

## SAFETY DATA SHEETS

**This SDS packet was issued with item:**

077122575

**The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).**

070434456 077122476 077122500

**The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).**

077106503 077106511 077106529 077106537 077122534 077122542 077122559 077122567 077124068 077124076  
077124084 077124092 077124100

## Safety Data Sheet acc. to ISO 11014

Printing date 06/12/2013

Version number 4

Reviewed on 06/12/2013

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

- **Product identifier**
- **Trade name:** **Multilink Automix (Base)**
- **Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the preparation**  
Self-curing resin-based dental luting material with light-curing option
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Ivoclar Vivadent Inc.  
175 Pineview Drive, Amherst, N.Y. 14228  
USA  
Tel. +1 800 533 6825  
Fax +1 716 691 2285  
  
Ivoclar Vivadent Inc.  
1-6600 Dixie Road  
Mississauga, Ontario  
L5T 2Y2  
Canada  
Phone: +1 905 670 8499  
Fax: +1 905 670 3102
- **Information department:** Quality Assurance / Regulatory Affairs
- **Emergency telephone number:**  
24 Hour Emergency Assistance:  
Emergency-Call USA - Infotrac: 1-800-535-5053  
Emergency-Call Canada - Canutec: 1-613-996-6666  
  
General MSDS Assistance:  
US: 1-800-533-6825  
Canada: 1-800-263-8182

### 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.
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**  
Irritant  
May cause sensitisation by skin contact.
- **Classification system:**  
The classification was made according to the latest editions of international substances lists, and expanded upon from 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.

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Trade name: **Multilink Automix (Base)**

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· **Code letter and hazard designation of product:**

Irritant

· **Hazard-determining components of labelling:**

Bis-GMA

2-hydroxyethyl methacrylate

· **Risk phrases:**

May cause sensitisation by skin contact.

· **Safety phrases:**

Do not breathe vapour.

Avoid contact with skin.

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

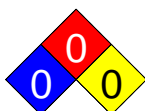
After contact with skin, wash immediately with plenty of water

Wear suitable gloves.

This material and its container must be disposed of as hazardous waste.

· **Additional information:** Void· **Hazard description:**· **WHMIS-symbols:**

D2B - Toxic material causing other toxic effects

· **Classification system:**· **NFPA ratings (scale 0 - 4)**

Health = 0

Fire = 0

Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**

Health = 0

Fire = 0

Reactivity = 0

· **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 the substances listed below with nonhazardous additions.· **Dangerous components:**

1565-94-2	Bis-GMA	10-<20%
868-77-9	2-hydroxyethyl methacrylate	3-<10%

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Trade name: **Multilink Automix (Base)**

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2867-47-2 2-dimethylaminoethyl methacrylate

0.3-&lt;1%

### 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.

### 5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**  
CO<sub>2</sub>, extinguishing 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.
- **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 protection against explosions and fires:** 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.

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Trade name: **Multilink Automix (Base)**

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- **Further information about storage conditions:**
  - Protect from exposure to the light.
  - Protect from heat and direct sunlight.
  - Keep receptacle tightly sealed.
- **Specific end use(s)** No further relevant information available.

### 8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**
- **Components 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 that were valid during the creation 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.
- **Breathing equipment:** Not required.
- **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

### 9 Physical and chemical properties

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

<b>Form:</b>	Pasty
<b>Color:</b>	According to product specification
- **Odor:** Characteristic
- **Odour threshold:** Not determined.
- **pH-value:** Not determined.
- **Change in condition**

<b>Melting point/Melting range:</b>	Undetermined.
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Trade name: **Multilink Automix (Base)**

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<b>Boiling point/Boiling range:</b>	Undetermined.
· <b>Flash point:</b>	Not applicable.
· <b>Flammability (solid, gaseous):</b>	Not applicable.
· <b>Auto igniting:</b>	Product is not selfigniting.
· <b>Danger of explosion:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
<b>Lower:</b>	Not determined.
<b>Upper:</b>	Not determined.
· <b>Vapor pressure:</b>	Not determined.
· <b>Density at 20 °C:</b>	2.05 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with Water:</b>	Nearly insoluble.
· <b>Partition coefficient (n-octanol/water):</b>	Not determined.
· <b>Viscosity:</b>	
<b>Dynamic:</b>	Not determined.
<b>Kinematic:</b>	Not determined.
· <b>Other information</b>	No further relevant information available.

### 10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **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.
- **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 internally approved calculation methods for preparations:

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## Safety Data Sheet

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Trade name: **Multilink Automix (Base)**

Irritant

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· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

7631-86-9 silicon dioxide, chemically prepared

3

· **NTP (National Toxicology Program)**

None of the ingredients is listed.

## 12 Ecological information

· **Toxicity**

· **Aquatic toxicity:** No further relevant information available.

· **Persistence and degradability** No further relevant information available.

· **Behavior 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 (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 packagings:**

· **Recommendation:** Disposal must be made according to official regulations.

## 14 Transport information

· **UN-Number**

· **DOT, TDG, ADN, IMDG, IATA** Void

· **UN proper shipping name**

· **DOT, TDG, ADN, IMDG, IATA** Void

· **Transport hazard class(es)**

· **DOT, TDG, ADN, IMDG, IATA**

· **Class** Void

· **Packing group**

· **DOT, TDG, IMDG, IATA** Void

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Trade name: **Multilink Automix (Base)**

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- |  |                 |
|--|-----------------|
| · <b>Environmental hazards:</b>  |                 |
| · <b>Marine pollutant:</b>   | No              |
| · <b>Special precautions for user</b>  | Not applicable. |
| · <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b> | Not applicable. |
| · <b>UN "Model Regulation":</b>  | -               |

### 15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Sara**

- **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

- **Section 313 (Specific toxic chemical listings):**

None of the ingredients is listed.

- **TSCA (Toxic Substances Control Act):**

All ingredients are listed.

- **Proposition 65**

- **Chemicals known to cause cancer:**

None of the ingredients is listed.

- **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

- **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

- **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

- **Carcinogenic categories**

- **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

- **TLV (Threshold Limit Value established by ACGIH)**

13760-80-0 ytterbium trifluoride

A4

- **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

- **Canadian substance listings:**

- **Canadian Domestic Substances List (DSL)**

65997-17-3 glass

41637-38-1 ethoxylated bisphenol A dimethacrylate

1565-94-2 Bis-GMA

868-77-9 2-hydroxyethyl methacrylate

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**Trade name: Multilink Automix (Base)**

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7631-86-9	silicon dioxide, chemically prepared
68909-20-6	Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica
1314-23-4	zirconium dioxide
2867-47-2	2-dimethylaminoethyl methacrylate
10287-53-3	ethyl p-dimethylaminobenzoate
10373-78-1	campherquinone
13463-67-7	titanium dioxide
1309-37-1	diiron trioxide
20344-49-4	iron hydroxide oxide
1317-61-9	triiron tetraoxide

**· Canadian Ingredient Disclosure list (limit 0.1%)**

None of the ingredients is listed.

**· Canadian Ingredient Disclosure list (limit 1%)**

868-77-9	2-hydroxyethyl methacrylate
7631-86-9	silicon dioxide, chemically prepared

**· Product related hazard informations:**

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.

**· Hazard symbols:**


Irritant

**· Hazard-determining components of labelling:**

Bis-GMA

2-hydroxyethyl methacrylate

**· Risk phrases:**

May cause sensitisation by skin contact.

**· Safety phrases:**

Do not breathe vapour.

Avoid contact with skin.

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

After contact with skin, wash immediately with plenty of water

Wear suitable gloves.

This material and its container must be disposed of as hazardous waste.

**· 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.

**· Abbreviations and acronyms:**

IMDG: International Maritime Code for Dangerous Goods

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**Safety Data Sheet**  
**acc. to ISO 11014**

Printing date 06/12/2013

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**Trade name: Multilink Automix (Base)**

*DOT: US Department of Transportation*

*IATA: International Air Transport Association*

*ACGIH: American Conference of Governmental Industrial Hygienists*

*NFPA: National Fire Protection Association (USA)*

*HMIS: Hazardous Materials Identification System (USA)*

*WHMIS: Workplace Hazardous Materials Information System (Canada)*

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CA

# Safety Data Sheet according to WHS Regulations

Printing date 13.02.2024

Version number 8

Revision: 22.11.2023


Hazardous according to criteria of Australian Safety and Compensation Council.

## 1 Identification

- **Product identifier**
- **Trade name:** **Multilink Automix (Base)**
- **Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** Polymer-based dental luting material (intraoral dual-curing)
- **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@ivoclar.com
- **Emergency telephone number:** 131 126 (Poisons Information Centre - 24 hours / 7 days)

## 2 Hazard(s) Identification

- **Classification of the substance or mixture**

Skin Irrit. 2	H315 Causes skin irritation.
Serious eye damage/irritation – Category 2A	H319 Causes serious eye irritation.
Skin Sens. 1	H317 May cause an allergic skin reaction.
STOT SE 3	H335 May cause respiratory irritation.
- **Label elements**
- **GHS label elements**  
The product is classified and labelled according to the Globally Harmonised System (GHS).
- **Hazard pictograms**  
  
GHS07
- **Signal word** Warning
- **Hazard-determining components of labelling:**  
2-hydroxyethyl methacrylate (2.5-10 %)  
ytterbium trifluoride (10-25 %)  
urethane dimethacrylate (<2.5 %)
- **Hazard statements**  
Causes skin irritation.

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## Safety Data Sheet

### according to WHS Regulations

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**Trade name: Multilink Automix (Base)**

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*Causes serious eye irritation.*

*May cause an allergic skin reaction.*

*May cause respiratory irritation.*

· **Precautionary statements**

*Avoid breathing dust/fume/gas/mist/vapours/spray.*

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

*IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.*

*IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.*

*Store locked up.*

*Dispose of contents/container in accordance with local/regional/national/international regulations.*

· **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: 13760-80-0	ytterbium trifluoride Skin Irrit. 2, H315; Serious eye damage/irritation – Category 2A, H319; STOT SE 3, H335	10-25%
CAS: 868-77-9	2-hydroxyethyl methacrylate Skin Irrit. 2, H315; Serious eye damage/irritation – Category 2A, H319; Skin Sens. 1, H317	2.5-10%
CAS: 72869-86-4	urethane dimethacrylate Serious eye damage/irritation – Category 2A, H319; Skin Sens. 1, H317	<2.5%
CAS: 2867-47-2	2-dimethylaminoethyl methacrylate Skin Corr. 1B, H314; Eye Dam. 1, H318; Acute Tox. 4, H302; Acute Tox. 4, H312; Skin Sens. 1, H317	<2.5%

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

### 4 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. Then 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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## Safety Data Sheet according to WHS Regulations

Printing date 13.02.2024

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Revision: 22.11.2023

Trade name: **Multilink Automix (Base)**

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### 5 Fire Fighting Measures

- **Suitable extinguishing agents:**  
CO<sub>2</sub>, 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.
- **Protective equipment:** No special measures required.

### 6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures**  
Wear protective equipment. Keep unprotected persons away.
- **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.
- **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 and personal protection

- **Additional information about design of technical facilities:** No further data; see section 7.
- **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.
- **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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AU

# Safety Data Sheet according to WHS Regulations

Printing date 13.02.2024

Version number 8

Revision: 22.11.2023

Trade name: **Multilink Automix (Base)**

## Protection of hands:



Protective gloves (EN 374)

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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.

## Not suitable are gloves made of the following materials:

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

## Eye protection: Safety glasses

\*

## 9 Physical and Chemical Properties

### General Information

Appearance:	Pasty
Form:	According to product specification
Colour:	Characteristic
Odour:	Not determined.
Odour threshold:	Not determined.
pH-value:	
Change in condition	Undetermined.
Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	Not applicable.
Flash point:	Not applicable.
Flammability (solid, gas):	Product is not selfigniting.
Ignition temperature:	Product does not present an explosion hazard.
Explosive properties:	
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
Vapour pressure:	Not determined.
Density at 20 °C:	2.02 g/cm <sup>3</sup>
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.

Other information No further relevant information available.

## 10 Stability and Reactivity

Reactivity No further relevant information available.

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## Safety Data Sheet

### according to WHS Regulations

Printing date 13.02.2024

Version number 8

Revision: 22.11.2023

Trade name: **Multilink Automix (Base)**

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- **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.
- **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** Based on available data, the classification criteria are not met.
- **Skin corrosion/irritation**  
Causes skin irritation.
- **Serious eye damage/irritation**  
Causes serious eye irritation.
- **Respiratory or skin sensitisation**  
May cause an allergic skin reaction.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure**  
May cause respiratory irritation.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.
- **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.

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

#### 14 Transport information

- |   |  |
|---|--|
| · <b>UN-Number</b>  | Void   |
| · <b>ADG, ADN, IMDG, IATA</b>   | Void   |
| · <b>UN proper shipping name</b>  | Void   |
| · <b>ADG, ADN, IMDG, IATA</b>   | Void   |
| · <b>Transport hazard class(es)</b>   |  |
| · <b>ADG, ADN, IMDG, IATA</b>   |  |
| · <b>Class</b>  | Void   |
| · <b>Packing group</b>  |  |
| · <b>ADG, IMDG, IATA</b>  | Void   |
| · <b>Environmental hazards:</b>   |  |
| · <b>Marine pollutant:</b>  | No   |
| · <b>Special precautions for user</b>                                       | Not applicable.  |
| · <b>Transport in bulk according to Annex II of Marpol and the IBC Code</b> | Not applicable.  |
| · <b>Transport/Additional information:</b>                                  | Product is not classified as a dangerous good for transport (ADR, IMDG, IATA). |
| · <b>UN "Model Regulation":</b>   | Void   |

#### 15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**

- **Australian Inventory of Industrial Chemicals**

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**



GHS07

- **Signal word** Warning

- **Hazard-determining components of labelling:**

2-hydroxyethyl methacrylate (2.5-10 %)

ytterbium trifluoride (10-25 %)

urethane dimethacrylate (&lt;2.5 %)

- **Hazard statements**

Causes skin irritation.

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AU



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*Causes serious eye irritation.**May cause an allergic skin reaction.**May cause respiratory irritation.*

· **Precautionary statements**

*Avoid breathing dust/fume/gas/mist/vapours/spray.**Wear protective gloves / eye protection / face protection.**IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.**IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.**Store locked up.**Dispose of contents/container in accordance with local/regional/national/international regulations.*

· **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 Regulation 2017/745 on Medical Devices (MDR).*

· **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.**H312 Harmful in contact with skin.**H314 Causes severe skin burns and eye damage.**H315 Causes skin irritation.**H317 May cause an allergic skin reaction.**H318 Causes serious eye damage.**H319 Causes serious eye irritation.**H335 May cause respiratory irritation.*

· **Contact:**

· **Abbreviations and acronyms:**

*ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)**RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)**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**Skin Corr. 1B: Skin corrosion/irritation – Category 1B**Skin Irrit. 2: Skin corrosion/irritation – Category 2**Eye Dam. 1: Serious eye damage/eye irritation – Category 1**Serious eye damage/irritation – Category 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*

· **\* Data compared to the previous version altered.**