

SAFETY DATA SHEET (GHS)

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE/PRODUCT AND MANUFACTURER/IMPORTER

1.1 Product identifier:-

Product name: Multilink Hybrid Abutment (Base)
Product number: Void

1.2 Other means of identification:-

Not applicable.

1.3 Recommended use of the chemical and restrictions on use:-

Not applicable.

Identified uses:

Self-curing dental luting composite for extraoral cementation

1.4 Details of the manufacturer and importer:-

Manufacturer:

Ivoclar Vivadent AG
 Bendorerstrasse 2
 FL-9494 Schaan
 PRINCIPALITY OF LIECHTENSTEIN

Importer:

Ivoclar Vivadent Pty Ltd
 1- 5 Overseas Drive Noble Park North VIC 3174
 Tel: + 61 3 9795 9599 Fax: + 61 3 9795 9645
 Email: info@ivoclarvivadent.com

1.5 Emergency phone number:

13 11 26
 Poisons Hotline (24 hours / 7 days)

2. HAZARD(S) IDENTIFICATION

2.1 GHS Classification:-

Skin Irrit. 2 H315 Causes skin irritation.
 Eye Irrit. 2 H319 Causes serious eye irritation.
 Skin Sens. 1 H317 May cause an allergic skin reaction.
 STOT SE 3 H335 May cause respiratory irritation.

2.2 GHS Label elements, including precautionary statements:-

Hazard Pictogram:



GHS07

Signal word:

Warning

Hazard-determining components of labelling:

Bis-GMA
 ytterbium trifluoride
 2-hydroxyethyl methacrylate
 2-dimethylaminoethyl methacrylate
 H315 Causes skin irritation.
 H319 Causes serious eye irritation.
 H317 May cause an allergic skin reaction.
 H335 May cause respiratory irritation

Hazard statements:

P280 Wear protective gloves/protective clothing/eye protection/face protection.
 P363 Wash contaminated clothing before reuse.
 P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
 P337+P313 If eye irritation persists: Get medical

Precautionary statements:

P280 Wear protective gloves/protective clothing/eye protection/face protection.
 P363 Wash contaminated clothing before reuse.
 P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
 P337+P313 If eye irritation persists: Get medical

| advice/attention.

2.3 Additional information: Void

Other hazards:-

Void.

Results of PBT and vPvB assessment;

PBT:

| Not applicable.

vPvB:

| Not applicable.

3 COMPOSITION/INFORMATION ON INGREDIENTS

Mixture of substances listed below with nonhazardous additions.

Ingredient name	CAS No.	Classification	Concentration
ytterbium trluoride	13760-80-0	Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	10-<25%
ethoxylated bisphenol A dimethacrylate	41637-38-1	Aquatic Chronic 4, H413	10-<25%
Bis-GMA	1565-94-2	Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	10-<25%
2-hydroxyethyl methacrylate	868-77-9	Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	3-<10%
2-dimethylaminoethyl methacrylate	2867-47-2	Acute Tox. 4, H302; Acute Tox. 4, H312; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	0.3-<1%

4. FIRST AID MEASURES

4.1 Description of necessary first aid measures:-

If inhaled:

Supply fresh air and to be sure call for a doctor.
In case of unconsciousness place patient stably in side position for transportation

In case of skin contact:

Rinse with water.

In case of eye contact:

Rinse opened eye for several minutes under running water.
Then consult a doctor

If swallowed:

Rinse out mouth and then drink plenty of water.
If symptoms persist consult doctor.

4.2 Symptoms caused by exposure:-

No further relevant information available

4.3 Medical attention and special treatment:-

No further relevant information available.

5. FIRE FIGHTING MEASURES

5.1 Suitable extinguishing equipment:-

Suitable extinguishing media:

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

Unsuitable extinguishing media:

No further relevant information available.

5.2 Specific hazards arising from the substance/mixture/product:-

No further relevant information available.

5.3 Special protective equipment and precautions for fire fighters:-

Special personal protective equipment:

No further relevant information available

Precautions:

No further relevant information available

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.

6.3 Methods and materials for containment and cleaning up:-

Pick up mechanically
 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

7.1 Precautions for safe handling:-

Only adequately trained personnel should handle this product.
 For use in dentistry only

7.2 Conditions for safe storage, including any incompatibilities:-

Store only in the original receptacle
 Protect from exposure to the light.
 Protect from heat and direct sunlight.
 Keep container tightly sealed.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Exposure control measures:-

Occupational exposure limits:

Component	CAS No.	Value	Parameters	Basis
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Ingredients with biological limit values:

8.2 Biological monitoring:-

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.
 Wash hands before breaks and at the end of work.
 Keep away from foodstuffs, beverages and feed.
 Avoid contact with the eyes and skin.

8.3 Control banding:-

Void

8.4 Engineering controls:-

Void

8.5 Individual protection measures include PPE:-

Eye/face protection:



Safety glasses

Required Use tightly fitting safety glasses as per Australian Standard AS 1336 and AS/NZS 1337.

Skin protection:



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.

Respiratory protection:



- Not suitable are gloves made of the following materials:

Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates.
Not Required

9. PHYSICAL/CHEMICAL PROPERTIES

9.1 Information on physical/chemical properties:-

- | | |
|---|--|
| a) Appearance/Form: | Pasty |
| b) Colour: | According to product specification |
| c) Odour: | Characteristic |
| d) Odour threshold: | Not determined. |
| e) pH-value (10 g/l) at 20 °C: | Not determined. |
| f) Melting point/melting range: | Not determined. |
| g) Boiling point/boiling range: | Not determined. |
| h) Flash point: | Not determined |
| i) Ignition temperature: | Not determined |
| j) Self-igniting: | Product is not self-igniting. |
| k) Danger of explosion: | Not determined. |
| l) Upper/lower flammability or explosive limits: | Lower Not determined
Upper Not determined. |
| m) Vapour pressure 20°C: | Not determined. |
| n) Density at 20°C: | ~1,95 g/cm ³ |
| o) Relative density: | Not determined. |
| p) Vapour density: | Not applicable. |
| q) Evaporation rate: | Not applicable. |
| r) Solubility in/miscibility with water: | Nearly insoluble |
| s) Partition coefficient: n- octanol/water: | Not determined. |
| t) Viscosity: | Dynamic Not applicable.
Kinematic Not applicable. |
| u) Solids content: | Not determined. |

10. STABILITY AND REACTIVITY

10.1 Reactivity:-

No further relevant information available.

10.2 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.

10.3 Possibility of hazardous reactions:-

No dangerous reactions known.

10.4 Conditions to avoid:-

Protect from exposure to the light.
Keep away from heat and direct sunlight.

10.5 Incompatible materials:-

No further relevant information available.

10.6 Hazardous decomposition products:-

None under normal conditions of storage and use.

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects:-

Acute toxicity / Values relevant for classification:

Skin corrosion/irritation:	Causes skin irritation.
Serious eye damage/eye irritation:	Causes serious eye irritation
Respiratory or skin sensitization:	May cause an allergic skin reaction
Germ cell mutagenicity:	No further relevant information available.
Carcinogenicity:	No further relevant information available.
Reproductive toxicity:	No further relevant information available.
Specific target organ toxicity - single exposure:	May cause respiratory irritation
Specific target organ toxicity - repeated exposure:	No further relevant information available.
Aspiration hazard:	No further relevant information available.
Additional information:	No further relevant information available.

11.2 Information on possible routes of exposure:-

Short Term (Acute) Exposure:	No further relevant information available.
Swallowed:	No further relevant information available.
Eyes:	No further relevant information available.
Skin:	No further relevant information available.
Inhaled:	No further relevant information available.
Long Term (Chronic) Exposure:	No further relevant information available.
Swallowed:	No further relevant information available.
Eyes:	No further relevant information available.
Skin:	No further relevant information available.
Inhaled:	No further relevant information available.

11.3 Early onset symptoms related to exposure:-

No further relevant information available.

11.4 Delayed health effects from exposure:-

No further relevant information available.

11.5 Exposure levels and health effects:-

No further relevant information available.

11.6 Interactive effects:-

No further relevant information available.

11.7 Other:-

No further relevant information available.

12. ECOLOGICAL INFORMATION

12.1 Ecotoxicity:-

No further relevant information available.

12.2 Persistence/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.

12.5 Other adverse effects:-

No further relevant information available.

Additional ecological information / General notes:-

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

12.6 Other adverse effects:-

No further relevant information available.

13. DISPOSAL CONSIDERATIONS

13.1 Disposal methods:-

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 ADR / IMDG / IATA:-	Void.
UN proper shipping name or technical name:-	
ADR:	Void.
IMDG, IATA:	Void.
Transport hazard class(es):	Void.
Label:	Void.
Packaging group:	Void.
Environmental hazards:	Not applicable.
Special precautions for user:	Not applicable.
Danger code:	Void.
EMS Number:	Void.
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).

15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance/mixture/product:-

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.

16. OTHER INFORMATION

Key to abbreviations/acronyms used in SDS:-	H302 Harmful if swallowed. H312 Harmful in contact with skin. H315 Causes skin irritation. H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. H335 May cause respiratory irritation. H413 May cause long lasting harmful effects to aquatic life.
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Key literature references/data sources used to compile SDS:-

Void

Copyright statement:-

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.

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).

LC50: Lethal concentration, 50 percent.

LD50: Lethal dose, 50 percent.

Flam. Liq. 2: Flammable liquids, Hazard Category 2.

Flam. Liq. 3: Flammable liquids, Hazard Category 3.

Acute Tox. 4: Acute toxicity, Hazard Category 4.

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2.

Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2.

Repr. 2: Reproductive toxicity, Hazard Category 2.

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3.

STOT RE 2: Specific target organ toxicity - Repeated exposure, Hazard Category 2.

Asp. Tox. 1: Aspiration hazard, Hazard Category 1.

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

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