

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



- · 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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- · 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:

· 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.

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.

· Eve protection: Safety glasses

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Information on basis abusinal J -l	ical muonautica
Information on basic physical and chem General Information	icai properties
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.

10 Stability and reactivity

Kinematic:

· Other information

- · 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.

Not determined.

No further relevant information available.

- · 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

- · 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.

UN-Number	
ADR/RID/ADN, ADN, IMDG, IATA	Void
UN proper shipping name	W
ADR/RID/ADN, ADN, IMDG, IATA	Void
Transport hazard class(es)	
ADR/RID/ADN, ADN, IMDG, IATA	
Class	Void
Packing group	
ADR/RID/ADN, IMDG, IATA	Void
Environmental hazards:	
Marine pollutant:	No
Special precautions for user	Not applicable.
Transport in bulk according to Annex II of Marpol	
	Not applicable.
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