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

· 1.1 Product identifier

• Trade name: Multilink Primer A

• 1.2 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
- 1.3 Details of the supplier of the safety data sheet
   Manufacturer/Supplier: Ivoclar Vivadent AG
   Bendererstrasse 2
   FL-9494 Schaan
   PRINCIPALITY OF LIECHTENSTEIN

*Tel:* +423 235 35 35 *Fax:* +423 235 33 60

 Further information obtainable from: Regulatory Affairs sds@ivoclarvivadent.com
 1.4 Emergency telephone number: +423 / 235 33 13 (Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein)

## **SECTION 2: Hazards identification**

- · 2.1 Classification of the substance or mixture
- $\cdot$  Classification according to Regulation (EC) No 1272/2008

Eye Dam. 1 H318 Causes serious eye damage.

· 2.2 Label elements

• Labelling according to Regulation (EC) No 1272/2008 The product is classified and labelled according to the CLP regulation.

· Hazard pictograms



· Signal word Danger

· Hazard-determining components of labelling:

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

· Hazard statements

H318 Causes serious eye damage.

· Precautionary statements

P280Wear protective gloves/protective clothing/eye protection/face protection.P305+P351+P338 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.

· 2.3 Other hazards

- · Results of PBT and vPvB assessment
- · PBT: Not applicable.

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3-<10%

· vPvB: Not applicable.

## **SECTION 3: Composition/information on ingredients**

#### · 3.2 Chemical characterisation: Mixtures

• Description: Mixture of substances listed below with nonhazardous additions.

#### · Dangerous components:

- CAS: 3077-12-1 2,2'-[(4-methylphenyl)imino]bisethanol
- EINECS: 221-359-1 Eye Dam. 1, H318; Acute Tox. 4, H302
- · Additional information: For the wording of the listed risk phrases refer to section 16.

#### **SECTION 4: First aid measures**

· 4.1 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.
- 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- $\cdot$  4.3 Indication of any immediate medical attention and special treatment needed
- No further relevant information available.

## **SECTION 5: Firefighting measures**

- · 5.1 Extinguishing media
- · Suitable extinguishing agents:
- CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- 5.2 Special hazards arising from the substance or mixture No further relevant information available.
- · 5.3 Advice for firefighters
- · Protective equipment: No special measures required.

## **SECTION 6: Accidental release measures**

- 6.1 Personal precautions, protective equipment and emergency procedures Not required.
- 6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- $\cdot$  6.3 Methods and material for containment and cleaning up:
- Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- · 6.4 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.

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#### **SECTION 7: Handling and storage**

• 7.1 Precautions for safe handling Only adequately trained personnel should handle this product. For use in dentistry only.

- Information about fire and explosion protection: No special measures required.
- 7.2 Conditions for safe storage, including any incompatibilities
- · Storage:
- Requirements to be met by storerooms and receptacles: Store only in the original receptacle.
- Information about storage in one common storage facility: Not required.
- · Further information about storage conditions:
- Store in a cool place.
- Keep container tightly sealed.
- Protect from heat and direct sunlight.
- 7.3 Specific end use(s) No further relevant information available.

#### **SECTION 8: Exposure controls/personal protection**

- Additional information about design of technical facilities: No further data; see item 7.
- · 8.1 Control parameters
- · Ingredients with limit values that require monitoring at the workplace:
- The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- · Personal protective equipment:
- General protective and hygienic measures: Usual hygienic measures for dental practice.
- · 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

### **SECTION 9: Physical and chemical properties**

- · 9.1 Information on basic physical and chemical properties
- · General Information
- · Appearance:
  - Form: Colour:

Fluid Colourless

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		(Contd. of page
Odour:	Characteristic	
Odour threshold:	Not determined.	
pH-value:	Not determined.	
Change in condition		
Melting point/Melting range:	Undetermined.	
<b>Boiling point/Boiling range:</b>	Undetermined.	
Flash point:	Not applicable.	
Self-igniting:	Product is not selfigniting.	
Danger of explosion:	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/wo	ater): Not determined.	
Viscosity:		
Dynamic:	Not determined.	
Kinematic:	Not determined.	
9.2 Other information	No further relevant information available.	

## **SECTION 10: Stability and reactivity**

· 10.1 Reactivity No further relevant information available.

- 10.2 Chemical stability Stable under normal handling and storage conditions.
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- 10.3 Possibility of hazardous reactions No dangerous reactions known.
- 10.4 Conditions to avoid No further relevant information available.
- 10.5 Incompatible materials: No further relevant information available.
- · 10.6 Hazardous decomposition products: None under normal conditions of storage and use.

## **SECTION 11: Toxicological information**

· 11.1 Information on toxicological effects

· Acute toxicity:

• Primary irritant effect:

• on the skin: No irritant effect.

 $\cdot$  on the eye: No irritating effect.

• Sensitisation: No sensitising effects known.

• Additional toxicological information: No further relevant information available.

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#### **SECTION 12: Ecological information**

· 12.1 Toxicity

- · Aquatic toxicity: No further relevant information available.
- · 12.2 Persistence and degradability No further relevant information available.
- 12.3 Bioaccumulative potential No further relevant information available.
- 12.4 Mobility in soil No further relevant information available.
- · 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.

- · 12.5 Results of PBT and vPvB assessment
- **PBT:** Not applicable.
- · vPvB: Not applicable.
- · 12.6 Other adverse effects No further relevant information available.

#### **SECTION 13: Disposal considerations**

- · 13.1 Waste treatment methods
- · Recommendation

\*

- Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
- · Uncleaned packaging:
- · Recommendation: Disposal must be made according to official regulations.

· 14.1 UN-Number · ADR, ADN, IMDG, IATA	Void
· 14.2 UN proper shipping name · ADR, ADN, IMDG, IATA	Void
· 14.3 Transport hazard class(es)	
ADR, ADN, IMDG, IATA	
· Class	Void
14.4 Packing group	
· ADR, IMDG, IATA	Void
14.5 Environmental hazards:	
• Marine pollutant:	No
14.6 Special precautions for user	Not applicable.
· 14.7 Transport in bulk according to Anne	x II of
MARPOL73/78 and the IBC Code	Not applicable.
Transport/Additional information:	Product is not classified as a dangerous good for transpor (ADR, IMDG, IATA).
· UN ''Model Regulation'':	-

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## SECTION 15: Regulatory information

· 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

· National regulations:

· Other regulations, limitations and prohibitive regulations

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

• 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

## **SECTION 16: Other information**

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

#### · Relevant phrases

\*

H302 Harmful if swallowed. 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
 GHS: Globally Harmonised System of Classification and Labelling of Chemicals
 EINECS: European Inventory of Existing Commercial Chemical Substances
 ELINCS: European List of Notified Chemical Substances
 CAS: Chemical Abstracts Service (division of the American Chemical Society)
 Acute Tox. 4: Acute toxicity, Hazard Category 4
 Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1
 \* Data compared to the previous version altered.

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

· 1.1 Product identifier

· Trade name: Multilink Primer B

• 1.2 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
- 1.3 Details of the supplier of the safety data sheet
   Manufacturer/Supplier: Ivoclar Vivadent AG
   Bendererstrasse 2
   FL-9494 Schaan
   PRINCIPALITY OF LIECHTENSTEIN

*Tel:* +423 235 35 35 *Fax:* +423 235 33 60

 Further information obtainable from: Regulatory Affairs sds@ivoclarvivadent.com
 1.4 Emergency telephone number: +423 / 235 33 13 (Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein)

## **SECTION 2: Hazards identification**

· 2.1 Classification of the substance or mixture

 $\cdot$  Classification according to Regulation (EC) No 1272/2008

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.

· 2.2 Label elements

· Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

· Hazard pictograms



· Signal word Danger

Hazard-determining components of labelling:

phosphonic acid acrylate 2-hydroxyethyl methacrylate

• Hazard statements

H314 Causas savara skin l

P280

H314 Causes severe skin burns and eye damage. H317 May cause an allergic skin reaction.

· Precautionary statements

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

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P301+P330+P331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting.

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P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

· 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.

· 2.3 Other hazards

×

· Results of PBT and vPvB assessment

· **PBT:** Not applicable.

· vPvB: Not applicable.

#### **SECTION 3: Composition/information on ingredients**

· 3.2 Chemical characterisation: Mixtures

· Description: Mixture of substances listed below with nonhazardous additions.

· Dangerous	components:
-------------	-------------

8		
CAS: 223681-84-3	3 phosphonic acid acrylate 2	
	Skin Corr. 1B, H314; Skin Sens. 1, H317	
	2-hydroxyethyl methacrylate	25-50%
EINECS: 212-782-2	Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	1
Additional information: For the wording of the listed risk phrases refer to section 16		

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

#### **SECTION 4: First aid measures**

#### · 4.1 Description of first aid measures

· After inhalation:

Supply fresh air and to be sure call for a doctor.

In case of unconsciousness place patient stably in side position for transportation.

- · After skin contact: Rinse with water.
- · After eye contact:
- Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- · After swallowing:
- Rinse out mouth and then drink plenty of water.
- If symptoms persist consult doctor.
- 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- 4.3 Indication of any immediate medical attention and special treatment needed
- No further relevant information available.

### **SECTION 5: Firefighting measures**

- · 5.1 Extinguishing media
- · Suitable extinguishing agents:
- CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- 5.2 Special hazards arising from the substance or mixture No further relevant information available.
- · 5.3 Advice for firefighters
- · Protective equipment: No special measures required.

#### **SECTION 6:** Accidental release measures

• 6.1 Personal precautions, protective equipment and emergency procedures Not required.

· 6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.

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## Trade name: Multilink Primer B

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• 6.3 Methods and material for containment and cleaning up: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Ensure adequate ventilation.

6.4 Reference to other sections
 See Section 7 for information on safe handling.
 See Section 8 for information on personal protection equipment.
 See Section 13 for disposal information.

## **SECTION 7: Handling and storage**

· 7.1 Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace. Only adequately trained personnel should handle this product. • Information about fire - and explosion protection: No special measures required.

· 7.2 Conditions for safe storage, including any incompatibilities

· Storage:

- Requirements to be met by storerooms and receptacles: Store only in the original receptacle.
- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions:

Store in a cool place.

Keep container tightly sealed.

Protect from heat and direct sunlight.

· 7.3 Specific end use(s) No further relevant information available.

## SECTION 8: Exposure controls/personal protection

· Additional information about design of technical facilities: No further data; see item 7.

· 8.1 Control parameters

· Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

• Additional information: The lists valid during the making were used as basis.

- · 8.2 Exposure controls
- · Personal protective equipment:
- General protective and hygienic measures: Usual hygienic measures for dental practice. 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.
- Respiratory protection:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

· Protection of hands:



Protective gloves

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

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(Contd. of page 3) Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

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

#### · Material of gloves

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

· Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye protection: Safety glasses

#### **SECTION 9: 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/Melting range:	Undetermined.	
Boiling point/Boiling range:	Undetermined.	
Flash point:	Not applicable.	
Self-igniting:	Product is not selfigniting.	
Danger of explosion:	Product does not present an explosion hazard.	
Explosion limits:		
Lower:	Not determined.	
Upper:	Not determined.	
Vapour pressure:	Not determined.	
Density at 20 °C:	1.04 g/cm <sup>3</sup>	
Relative density	Not determined.	
Vapour density	Not determined.	
Evaporation rate	Not determined.	
Solubility in / Miscibility with		
water:	Partly miscible.	
Partition coefficient (n-octanol/wat	er): Not determined.	
Viscosity:		
Dynamic:	Not determined.	
Kinematic:	Not determined.	
9.2 Other information	No further relevant information available.	

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#### **SECTION 10: Stability and reactivity**

· 10.1 Reactivity No further relevant information available.

- 10.2 Chemical stability Stable under normal handling and storage conditions.
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- 10.3 Possibility of hazardous reactions No dangerous reactions known.
- 10.4 Conditions to avoid No further relevant information available.
- 10.5 Incompatible materials: No further relevant information available.
- · 10.6 Hazardous decomposition products: None under normal conditions of storage and use.

#### **SECTION 11: Toxicological information**

- · 11.1 Information on toxicological effects
- · Acute toxicity:
- Primary irritant effect:
- on the skin: Irritant to skin and mucous membranes.
- on the eye: Irritating effect.
- Sensitisation: Sensitisation possible through skin contact.
- · Additional toxicological information: No further relevant information available.

#### **SECTION 12: Ecological information**

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- · 12.2 Persistence and degradability No further relevant information available.
- 12.3 Bioaccumulative potential No further relevant information available.
- 12.4 Mobility in soil No further relevant information available.
- 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.

- · 12.5 Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · **vPvB:** Not applicable.
- · 12.6 Other adverse effects No further relevant information available.

#### **SECTION 13: Disposal considerations**

- · 13.1 Waste treatment methods
- · Recommendation

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

- Uncleaned packaging:
- · Recommendation: Disposal must be made according to official regulations.

## **SECTION 14: Transport information**

· 14.1 UN-Number

· ADR, ADN, IMDG, IATA

Void

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· 14.2 UN proper shipping name · ADR, ADN, IMDG, IATA	Void
· 14.3 Transport hazard class(es)	
· ADR, ADN, IMDG, IATA · Class	Void
· 14.4 Packing group · ADR, IMDG, IATA	Void
· 14.5 Environmental hazards: · Marine pollutant:	No
· 14.6 Special precautions for user	Not applicable.
· 14.7 Transport in bulk according to Anne MARPOL73/78 and the IBC Code	<b>x II of</b> Not applicable.
· Transport/Additional information:	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).
· UN ''Model Regulation'':	-

#### **SECTION 15: Regulatory information**

· 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

- · National regulations:
- Other regulations, limitations and prohibitive regulations
- The product is a medical device according to the Directive 93/42/EEC.
- · 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

## **SECTION 16: Other information**

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

#### · Relevant phrases

H314 Causes severe skin burns and eye damage. H315 Causes skin irritation. H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. · Abbreviations and acronvms: ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances ELINCS: European List of Notified Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) Skin Corr. 1B: Skin corrosion/irritation, Hazard Category 1B Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2 Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1 Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2 Skin Sens. 1: Sensitisation - Skin, Hazard Category 1  $\cdot$  \* Data compared to the previous version altered.