

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 24.01.2012


Version number 4


Revision: 24.01.2012

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

- **Product identifier**
- **Trade name: Multilink Implant (Catalyst)**
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the preparation**
Self-curing luting composite with light-curing option for the cementation of restorations on implant abutments
- **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
msds@ivoclarvivadent.com
- **Emergency telephone number:** +423 / 235 33 13

2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
 **Xi; Sensitising**
R43: May cause sensitisation by skin contact.
- **Classification system:**
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

- **Label elements**
- **Labelling according to EU guidelines:**
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 Dangerous Substance Directive 1999/45/EC usually if they are in the finished state and intended for the final user.
- **Code letter and hazard designation of product:**
 **Xi Irritant**
- **Hazard-determining components of labelling:**
2-hydroxyethyl methacrylate
urethane dimethacrylate
dibenzoyl peroxide
- **Risk phrases:**
43 May cause sensitisation by skin contact.
- **Safety phrases:**
24 Avoid contact with skin.
26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

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- 28 After contact with skin, wash immediately with plenty of water.
 37 Wear suitable gloves.
 60 This material and its container must be disposed of as hazardous waste.
- **Other hazards**
 - **Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.

3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

- **Dangerous components:**

CAS: 41637-38-1	ethoxylated bisphenol A dimethacrylate ☒ Xi R36/38	10-25%
CAS: 868-77-9 EINECS: 212-782-2	2-hydroxyethyl methacrylate ☒ Xi R36/38; ☒ Xi R43	2.5-10%
CAS: 1565-94-2	Bis-GMA ☒ Xi R36/38	2.5-10%
CAS: 72869-86-4 EINECS: 276-957-5	urethane dimethacrylate ☒ Xi R36; ☒ Xi R43 R52/53	2.5-10%
CAS: 94-36-0 EINECS: 202-327-6	dibenzoyl peroxide ☒ Xi R36; ☒ Xi R43; ☒ E R3; ☒ O R7	≤ 2.5%

- **Additional information:** For the wording of the listed risk 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:** 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 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture** No further relevant information available.

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- **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:**
Store in a cool place.
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.
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
Keep away from foodstuffs, beverages and feed.
- **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. 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

9 Physical and chemical properties

· **Information on basic physical and chemical properties**· **General Information**· **Appearance:**

· Form:	Pasty
· Colour:	According to product specification
· Odour:	Characteristic
· Odour threshold:	Not determined.

· **pH-value:** Not applicable.· **Change in condition**

· Melting point/Melting range:	Undetermined.
· Boiling point/Boiling range:	Undetermined.

· **Flash point:** Not applicable.· **Flammability (solid, gaseous):** Not determined.· **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 applicable.· **Density:** Not determined.· **Relative density** Not determined.· **Vapour density** Not applicable.· **Evaporation rate** Not applicable.· **Solubility in / Miscibility with water:**

Nearly insoluble.

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- **Segregation coefficient (n-octanol/water):** Not determined.
- **Viscosity:**
 - Dynamic:** Not applicable.
 - Kinematic:** Not applicable.
- **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:**
- **Primary irritant effect:**
 - on the skin:** No irritant effect.
 - on the eye:** No irritating effect.
- **Sensitization:** Sensitization possible through skin contact.
- **Additional toxicological information:**
 - The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
 - Irritant

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.

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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
· ADR, ADN, IMDG, IATA | Void |
| · UN proper shipping name
· ADR, ADN, IMDG, IATA | Void |
| · Transport hazard class(es)
· ADR, ADN, IMDG, IATA
· Class | Void |
| · Packing group
· ADR, IMDG, IATA | Void |
| · Environmental hazards:
· Marine pollutant: | No |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |

15 Regulatory information

- **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 EC-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**
R3 Extreme risk of explosion by shock, friction, fire or other sources of ignition.
R36 Irritating to eyes.
R36/38 Irritating to eyes and skin.
R43 May cause sensitisation by skin contact.
R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R7 May cause fire.
- *** Data compared to the previous version altered.**