SAFETY DATA SHEETS

This SDS packet was issued with item:

077106677

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).

077081102 077106503 077106511 077106529 077106537 077106685 077122468 077122484 077122492 077122617 077175425

3610-622



175 Pineview Drive, AMHERST NY 14228 2785 Skymark Ave. Unit 1, Mississauga, Ontario L4W 4Y3

For emergency only call INFOTRAC: 1-800-535-5053 In Canada, call CANUTEC: 613-996-6666

Page 1

FOR PROFESSIONAL DENTAL USE ONLY

Section 1: Product Identification & Use Primer

Product Multilink Metal Primer

Product # 576827

Section 2.1: Hazardous Ingredients					
Component	% Range	CAS#	PEL*	TLV*	LD50/LC50/TDLo
Tert. butyl alcohol	< 70	75-65-0	n.av.	n.av.	LD50 for rat is 3500 mg/kg
Methyl isobutyl ketone	< 25	108-10-1	n.av.	n.av.	LD50 for rat is 2080 mg/kg
Phosphonic acid acrylate	< 6	223681-84-3	n.av.	n.av.	
Benzoylperoxide	< 2	94-36-0		n.av.	LD50 for rat is > 7710 mg/kg
Ethoxylated Bis-EMA	0-5	41637-38-1		200 ppm	

Section 2.2: Other Ingredients *All Exposure limits are in milligram per cubic meter of air (mg/m3)

Component

% Range

CAS#

PEL*

TLV*

LD50/LC50/TDLo

Section 3: Physical Data

Boiling Point °C:

Melting Point °C:

n. ap.

pH: n. det.

Vapor Pressure mm Hg: n. ap.

Vapor Density air 1:

n. det.

Odor Threshold:

characteristic

Specific Gravity H₂O--1g/cm³: n. ap.

Appearance / Odor:

Clear liquid

Flash Point °C:

Section 4: Fire or Explosion Data 11

Autoignition °C: > 400

1.2 val %

Solubility in water: partially miscible

Flammable Limits % In Air / Upper: 9 val.% Extinguisher Media:

Not required.

Other Fire and Explosion Hazards: Highly flammable

Hazardous Combustion Products: Avoid ignition sources such as flames or spark producing equipment.



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Page 2

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Section 5: Reactivity Data

Chemical Stability: No

If No... Under What Conditions: n. ap.

Incompatibility with other Substances: Not required.

If So...Which Ones:

n. ap.

Reactivity and Under What Conditions: Polymerization with heat buildup may occur.

Hazardous Polymerization:

Avoid ignition sources such as flames or spark producing equipment.

Section 6: Toxicological Properties

Primary Routes of Entry:

Ingestion, inhalation, eyes, skin

Symptoms of Acute Exposure: Do not breathe vapor. Signs and symptoms of excessive exposure may be narcotic effects. Symptoms of Chronic Exposure: Prolonged or repeated skin contact may cause allergic skin reactions in some individuals.

Medical Conditions Generally Aggravated by Exposure:

Excessive exposure may cause eye and respiratory irritation.

Carcinogen/

Potential Carcinogen: No

NTP: No

Teratogenicity:

No

Reproductive Toxicity: No

No **Embryo Toxin:**

Sensitization:

Section 7: Preventative Measures

Eyes:

Safety goggles

Gloves: Solvent resistant gloves

OSHA Reg.: No

IARC No

Ventilation:

Provide adequate local ventilation.

Respiratory Protection: Leak and Spill Procedure: In poorly ventilated areas, use air-purifying respiratory protection apparatus (type A). Clean up with absorbent material. Do not allow to flow off into the drains or waters.

Waste Disposal Methods:

Dispose of according to all local, state, provincial and federal regulations

Storage:

Store at 2-8°C / 36-46°F.

Shipment:

UN # 1120 Class 3

Other Preventative Measures:

Avoid direct contact with eyes and skin.

Section 8: First Aid Measure

Inhalation: Remove victim to fresh air. If respiratory irritation is experienced, call a physician.

Ingestion: After ingestion call a physician immediately and show this safety data sheet. Do not induce vomiting. Give large amount s of water.

Eves:

Flush with plenty of water (10-15 Min.). Call a physician.

Skin:

Wash thoroughly with soap and water.

Section 9: Preparation Data

Prepared by: Anderjeet Gulati (716) 691-0010

Date: March 15, 2004

Disclaimer: The information and recommendations are taken from sources believed to be accurate; however, Ivoclar Vivadent, Inc. makes no w respect to the accuracy of the information or the suitability of the recommendation and assumes no liability to any user thereof.

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Phosphonic acid acrylate	< 6	223681-84-3	n.av.	n.av.	
Benzoylperoxide	< 2	94-36-0		n.av.	LD50 for rat is > 7710 mg/kg
Ethoxylated Bis-EMA	0-5	41637-38-1		200 ppm	

Section 2.2: Other Ingredients *All Exposure limits are in milligram per cubic meter of air (mg/m3)

Component

% Range

CAS#

PEL*

TLV*

LD50/LC50/TDLo

Section 3: Physical Data

Boiling Point °C:

Melting Point °C:

n. ap.

pH: n. det.

Vapor Pressure mm Hg: n. ap.

Vapor Density air 1:

n. det.

Odor Threshold:

characteristic

Specific Gravity H₂O--1g/cm³: n. ap.

Appearance / Odor:

Clear liquid

Flash Point °C:

Section 4: Fire or Explosion Data 11

Autoignition °C: > 400

1.2 val %

Solubility in water: partially miscible

Flammable Limits % In Air / Upper: 9 val.% Extinguisher Media:

Not required.

Other Fire and Explosion Hazards: Highly flammable

Hazardous Combustion Products: Avoid ignition sources such as flames or spark producing equipment.



175 Pineview Drive, AMHERST NY 14228 2785 Skymark Ave. Unit 1, Mississauga, Ontario L4W 4Y3

Page 2

For emergency only call INFOTRAC: 1-800-635-5053 In Canada, call CANUTEC: 613-996-6666

FOR PROFESSIONAL DENTAL USE ONLY

Section 5: Reactivity Data

Chemical Stability: No

If No... Under What Conditions: n. ap.

Incompatibility with other Substances: Not required.

If So...Which Ones:

n. ap.

Reactivity and Under What Conditions: Polymerization with heat buildup may occur.

Hazardous Polymerization:

Avoid ignition sources such as flames or spark producing equipment.

Section 6: Toxicological Properties

Primary Routes of Entry:

Ingestion, inhalation, eyes, skin

Symptoms of Acute Exposure: Do not breathe vapor. Signs and symptoms of excessive exposure may be narcotic effects. Symptoms of Chronic Exposure: Prolonged or repeated skin contact may cause allergic skin reactions in some individuals.

Medical Conditions Generally Aggravated by Exposure:

Excessive exposure may cause eye and respiratory irritation.

Carcinogen/

Potential Carcinogen: No

NTP: No

Teratogenicity:

No

Reproductive Toxicity: No

No **Embryo Toxin:**

Sensitization:

Section 7: Preventative Measures

Eyes:

Safety goggles

Gloves: Solvent resistant gloves

OSHA Reg.: No

IARC No

Ventilation:

Provide adequate local ventilation.

Respiratory Protection: Leak and Spill Procedure: In poorly ventilated areas, use air-purifying respiratory protection apparatus (type A). Clean up with absorbent material. Do not allow to flow off into the drains or waters.

Waste Disposal Methods:

Dispose of according to all local, state, provincial and federal regulations

Storage:

Store at 2-8°C / 36-46°F.

Shipment:

UN # 1120 Class 3

Other Preventative Measures:

Avoid direct contact with eyes and skin.

Section 8: First Aid Measure

Inhalation: Remove victim to fresh air. If respiratory irritation is experienced, call a physician.

Ingestion: After ingestion call a physician immediately and show this safety data sheet. Do not induce vomiting. Give large amount s of water.

Eves:

Flush with plenty of water (10-15 Min.). Call a physician.

Skin:

Wash thoroughly with soap and water.

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Prepared by: Anderjeet Gulati (716) 691-0010

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Material Safety Data Sheet

Multilink Automix



Date of issue / Reference 01.10.2007 lise / Version 2

Replaces version of 22.03.2005 hot

Date of printing 01.10.2007 **Sheet No. 1582** Page 1 of 5

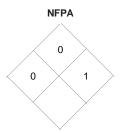
Company Ivoclar Vivadent AG, Bendererstrasse 2, FL - 9494 Schaan

Principality of Liechtenstein

1 Commercial product name and supplier

1.1 Commercial product name / Designation

Multilink Automix



HMIS			
Н	0		
F	0		
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 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 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

22-26 % Dimethacrylates (CAS No. 1565-94-2, 72869-86-4, 41637-

38-1)

R36/38: Irritating to eyes and skin.

CAS No. 868-77-9 6-7 % HEMA

Xi: Irritant. R43: May cause sensitisation by skin contact. R36/38: Irritating to eyes and

skin.

CAS No. 94-36-0 < 1 % Benzoylperoxide

Xi: Irritant. E: Explosive. R2: Risk of explosion by shock, friction, fire or other sources of

 $ignition.\ R36: Irritating\ to\ eyes.\ R43:\ May\ cause\ sensitisation\ by\ skin\ contact.$

2.3 Further information None.

Multilink Automix **Material Safety Data Sheet** Date of issue / Reference 01.10.2007 lise / Version 2 22.03.2005 Replaces version of hot 01.10.2007 Date of printing Page 2 of 5 Sheet No. 1582 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. First aid measures 4.1 Flush with plenty of water. Consult a physician if irritation persists. Eye contact 4.2 Skin contact Wash thoroughly with water. 4.3 Ingestion Give large amounts of water. No hazards anticipated from swallowing small amounts incidentally to normal handling. If you feel unwell, seek medical advice (show this safety data sheet). 4.4 Inhalation Remove to fresh air. 4.5 Further information None. 5 Fire-fighting measures 5.1 Suitable extinguishing media Water fog, carbon dioxide, foam, dry chemicals. 5.2 Extinguishing media to avoid None known Test method: 5.3 Flash point 5.4 Ignition temperature not determined 5.5 **Explosion limits** Lower: Upper: not determined 5.6 Further information None. Clean up mechanically. 6 Accidental release measures Dispose of according to local and national regulations. 7 Handling and storage 7.1 Only adequately trained personnel should handle this product. Handling Keep out of reach of children. Usual hygienic measures for dental practice. 7.2 Industrial hygiene When using, do not eat, drink or smoke.

Not required.

Store at 2-8 °C

Avoid exposure to direct sunlight.

7.3

7.4

7.5

Storage

Place of storage

Fire- and explosion-protection

Material Safety Data Sheet

Multilink Automix



Date of issue / Reference 01.10.2007 lise / Version 2

Replaces version of 22.03.2005 hot

Date of printing 01.10.2007 **Sheet No. 1582** Page 3 of 5

8 Exposure controls / Personal protection

8.1 Technical measures Good general ventilation should be sufficient.

8.2 Control of threshold limits None established.

8.3 Personal protective equipment

8.3.1 Respiratory protection Not required.

8.3.2 Hand protection Gloves.

Commercial medical gloves do not provide protection against the

sensitizing effect of methacrylates.

8.3.3 Eye protection Safety goggles.

8.3.4 Other None.

9 Physical and chemical properties

9.1 Appearance Paste

9.2 Colour off-white to cream9.3 Odour practically odourless

9.4 Change of physical state Test method:

not applicable

9.5 Density

not determined

9.6 Vapour pressure

not applicable

9.7 Viscosity

not determined

9.8 Solubility

Solubility in water < 0.1 %

9.9 pH

not determined

9.10 Further information None.

Material Safety Data Sheet

Multilink Automix



Date of issue / Reference lise / Version 2 01.10.2007 22.03.2005 Replaces version of hot 01.10.2007 Date of printing Sheet No. 1582 Page 4 of 5 10 Stability and reactivity 10.1 Thermal decomposition None, if used in accordance to instructions. 10.2 None under normal conditions of storage and use. Hazardous decomposition products 10.3 Hazardous reactions None. 10.4 Further information Avoid heat. 11 **Toxicological information** Acute toxicity 11.1 This product possesses no cytotoxic potential. non-mutagenic 11.2 Uncured material: prolonged or frequently repeated skin contact Subacute / Chronic toxicity may cause allergic skin reactions. 11.3 Further information No hazards anticipated from swallowing small amounts incidentally to normal handling. No ecological problems to be anticipated if properly handled and 12 **Ecological information** used. nearly insoluble Take to a waste incineration plant, under conditions approved by the 13 **Disposal considerations** local authority. 14 **Transport information** 14.1 RID Transport at land **ADR UN Number** Kemler Number Packing Group Proper shipping name **ADNR IMDG** Transport at sea **UN Number EMS MFAG** Packing Group Proper shipping name

Material Safety Data Sheet Multilink Automix lise / Version 2 Date of issue / Reference 01.10.2007 22.03.2005 Replaces version of hot 01.10.2007 Date of printing Page 5 of 5 **Sheet No. 1582** 14.3 Air transport ICAO / IATA-DGR UN Number Proper shipping name Subsidiary Risk Labels Packing Group Passenger airplane **Packing Instructions** max. Cargo Airplane **Packing Instructions** max. 14.4 Further information Product is not classified as a dangerous 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 regulations and has been reviewed by the US Food and drug Administration. This product does not require classification as Dangerous Goods. 15.1 National regulations 15.2 NFPA Storage Further information 15.3 None.

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.

Version: 2

Changes: 1.5

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

16

Other information

91/155/EEC



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 Primer A
- · 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 and self-etching primer
- 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

Eye Dam. 1 H318 Causes serious eye damage.

- · Label elements
- · GHS label elements

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

· Hazard pictograms



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

2,2'-[(4-methylphenyl)imino]bisethanol

· Hazard statements

Causes serious eye damage.

· Precautionary statements

Wear eye protection / face protection.

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

· 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.

(Contd. on page 2)

Printing date 12.12.2019 Version number 6 Revision: 12.12.2019

Trade name: Multilink Primer A

(Contd. of page 1)

- · 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:

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

4 First aid measures

- · Description of first aid measures
- · General information: No special measures required.
- · After inhalation: Supply fresh air; consult doctor in case of complaints.
- · After skin contact:

Rinse with water.

Generally the product does not irritate the skin.

· 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 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:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

· Reference to other sections

No dangerous substances are released.

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

(Contd. on page 3)

Printing date 12.12.2019 Version number 6 Revision: 12.12.2019

Trade name: Multilink Primer A

(Contd. of page 2)

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.

Keep container tightly sealed.

Protect from heat and direct sunlight.

· 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.

- · Respiratory protection: Not required.
- Protection of hands:

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.

· Eve protection: Safety glasses

N7

Printing date 12.12.2019 Version number 6 Revision: 12.12.2019

Trade name: Multilink Primer A

(Contd. of page 3)

Information on basic physical and c	chemical properties
General Information Appearance:	
Form:	Fluid
Colour:	Colourless
Odour:	Characteristic
Odour threshold:	Not determined.
pH-value:	Not determined.
Change in condition	
Melting point/freezing point:	Undetermined.
Initial boiling point and boiling ra	inge: Undetermined.
Flash point:	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:	Not determined.
Relative density	Not determined.
Vapour density	Not determined.
Evaporation rate	Not determined.
Solubility in / Miscibility with	
water:	Soluble.

10 Stability and reactivity

· Viscosity:

Dynamic:

Kinematic:

· Other information

· Partition coefficient: n-octanol/water:

- · 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.

Not determined.

Not determined.

Not determined.

No further relevant information available.

- · Possibility of hazardous reactions No dangerous reactions known.
- · Conditions to avoid No further relevant information available.
- · 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.

(Contd. on page 5)

Printing date 12.12.2019 Version number 6 Revision: 12.12.2019

Trade name: Multilink Primer A

(Contd. of page 4)

- · Respiratory or skin sensitisation No sensitising effects known.
- · 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

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

UN-Number	
ADR/RID/ADN, ADN, IMDG, IATA	Void
UN proper shipping name	W · 1
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 Marpol	
and the IBC Code	Not applicable.
Transport/Additional information:	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).

Printing date 12.12.2019 Version number 6 Revision: 12.12.2019

Trade name: Multilink Primer A

(Contd. of page 5)

· 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

None of the ingredients is listed.

· GHS label elements

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

· Hazard pictograms



GHS05

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

2,2'-[(4-methylphenyl)imino]bisethanol

· Hazard statements

Causes serious eve damage.

· Precautionary statements

Wear eye protection / face protection.

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

- · 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

H302 Harmful if swallowed.

H318 Causes serious eye damage.

· Abbreviations and acronyms:

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

Acute Tox. 4: Acute toxicity – Category 4

Eye Dam. 1: Serious eye damage/eye irritation – Category 1