

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 Automix (Catalyst)
- · 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 resin-based dental luting material with light-curing option

- 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

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2A H319 Causes serious eye irritation.

Skin Sens. 1 H317 May cause an allergic skin reaction. STOT SE 3 H335 May cause respiratory irritation.

Aquatic Chronic 4 H413 May cause long lasting harmful effects to aquatic life.

- · Label elements
- · GHS label elements

The product is classified and labelled according to the Globally Harmonised System (GHS).

· Hazard pictograms



- · Signal word Warning
- · Hazard-determining components of labelling:

urethane dimethacrylate 2-hydroxyethyl methacrylate dibenzoyl peroxide

· Hazard statements

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

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May cause respiratory irritation.

May cause long lasting harmful effects to aquatic life.

· Precautionary statements

Avoid contact during pregnancy/while nursing.

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

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

If eye irritation persists: 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.

- · 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	s:	
CAS: 13760-80-0	ytterbium trifluoride	10-25%
EINECS: 237-354-2	Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335	
CAS: 41637-38-1	Bis-EMA	10-25%
EC number: 609-946-4	Aquatic Chronic 4, H413	
CAS: 72869-86-4	urethane dimethacrylate	2.5-10%
EINECS: 276-957-5	Eye Irrit. 2A, H319; Skin Sens. 1, H317; Aquatic Acute 3, H402; Aquatic Chronic 3, H412	
CAS: 868-77-9	2-hydroxyethyl methacrylate	2.5-10%
EINECS: 212-782-2	Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	
CAS: 94-36-0	dibenzoyl peroxide	<2.5%
EINECS: 202-327-6	Org. Perox. B, H241; Eye Irrit. 2, H319; Skin Sens. 1, H317	

[·] Additional information: For the wording of the listed hazard phrases refer to section 16.

4 First aid measures

- · 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.

- · 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.

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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: Pick up mechanically.
- 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.

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:

Protect from exposure to the light.

Protect from heat and direct sunlight.

Keep container tightly sealed.

· 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.

Wash hands before breaks and at the end of work.

Keep away from foodstuffs, beverages and feed.

Avoid contact with the eyes and skin.

· Respiratory protection: Not required.

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· Protection of hands:



Protective gloves

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.

· Eye protection: Safety glasses

Physical and chemical properties	
· Information on basic physical and chem	ical properties
General Information	icui properues
· Appearance:	
Form:	Pasty
Colour:	According to product specification
· 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.
· Flammability (solid, gas):	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 at 20 °C:	2.05 g/cm^3
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with	
water:	Nearly insoluble.
Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.

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· 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

Protect from exposure to the light.

Keep away from heat and direct sunlight.

- · 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.
- · Respiratory or skin sensitisation Sensitisation possible through skin contact.
- · 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:
- $\cdot \textit{Bioaccumulative potential} \ \textit{No further relevant information available}.$
- · 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.

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

Transport information	
UN-Number ADR/RID/ADN, ADN, IMDG, IATA	Void
UN proper shipping name 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 and the IBC Code	Marpol 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
- • New Zealand Inventory of Chemicals

 All ingredients are listed.

 • HSNO Approval numbers

 CAS: 41637-38-1 Bis-EMA
 HSR007296

 CAS: 868-77-9 2-hydroxyethyl methacrylate
 HSR003005
 - GHS label elements

The product is classified and labelled according to the Globally Harmonised System (GHS).

· Hazard pictograms



- · Signal word Warning
- · Hazard-determining components of labelling: urethane dimethacrylate 2-hydroxyethyl methacrylate dibenzoyl peroxide

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· Hazard statements

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

May cause respiratory irritation.

May cause long lasting harmful effects to aquatic life.

· Precautionary statements

Avoid contact during pregnancy/while nursing.

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

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

If eye irritation persists: Get medical advice/attention.

- · 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

H241 Heating may cause a fire or explosion.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H402 Harmful to aquatic life.

H412 Harmful to aquatic life with long lasting effects.

H413 May cause long lasting harmful effects to aquatic life.

· 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

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

Org. Perox. B: Organic peroxides – Type B

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A

Skin Sens. 1: Skin sensitisation – Category 1

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

Aquatic Acute 3: Hazardous to the aquatic environment - acute aquatic hazard - Category 3

Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard - Category 3

Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard - Category 4