Embryo Toxin: No **Sensitization:** Yes

Section 7: Preventative Measures

Eyes: Safety goggles **Gloves:** Solvent resistant gloves
Ventilation: Provide adequate local ventilation.
Respiratory Protection: In poorly ventilated areas, use air-purifying respiratory protection apparatus (type A).
Leak and Spill Procedure: Clean up with absorbent material. Do not allow to flow off into the drains or waters.
Waste Disposal Methods: Dispose of according to all local, state, provincial and federal regulations
Storage: Store at 2-8°C / 36-46°F.
Shipment: UN # 1120 Class 3
Other Preventative Measures: Avoid direct contact with eyes and skin.

Section 8: First Aid Measure


Inhalation: Remove victim to fresh air. If respiratory irritation is experienced, call a physician.
Ingestion: After ingestion call a physician immediately and show this safety data sheet. Do not induce vomiting. Give large amount s of water.
Eyes: Flush with plenty of water (10-15 Min.). Call a physician.
Skin: Wash thoroughly with soap and water.

Section 9: Preparation Data

Prepared by: Anderjeet Gulati (716) 691-0010 **Date:** March 15, 2004 **Ref:**

Disclaimer: The information and recommendations are taken from sources believed to be accurate, however, Ivoclar Vivadent, Inc. makes no warranty with respect to the accuracy of the information or the suitability of the recommendation and assumes no liability to any user thereof.

3610-ba2

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Boiling Point °C:	n. ap.	Melting Point °C:	n. ap.	pH:	n. det.
Vapor Pressure mm Hg:	n. ap.	Vapor Density air 1:	n. det.		
Odor Threshold:	characteristic	Specific Gravity H ₂ O—1g/cm ³ :	n. ap.		
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Flammable Limits % In Air / Upper:	9 val.%	Lower:	1.2 val %		
Extinguisher Media:	Not required.				
Other Fire and Explosion Hazards:	Highly flammable				
Hazardous Combustion Products:	Avoid ignition sources such as flames or spark producing equipment.				

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Section 5: Reactivity Data

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Incompatibility with other Substances: Not required.
If So...Which Ones: n. ap.
Reactivity and Under What Conditions: Polymerization with heat buildup may occur.
Hazardous Polymerization: Avoid ignition sources such as flames or spark producing equipment.

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Symptoms of Acute Exposure: Do not breathe vapor. Signs and symptoms of excessive exposure may be narcotic effects.
Symptoms of Chronic Exposure: Prolonged or repeated skin contact may cause allergic skin reactions in some individuals.

Medical Conditions Generally Aggravated by Exposure: Excessive exposure may cause eye and respiratory irritation.

Carcinogen/Potential Carcinogen: No **NTP:** No **IARC:** No **OSHA Reg.:** No
Teratogenicity: No **Reproductive Toxicity:** No
Embryo Toxin: No **Sensitization:** Yes

Section 7: Preventative Measures

Eyes: Safety goggles **Gloves:** Solvent resistant gloves
Ventilation: Provide adequate local ventilation.
Respiratory Protection: In poorly ventilated areas, use air-purifying respiratory protection apparatus (type A).
Leak and Spill Procedure: Clean up with absorbent material. Do not allow to flow off into the drains or waters.
Waste Disposal Methods: Dispose of according to all local, state, provincial and federal regulations
Storage: Store at 2-8°C / 36-46°F.
Shipment: UN # 1120 Class 3
Other Preventative Measures: Avoid direct contact with eyes and skin.

Section 8: First Aid Measure

Inhalation: Remove victim to fresh air. If respiratory irritation is experienced, call a physician.
Ingestion: After ingestion call a physician immediately and show this safety data sheet. Do not induce vomiting. Give large amount s of water.
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Material Safety Data Sheet

Multilink Automix



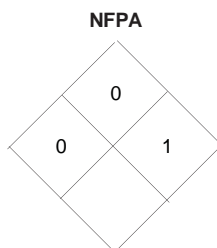
Date of issue / Reference 01.10.2007 lise / Version 2
Replaces version of 22.03.2005 hot
Date of printing 01.10.2007 **Sheet No. 1582**

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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 Automix**



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
- 22-26 % 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.

Material Safety Data Sheet

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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 Test method:
 - 5.4 Ignition temperature not determined
 - 5.5 Explosion limits Lower:
Upper:
not determined
 - 5.6 Further information None.
-

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 2-8 °C
- 7.4 Place of storage Avoid exposure to direct sunlight.
- 7.5 Fire- and explosion-protection Not required.

Material Safety Data Sheet

Multilink Automix



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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
- 9.10 Further information None.

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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
- | | | | |
|----------------------|-----|------|-----|
| ADNR | --- | 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 regulations and has been reviewed by the US Food and drug Administration.
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: 2
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

Safety Data Sheet
acc. to OSHA HCS

Printing date 05/07/2015

Version number 6

Reviewed on 03/11/2015

1 Identification


- **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 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**
Eye Dam. 1 H318 Causes serious eye damage.

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

GHS05
- **Signal word** Danger
 - **Hazard-determining components of labeling:**
2,2'-[(4-methylphenyl)imino]bisethanol
 - **Hazard statements**
Causes serious eye damage.
 - **Precautionary statements**
Wear eye protection / face protection.

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Trade name: **Multilink Primer A**

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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 are exempt from the labeling provisions of GHS according to the Hazard Communication Standard (HCS).

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



· **HMS-ratings (scale 0 - 4)**

HEALTH	1	Health = 1
FIRE	0	Fire = 0
REACTIVITY	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:**

3077-12-1	2,2'-[(4-methylphenyl)imino]bisethanol	5-<10%
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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:**

CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

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- **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.
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:**
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.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:** Usual hygienic measures for dental practice.
- **Breathing equipment:** 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

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Trade name: **Multilink Primer A**

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· **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.
· 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:** 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.

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Trade name: **Multilink Primer A**

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- **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:** 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.
- **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.

US

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Trade name: **Multilink Primer A**

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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.

· **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.

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Safety Data Sheet acc. to OSHA HCS

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· **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

· **Signal word Danger**

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

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.

· **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 / 5**

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

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

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