

Printing date 06/11/2013 Version number 1 Reviewed on 06/11/2013

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

- · Product identifier
- · Trade name: Multilink Speed (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-adhesive self-curing dental resin cement 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.

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Mississauga, Ontario

L5T 2Y2

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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

Irritating to eyes. 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/EWG usually if they are in the finished state and intended for the final user.

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Trade name: Multilink Speed (Base)

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· Code letter and hazard designation of product:



Irritant

· Hazard-determining components of labelling:

urethane dimethacrylate triethyleneglycol dimethacrylate

· Risk phrases:

Irritating to eyes.

May cause sensitisation by skin contact.

· Safety phrases:

Avoid contact with skin.

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

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 = 1Fire = 0Reactivity = 0

· HMIS-ratings (scale 0 - 4)



1 Health = 1Fire = 0

REACTIVITY 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:		
72869-86-4	urethane dimethacrylate	10-<20%
109-16-0	triethyleneglycol dimethacrylate	3-<10%
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25852-47-5 polyethylene glycol dimethacrylate

2.5-<3%

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, 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.
- $\cdot \textit{Environmental precautions:} \ \textit{Do not allow to enter sewers/ surface or ground water.}$
- · 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.
- · Further information about storage conditions:

Protect from exposure to the light.

Protect from heat and direct sunlight.

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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
- $\cdot \textit{Components with limit values that require monitoring at the workplace:} \\$

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.

Avoid contact with the eyes and skin.

Keep away from foodstuffs, beverages and feed.

· Breathing equipment:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

· 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

Color: According to product specification

Odor: CharacteristicOdour threshold: Not determined.

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· pH-value:	Not determined.	
· Change in condition		
Melting point/Melting range:	Undetermined.	
Boiling point/Boiling range:	Undetermined.	
· Flash point:	Not applicable.	
Auto igniting: Product is not selfigniting.		
· Danger of explosion:	Product does not present an explosion hazard.	
· Explosion limits:		
Lower:	Not determined.	
Upper:	Not determined.	
· Vapor pressure:	Not determined.	
· Density:	Not determined.	
Relative density	Not determined.	
· Vapour density	Not determined.	
· Evaporation rate	Not determined.	
· Solubility in / Miscibility with		
Water:	Nearly insoluble.	
· Partition coefficient (n-octanol/wa	ter): Not determined.	
· Viscosity:		
Dynamic:		
Kinematic:		
· 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.

Photoreactive (Danger of polymerization).

- 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: Irritating effect.
- · Sensitization: Sensitization possible through skin contact.

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· Additional toxicological information:

The product shows the following dangers according to internally approved calculation methods for preparations:

Irritant

· 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.

· 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	

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· Packing group · DOT, TDG, IMDG, IATA	Void	
· Environmental hazards: · Marine pollutant:	No	
· Special precautions for user	Not applicable.	
· Transport in bulk according to Annex MARPOL73/78 and the IBC Code	II of Not applicable.	
· UN ''Model Regulation'':	-	

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)

None of the ingredients is listed.

· 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)

109-16-0 triethyleneglycol dimethacrylate

25852-47-5 polyethylene glycol dimethacrylate

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7631-86-9	silicon dioxide, chemically prepared		
13463-67-7	titanium dioxide		
1309-37-1	diiron trioxide		
20344-49-4	iron hydroxide oxide		
1317-61-9	triiron tetraoxide		
10287-53-3	ethyl p-dimethylaminobenzoate		
10373-78-1	campherquinone		
· Canadian I	· Canadian Ingredient Disclosure list (limit 0.1%)		
None of the ingredients is listed.			
· Canadian Ingredient Disclosure list (limit 1%)			
109-16-0	triethyleneglycol dimethacrylate		
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/EWG usually if they are in the finished state and intended for the final user.

· Hazard symbols:



Irritant

· Hazard-determining components of labelling:

urethane dimethacrylate triethyleneglycol dimethacrylate

· Risk phrases:

Irritating to eyes.

May cause sensitisation by skin contact.

· Safety phrases:

Avoid contact with skin.

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

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

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

NFPA: National Fire Protection Association (USA)

 ${\it HMIS: Hazardous\ Materials\ Identification\ System\ (USA)}$

 $WHMIS:\ Workplace\ Hazardous\ Materials\ Information\ System\ (Canada)$