

Safety Data Sheet according to WHS Regulations

Printing date 12.12.2019

Version number 6

Revision: 12.12.2019

Hazardous according to criteria of Australian Safety and Compensation Council.

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 AG
Bendererstrasse 2
9494 Schaan
PRINCIPALITY OF LIECHTENSTEIN
Tel: +423 235 35 35 / Fax: +423 235 33 60
- **Importer:**
Ivoclar Vivadent Pty. Ltd.
1- 5 Overseas Drive
Noble Park North VIC 3174
Tel: + 61 3 9795 9599 / Fax: + 61 3 9795 9645
- **Further information obtainable from:**
Regulatory Affairs
sds@ivoclarvivadent.com
- **Emergency telephone number:** 131 126 (Poisons Information Centre - 24 hours / 7 days)

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 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.

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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.

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

vPvB: Not applicable.

3 Composition and 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%
	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).

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- **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 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 and 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.

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Trade name: **Multilink Primer A**· **Eye protection:** Safety glasses

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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.

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11 Toxicological Information

- **Information on toxicological effects**
- **Acute toxicity**
- **Skin corrosion/irritation** No irritant effect.
- **Serious eye damage/irritation** No irritating effect.
- **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

- | | |
|-------------------------------------|------|
| · UN-Number | |
| · ADG, ADN, IMDG, IATA | Void |
| · UN proper shipping name | |
| · ADG, ADN, IMDG, IATA | Void |
| · Transport hazard class(es) | |
| · ADG, ADN, IMDG, IATA | |
| · Class | Void |
| · Packing group | |
| · ADG, IMDG, IATA | Void |
| · Environmental hazards: | |
| · Marine pollutant: | No |

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· Special precautions for user	Not applicable.
· Transport in bulk according to Annex II of Marpol 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**

· **Australian Inventory of Chemical Substances**

All ingredients are listed.

· **Standard for the Uniform Scheduling of Medicines and Poisons**

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)

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*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*

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