# **SAFETY DATA SHEETS**

# This SDS packet was issued with item: 077122542

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 077122559 077122567 077122575 077124068 077124076 077124084 077124092 077124100

Material Safety Data Sheet Date of issue / Reference		Multilink		ivoclar vivadeni	
Replaces version of		01.10.2007 11.04.2005	lise / Version 3 hot		
-	of printing	01.10.2007	Sheet No. 1529		Page 1 of
Company		Ivoclar Vivadent AG, Bendererstrasse 2, FL - 9494 Schaan Principality of Liechtenstein			
1	Commercial product name and sup	plier			
1.1	Commercial product name / Designation	Multilin	K		
		NFPA	· –	HM	15
				н	0
		0		F	0
		0	1	R	1
				С	
1.2	Application / Use	Resin based	dental luting material		
1.3	Producer	Ivoclar Vivadent AG, Bendererstrasse 2, 9494 Schaan Principality of Liechtenstein (FL)			
1.4	Supplier	Ivoclar Vivadent, Inc. 175 Pineview Drive, Amherst NY 14228, USA 2785 Skymark Ave., Unit 1 Mississagua, ON L4W4Y3, Canada MSDS prepared by Andejeet Gulati. Tel. No. 716 691-0010			
1.5	24 Hour Emergency Assistance		Call USA- Infotrac: 1-80 Call Canada - Canutec: 1		
	General MSDS Assistance	US: 1-800-53 Canada: 1-80			
2	Composition				
2.1	Chemical characterization	Base and Catalyst Pastes of dimethacrylates, hydroxyethyl methacrylate (HEMA), inorganic fillers, ytterbiumtrifluoride, initiators, stabilizers and pigments			
2.2	Hazardous components				
		38-1)	nethacrylates (CAS No. 2 g to eyes and skin.	1565-9	94-2, 72869-86-4, 41637-
	CAS No. 868-77-9	6-7 % HEMA	A	n contact	t. R36/38: Irritating to eyes and
	CAS No. 94-36-0		• •		c, friction, fire or other sources o ation by skin contact.
2.3	Further information	None.			

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3	Hazards identification	Uncured material: May cause sensitization by skin contact. Direct contact may cause eye and skin irritation. The material is contraindicated if a person is known to be allergic to any of the ingredients of the product.		
4	First aid measures			
4.1	Eye contact	Flush with pl	enty of water. Consult a physician	if irritation persists.
4.2	Skin contact	Wash thorou	ghly with water.	
4.3	Ingestion	swallowing s	nounts of water. No hazards anticip mall amounts incidentally to norma seek medical advice (show this safe	al handling. If you
4.4	Inhalation	Remove to fr	esh air.	
4.5	Further information	None.		
5	Fire-fighting measures			
5.1	Suitable extinguishing media	Water fog, ca	urbon dioxide, foam, dry chemicals.	
5.2	Extinguishing media to avoid	None known		
5.3	Flash point			Test method:
5.4	Ignition temperature	not determin	ed	
5.5	Explosion limits	Lower: Upper: not determine		
5.6	Further information	None.		
6	Accidental release measures	Clean up mee Dispose of ac	chanically. cording to local and national regul	ations.
7	Handling and storage			
7.1	Handling		ely trained personnel should handl each of children.	e this product.
7.2	Industrial hygiene		ic measures for dental practice. do not eat, drink or smoke.	
7.3	Storage		°C / 36-82 °F (Base) t paste in the refrigerator (2-8 °C / 2	36-46 °F) !
7.4	Place of storage	Avoid exposu	are to direct sunlight.	

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7.5	Fire- and explosion-protection	Not required.		1450 5 61 5
8	Exposure controls / Personal protec	ction		
8.1	Technical measures		ventilation should be suffici	ent.
8.2	Control of threshold limits	None establis	hed.	
8.3	Personal protective equipment			
8.3.1	Respiratory protection	Not required.		
	2 Hand protection	Gloves. Commercial	medical gloves do not provid fect of methacrylates.	le protection against the
8.3.3	Eye protection	Safety goggle	es.	
8.3.4	Other	None.		
9	Physical and chemical properties			
9.1	Appearance	Paste		
9.2	Colour	off-white to cre	eam	
9.3	Odour	practically odo	ourless	
9.4	Change of physical state			Test method:
		not applicable		
9.5	Density			
		not determined	ł	
9.6	Vapour pressure			
		not applicable		
9.7	Viscosity			
		not determined	1	
9.8	Solubility		<u>م</u>	
2.0	Solubility in water	< 0.1 %		
	Solutinity in water	< 0.1 /0		
9.9	рН	not determined	1	

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	Further information	None.		<u></u>		
10	Stability and reactivity					
10.1	Thermal decomposition	None, if used	in accordance to	instructions.		
10.2 10.3	Hazardous decomposition products Hazardous reactions	None under n None.	normal conditions	s of storage and use	e.	
10.4	Further information	Avoid heat.				
11	Toxicological information					
11.1	Acute toxicity	This product possesses no cytotoxic potential. non-mutagenic				
11.2	Subacute / Chronic toxicity	Uncured material: prolonged or frequently repeated skin contact may cause allergic skin reactions.				
11.3	Further information	No hazards anticipated from swallowing small amounts incidentally to normal handling.				
12	Ecological information	No ecological problems to be anticipated if properly handled and used. nearly insoluble				
13	Disposal considerations	Take to a waste incineration plant, under conditions approved by the local authority.				
14	Transport information					
14.1	Transport at land	ADR		RID		
		UN Number Packing Grou Proper shippi	-		ber	
14.2	Transport at sea	ADNR		IMDG		
		UN Number EMS Packing Grou Proper shippi	-	MFAG		

Obtained by Global Safety Management, Inc. www.globalsafetynet.com (Tel: 1-813-435-5161)

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14.3	Air transport	ICAO / IATA	-DGR	
		UN Number Proper shippir	ng name	
		Subsidiary Ris	sk	
		Labels		
		Packing Group	-	
	Passenger airplane	Packing Instru	uctions	
		max.		
	Cargo Airplane	Packing Instru	ictions	
		max.		
14.4	Further information	Product is not	classified as a d	angerous good for transport.
15	Regulatory information	The product is a medical device according to the EC-directive 93/42/EEC. This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada. This product does not require classification as Dangerous Goods.		
15.1	National regulations	This product of	ioes not require	classification as Dangerous Goods.
15.1	NFPA Storage			
	-			
15.3	Further information	None.		
16	Other information	Version: 3 Changes: 1.5		

The above mentioned data correspond to our present state of knowledge and experience. The safety data sheet serves as description of the products in regard to necessary safety measures. The indications do not have the meaning of guarantees on properties.

This safety data sheet has been generated with the safety database 'ChemManager', © ASSIST Applied Software Solutions in Science and Technology AG, Weiherweg 3, CH-4104 Oberwil, Switzerland

91/155/EEC

Printing date 01/16/2013

vivadeni:

Version number 4

Reviewed on 01/16/2013

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
- · 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/ EWG usually if they are in the finished state and intended for the final user.

· Code letter and hazard designation of product:



Irritant

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• *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.

Classification system:
NFPA ratings (scale 0 - 4)



Health = 0Fire = 0 Reactivity = 0

· HMIS-ratings (scale 0 - 4)

HEALTHImage: 0Health = 0FIREImage: 0Fire = 0REACTIVITYImage: 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	1-<10%	
2867-47-2	2-dimethylaminoethyl methacrylate	0.1-<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.

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- 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.
- 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.
- 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.

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- · 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

Information on basic physical and General Information	chemical properties	
Appearance:		
Form:	Pasty	
Color:	According to product specification	
Odor:	Characteristic	
Odour threshold:	Not determined.	
pH-value:	Not determined.	
Change in condition		
Melting point/Melting range:	Undetermined.	
Boiling point/Boiling range:	Undetermined.	
Flash point:	Not applicable.	
Flammability (solid, gaseous):	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 at 20 °C (68 °F):	2.05 g/cm <sup>3</sup> (17.107 lbs/gal)	
Relative density	Not determined.	
Vapour density	Not determined.	

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· Evaporation rate	Not determined.	
· Solubility in / Miscibility with		
Water:	Nearly insoluble.	
· Partition coefficient (n-octanol	/water): Not determined.	
· Viscosity:		
<b>D</b> 1	Not determined.	
Dynamic:	ivoi determined.	
Dynamic: Kinematic:	Not determined.	

## 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:
- Irritant
- · Carcinogenic categories

· IARC (International Agency for Research on Cancer)

7631-86-9 silicon dioxide, chemically prepared

· 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.

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- *Mobility in soil* No further relevant information available.
- $\cdot$  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, ADR, ADN, IMDG, IATA Void · UN proper shipping name · DOT, ADR, ADN, IMDG, IATA Void · Transport hazard class(es) · DOT, ADR, ADN, IMDG, IATA · Class Void · Packing group · DOT, 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

• Sara

· Section 355 (extremely hazardous substances):

None of the ingredients is listed.

• Section 313 (Specific toxic chemical listings):

None of the ingredients is listed.

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## • 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

· 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.

#### · 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:



- *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.

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# Trade name: Multilink Automix (Base)

This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada.

· 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.

• \* Data compared to the previous version altered.

USA