SAFETY DATA SHEETS

This SDS packet was issued with item:

077089550

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

077086747

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).

077083538 077086663



Printing date 02/27/2013 Version number 8

Reviewed on 02/27/2013

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

- · Product identifier
- · Trade name: Syntac Adhesive
- · Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.
- · Application of the substance / the preparation Enamel-Dentin Bonding Agent
- · 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

Harmful

Harmful by inhalation and if swallowed.

Irritant

Irritating to respiratory system and skin. Risk of serious damage to eyes. May cause sensitisation by inhalation and 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.

(Contd. on page 2)

- IISA

Printing date 02/27/2013 Version number 8 Reviewed on 02/27/2013

Trade name: Syntac Adhesive

(Contd. of page 1)

· Code letter and hazard designation of product:



Harmful

· Risk phrases:

Harmful by inhalation and if swallowed.

Irritating to respiratory system and skin.

Risk of serious damage to eyes.

May cause sensitisation by inhalation and skin contact.

· Safety phrases:

Do not breathe vapour/spray.

Avoid contact with skin.

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

Wear suitable gloves and eye/face protection.

In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). This material and its container must be disposed of as hazardous waste.

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



Health = 2 Fire = 0Reactivity = 0

· HMIS-ratings (scale 0 - 4)



- · 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:		
25852-47-5 polyethylene glycol dimethacrylate	25-50%	
111-30-8 glutaral .	2.5-10%	

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: Immediately rinse with water.
- · After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.

(Contd. on page 3)

-USA

Printing date 02/27/2013 Version number 8 Reviewed on 02/27/2013

Trade name: Syntac Adhesive

(Contd. of page 2)

- · After swallowing: Do not induce vomiting; immediately call for medical help.
- · 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.

- · For safety reasons unsuitable extinguishing agents: Water with full jet
- · Special hazards arising from the substance or mixture No further relevant information available.
- · Advice for firefighters
- · Protective equipment: Mouth respiratory protective device.
- · Additional information Cool endangered receptacles with water spray.

6 Accidental release measures

· Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

· Environmental precautions:

Dilute with plenty of water.

Do not allow to enter sewers/ surface or ground water.

 $\cdot \textit{Methods and material for containment and cleaning up:} \\$

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

Dispose contaminated material as waste according to item 13.

Ensure adequate ventilation.

· 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.

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

- · 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: Keep receptacle tightly sealed.
- · Specific end use(s) No further relevant information available.

USA

(Contd. on page 4)

Printing date 02/27/2013 Version number 8 Reviewed on 02/27/2013

Trade name: Syntac Adhesive

(Contd. of page 3)

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:

111-30-8 glutaral

REL Short-term value: C 0.8 mg/m³, C 0.2 ppm

See Pocket Guide App. C

TLV Short-term value: C 0.2 mg/m³, C 0.05 ppm

SEN; activated or inactivated

- · 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.

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

Keep away from foodstuffs, beverages and feed.

Do not inhale gases / fumes / aerosols.

Avoid contact with the eyes and skin.

· 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.

· Not suitable are gloves made of the following materials:

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

· Eye protection:



Tightly sealed goggles

USA

(Contd. on page 5)

Printing date 02/27/2013 Version number 8 Reviewed on 02/27/2013

Trade name: Syntac Adhesive

(Contd. of page 4)

Physical and chemical proper	ties — — — — — — — — — — — — — — — — — — —			
· Information on basic physical and chemical properties				
· General Information				
· Appearance:				
Form:	Fluid			
Color:	Colorless			
· 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):	1.38 g/cm³ (11.516 lbs/gal)			
Relative density	Not determined.			
· Vapour density	Not determined.			
Evaporation rate	Not determined.			
Solubility in / Miscibility with				
Water:	Fully miscible.			
Partition coefficient (n-octanol/wat	t er): 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.
- · Chemical stability Stable under normal handling and storage conditions.
- · Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Possibility of hazardous reactions No dangerous reactions known.
- · Conditions to avoid No further relevant information available.
- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: None under normal conditions of storage and use.

TC A

(Contd. on page 6)

Printing date 02/27/2013 Version number 8 Reviewed on 02/27/2013

Trade name: Syntac Adhesive

(Contd. of page 5)

11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity:

· LD/LC50 values	s that are re	levant for cl	lassification:
------------------	---------------	---------------	----------------

111-30-8 glutaral

Oral LD50 134 mg/kg (rat)
Dermal LD50 2560 mg/kg (rabbit)

- · Primary irritant effect:
- · on the skin: Irritant to skin and mucous membranes.
- · on the eye: Strong irritant with the danger of severe eye injury.
- · Sensitization:

Sensitization possible through inhalation.

Sensitization possible through skin contact.

· Additional toxicological information:

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

Harmful

Irritant

- · Carcinogenic categories
- · 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.
- $\cdot \textit{Additional ecological information:}$
- · General notes:

Water hazard class 3 (Self-assessment): extremely hazardous for water

Do not allow product to reach ground water, water course or sewage system, even in small quantities.

- · 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.

(Contd. on page 7)

USA

Printing date 02/27/2013 Version number 8 Reviewed on 02/27/2013

Trade name: Syntac Adhesive

(Contd. of page 6)

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

UN-Number	Void
DOT, ADR, ADN, IMDG, IATA	voia
UN proper shipping name	
DOT, ADN, IMDG, IATA	Void
ADR	2922 CORROSIVE LIQUID, TOXIC, N.O.S. (glutaral)
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

- $\cdot \textit{Safety, health and environmental regulations/legislation specific for the substance or \textit{mixture}}\\$
- · 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.

(Contd. on page 8)

- USA

Printing date 02/27/2013 Version number 8 Reviewed on 02/27/2013

Trade name: Syntac Adhesive

(Contd. of page 7)

· Carcinogenic categories

· EPA (Environmental Protection Agency)

None of the ingredients is listed.

· TLV (Threshold Limit Value established by ACGIH)

111-30-8 glutaral

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.

· 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:



Harmful

· Risk phrases:

Harmful by inhalation and if swallowed.

Irritating to respiratory system and skin.

Risk of serious damage to eyes.

May cause sensitisation by inhalation and skin contact.

· Safety phrases:

Do not breathe vapour/spray.

Avoid contact with skin.

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

Wear suitable gloves and eye/face protection.

In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). 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.

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.

* ***

IVOCLAR NORTH AMERICA

175 Pineview Drive, AMHERST NY 14228 23 Hennover Drive, ST. CATHARINES, ONTARIO L2W 1A3

Syntac^a Primer

Page 1

For emergency only call INFOTRACT: In Canada, call CANUTEC:

1-800-535-5053 613-996-6666

FOR PROFESSIONAL DENTAL USE ONLY

Section 1: Product Identification & Use Dentin Bonding Primer

Product Syntac® Primer

Product # 6070100

Component	% Range	CAS#	PEL	TLV	LD50/LC50/TDLo
Tetraethylene glycoldimethacrylate	15-40	n.av,	n.ay.	ก.ฮง.	n.av.
Acetone	30-60	67-64-1	1000 ppm	750ppm	5500 mg/kg LD-50 (ivn-rat
Matelc acid	1-5	110-16-7	n.ev.	n.ev.	708 mg/kg LD-50 (oral rat)
Additional ingredients:					
Water	15-40				

LD-50 (oral rat) Syntac Primer > 5000 mg/kg

Section 3: Physical Data

Boiling Point °C;

n.ep.

Melting Point °C:

п.ар.

pH: 1.3

Vapor Pressure mm Hg:

п.ар.

Vapor Density air 1:

n.ap.

Odor Threshold:

None

Specific Gravity H,O-1g/cm³:

1.39 g/cm3 (20 °C)

Appearance / Odor:

clear liquids, acetone odor

Section 4: Fire or Explosion Data

Flash Point °C:

< 23 °C

Autoignition *C: >500 *C

Solubility in water: partially miscible

Flammable Limits % in Air / Upper: 13

Lower:

2.5

Extinguisher Media:

Water fog, carbon dioxide, foam, dry chemicals

Other Fire and Explosion Hazards: Acelone, flammeble when exposed to heat or flame

Hazardous Combustion Products: Cool containers in the vicinity of the blaze using a water sprey.

Variolink II Kit [Vivadent/Ivoclar]

Obtained by Global Safety Management, www.globalsafetynet.com, (877) 683-7460

IVOCLAR NORTH AMERICA包

NOCLAR

Syntac* Primer

Page 2

175 Pineview Drive, AMHERST NY 14228 23 Hannover Drive, ST. CATHARINES, ONTARIO L2W 1A3

For emergency only call INFOTRACT: In Canada, call CANUTEC:

1-800-535-5053 613-998-6666

for professional dental use only

Section 5: Reactivity Data

Chemical Stability: Stable

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

incompatibility with other Substances: No

If So...Which Ones:

n.ap.

Reactivity and Under What Conditions: no Hazardous Polymerization:

Will not occur

Section 6: Toxicological Properties

Primary Routes of Entry:

Ingestion, inhelation, eyes, skin

Symptoms of Acute Exposure:

LD-50 (oral rat) is > 5000 mg/kg.

Symptoms of Chronic Exposure: Prolonged or repeated exposure to uncured material may cause irritation of the skin, mucous membranes and eyes.

Medical Conditions Generally

Aggravated by Exposure:

Highly figmmebia, Irritating to eyes and skin. May cause sensitization by skin contact.

NTP: No

Carcinogen/

Potential Carcinogen:

LARC No

OSHA Reg.:

Nο

Teratogenicity:

No No

Reproductive Toxicity: No

Embryo Toxin:

No

Sensitization:

Section 7: Preventative Measures

Eyes:

Safety goggles

Gloves: Rubber gloves

Ventilation:

Use only with adequate ventilation.

Respiratory Protection:

in poorly ventilated areas, use respiratory protection apparatus.

Leak and Spill Procedure:

Clean up with absorpent material. Clean area with large amounts of water. Prevent skin and eye contact.

Waste Disposal Methods:

Take to a special waste incineration plant, in line with local regulations.

Storage:

Store at 2-28°C / 26-82°F.

Shipment:

UN# 1090

Other Preventative Measures:

Avoid inhelation of vapors and skin, muccus membran and eye contact. Only adequately trained personnel should

handle this product.

Section 8: First Aid Measure

inhalation:

Remove viotim to fresh air.

Ingestion:

After ingestion call a physician immediately and show packaging or label.

Eyes:

Flush eyes with water for 15 minutes, consult physician

Skin:

Wash thoroughly with soap and water.

Section 9: Preparation Data

Prepared by: Peter Mancuso (716) 691-0010

Date: July 19, 1998

Ref:

The information and recommendations are taken from sources believed to be accurate; however, horder North America makes no warranty with

respect to the accuracy of the information or the suitability of the recommendation and assumes no liability to any user thereof.



Printing date 09/22/2011 Version number 6 Reviewed on 09/22/2011

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

- · Product identifier
- · Trade name: Heliobond
- · Application of the substance / the preparation Light-curing primer agent
- · 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.

2785 Skymark Avenue, Unit 1, Mississauga, Ontario LAW4Y3

CANADA

Tel. +1 800 263 8182

Fax +1 905 238 5711

- · 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 Composition/information on ingredients

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

· Dangerous	rous components:			
1565-94-2	Bis-GMA	♦ <i>H315; H319</i>	50-100%	
109-16-0	triethyleneglycol dimethacrylate	♦ Н315; Н319; Н317; Н335	25-50%	

3 Hazards identification

- · Classification of the substance or mixture
- · Classification according to Directive 67/548/EEC or Directive 1999/45/EC



Irritating to eyes, respiratory system and skin. 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.

(Contd. on page 2)

Printing date 09/22/2011 Version number 6 Reviewed on 09/22/2011

Trade name: Heliobond

(Contd. of page 1)

· Code letter and hazard designation of product:



Irritant

· Hazard-determining components of labelling:

triethyleneglycol dimethacrylate

· Risk phrases:

Irritating to eyes, respiratory system and skin.

May cause sensitisation by skin contact.

· Safety phrases:

Do not breathe fumes/aerosol.

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.

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



Health = 1 Fire = 0Reactivity = 0

· HMIS-ratings (scale 0 - 4)



REACTIVITY 0 Reactivity = 0

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: Immediately rinse with water.
- · After eve contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

· After swallowing: If symptoms persist consult doctor.

5 Firefighting measures

· 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.
- · 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).

(Contd. on page 3)

USA

Printing date 09/22/2011 Version number 6 Reviewed on 09/22/2011

Trade name: Heliobond

(Contd. of page 2)

Ensure adequate ventilation.

· 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.

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

- · Information about protection against explosions and fires: 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.

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.
- · 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.
- · Personal protective equipment:
- · General protective and hygienic measures:

Usual hygienic measures for dental practice.

Wash hands before breaks and at the end of work.

Do not inhale gases / fumes / aerosols.

Avoid contact with the eyes and skin.

Keep away from foodstuffs, beverages and feed.

- · 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. 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.

(Contd. on page 4)

-USA

Printing date 09/22/2011 Version number 6 Reviewed on 09/22/2011

Trade name: Heliobond

(Contd. of page 3)

· 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

Physical and chemical properti	es
General Information	
Appearance:	
Form:	Fluid
Color:	Yellowish
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):	1.14 g/cm³ (9.513 lbs/gal)
Relative density	Not determined.
Vapour density	Not determined.
Evaporation rate	Not determined.
Solubility in / Miscibility with	
Water:	Not miscible or difficult to mix.
Segregation coefficient (n-octonol/we	ater): Not determined.
Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
Other information	No further relevant information available.

10 Stability and reactivity

- · Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: None under normal conditions of storage and use.

11 Toxicological information

- · Acute toxicity:
- · Primary irritant effect:
- · on the skin: Irritant to skin and mucous membranes.

(Contd. on page 5)

Printing date 09/22/2011 Version number 6 Reviewed on 09/22/2011

Trade name: Heliobond

(Contd. of page 4)

- · on the eye: 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

12 Ecological information

- · Acquatic toxicity: No further relevant information available.
- $\cdot \textit{Persistence and degradability} \ \textit{No further relevant information available}.$
- · Behavior in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- · Additional ecological information:
- · General notes:

Water hazard class 2 (Self-assessment): hazardous for water

Do not allow product to reach ground water, water course or sewage system.

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	W · 1
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.

-USA

(Contd. on page 6)

Printing date 09/22/2011 Version number 6 Reviewed on 09/22/2011

Trade name: Heliobond

(Contd. of page 5)

15 Regulatory information

- · 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.

· NTP (National Toxicology Program)

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.

· 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:

 $trie thy lene gly col\ dimetha crylate$

· Risk phrases:

Irritating to eyes, respiratory system and skin. May cause sensitisation by skin contact.

· Safety phrases:

Do not breathe fumes/aerosol. Avoid contact with skin.

(Contd. on page 7)

Printing date 09/22/2011 Version number 6 Reviewed on 09/22/2011

Trade name: Heliobond

(Contd. of page 6)

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. 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.

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.

USA



Printing date 01/14/2019 Version number 10 Reviewed on 01/14/2019

1 Identification

- · Product identifier
- Trade name: Syntac Adhesive
- · Application of the substance / the mixture Enamel-Dentin Bonding Agent
- · 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 SDS Assistance: US: 1-800-533-6825 Canada: 1-800-263-8182

2 Hazard(s) identification

· Classification of the substance or mixture

Acute Tox. 4 H302 Harmful if swallowed. Skin Irrit. 2 H315 Causes skin irritation.

Eye Dam. 1 H318 Causes serious eye damage.

Resp. Sens. 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

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 labeled according to the Globally Harmonized System (GHS).

· Hazard pictograms







GHS05

IS05 GHS07

507 GHS0

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

glutaral

polyethylene glycol dimethacrylate

(Contd. on page 2)

Printing date 01/14/2019 Version number 10 Reviewed on 01/14/2019

Trade name: Syntac Adhesive

(Contd. of page 1)

· Hazard statements

Harmful if swallowed.

Causes skin irritation.

Causes serious eye damage.

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

May cause an allergic skin reaction.

May cause respiratory irritation.

· Precautionary statements

Avoid breathing dust/fume/gas/mist/vapors/spray

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

If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.

If skin irritation or rash occurs: Get medical advice/attention.

If experiencing respiratory symptoms: Call a POISON CENTER/doctor.

Additional information:

Medical devices are exempt from the labeling provisions of GHS according to the Hazard Communication Standard (HCS).

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



Health = 2 Fire = 0Reactivity = 0

· HMIS-ratings (scale 0 - 4)



- · 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:			
CAS: 25852-47-5	polyethylene glycol dimethacrylate	25-50%	
CAS: 111-30-8	glutaral	2.5-<10%	

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: Immediately rinse with water.
- · After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.
- · After swallowing: Do not induce vomiting; immediately call for medical help.
- · Information for doctor:
- Most important symptoms and effects, both acute and delayed No further relevant information available.

(Contd. on page 3)

Printing date 01/14/2019 Version number 10 Reviewed on 01/14/2019

Trade name: Syntac Adhesive

(Contd. of page 2)

· Indication of any immediate medical attention and special treatment needed No further relevant information available.

5 Fire-fighting measures

- · Extinguishing media
- · Suitable extinguishing agents:
- CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- · For safety reasons unsuitable extinguishing agents: Water with full jet
- · Special hazards arising from the substance or mixture No further relevant information available.
- · Advice for firefighters
- · Protective equipment: Mouth respiratory protective device.
- · Additional information Cool endangered receptacles with water spray.

6 Accidental release measures

· Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

· Environmental precautions:

Dilute with plenty of water.

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).

Dispose contaminated material as waste according to item 13.

Ensure adequate ventilation.

· 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.

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

- 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: 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.

(Contd. on page 4)

Printing date 01/14/2019 Version number 10 Reviewed on 01/14/2019

Trade name: Syntac Adhesive

(Contd. of page 3)

- · Control parameters
- · Components with limit values that require monitoring at the workplace:

The following constituent is the only constituent of the product which has a PEL, TLV or other recommended exposure limit.

At this time, the remaining constituent has no known exposure limits.

CAS: 111-30-8 glutaral

REL Ceiling limit value: 0.8 mg/m³, 0.2 ppm

See Pocket Guide App. C

TLV Ceiling limit value: 0.2 mg/m³, 0.05 ppm

(SEN) NIC-DSEN; RSEN; activated or inactivated

- · 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 and dental laboratories.

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

Keep away from foodstuffs, beverages and feed.

Do not inhale gases / fumes / aerosols.

Avoid contact with the eyes and skin.

Breathing equipment:

Not necessary if room is well-ventilated.

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

After use of gloves apply skin-cleaning agents and skin cosmetics.

· Material of gloves

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· 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:



Tightly sealed goggles

· **Body protection:** Protective work clothing

9 Physical and chemical properties

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

Form: Fluid

(Contd. on page 5)

Printing date 01/14/2019 Version number 10 Reviewed on 01/14/2019

Trade name: Syntac Adhesive

		(Contd. of page
Color:	Colorless	
Odor:	Characteristic	
Odor 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):	1.074 g/cm³ (8.963 lbs/gal)	
Relative density	Not determined.	
Vapor density	Not determined.	
Evaporation rate	Not determined.	
Solubility in / Miscibility with		
Water:	Fully miscible.	
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.
- · Chemical stability Stable under normal handling and storage conditions.
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Possibility of hazardous reactions No dangerous reactions known.
- · Conditions to avoid No further relevant information available.
- $\cdot \textbf{\it Incompatible materials:} \ \textit{No further relevant information available}.$
- · Hazardous decomposition products: None under normal conditions of storage and use.

11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity:
- · on the skin: Irritant to skin and mucous membranes.
- on the eye: Strong irritant with the danger of severe eye injury.
- · Sensitization:
- Sensitization possible through inhalation.
- Sensitization possible through skin contact.

(Contd. on page 6)

Printing date 01/14/2019 Version number 10 Reviewed on 01/14/2019

Trade name: Syntac Adhesive

(Contd. of page 5)

- · Additional toxicological information: No further relevant information available.
- · Carcinogenic categories
- · NTP (National Toxicology Program)

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

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 3 (Self-assessment): extremely hazardous for water

Do not allow product to reach ground water, water course or sewage system, even in small quantities.

- · 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/RID/ADN, ADN, IMDG, IATA Void
- · UN proper shipping name

· DOT, ADN, IMDG, IATA Void

· ADR/RID/ADN 2922 CORROSIVE LIQUID, TOXIC, N.O.S. (glutaral)

- · Transport hazard class(es)
- · DOT, ADR/RID/ADN, ADN, IMDG, IATA
- Class
- · Packing group
- · DOT, ADR/RID/ADN, IMDG, IATA Void
- · Environmental hazards:
- · Marine pollutant: No

(Contd. on page 7)

Printing date 01/14/2019 Version number 10 Reviewed on 01/14/2019

Trade name: Syntac Adhesive

	(Contd. of page
· Special precautions for user	Not applicable.
· Transport in bulk according to Annex MARPOL73/78 and the IBC Code	II of Not applicable.
· Transport/Additional information:	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).
· UN ''Model Regulation'':	Void

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)

CAS: 111-30-8 glutaral

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

None of the ingredients is listed.

· GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

· Hazard pictograms







GHS05

GHS07

· Signal word Danger

(Contd. on page 8)

A4

Printing date 01/14/2019 Version number 10 Reviewed on 01/14/2019

Trade name: Syntac Adhesive

(Contd. of page 7)

· Hazard-determining components of labeling:

glutaral

polyethylene glycol dimethacrylate

· Hazard statements

Harmful if swallowed.

Causes skin irritation.

Causes serious eve damage.

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

May cause an allergic skin reaction.

May cause respiratory irritation.

· Precautionary statements

Avoid breathing dust/fume/gas/mist/vapors/spray

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

If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.

If skin irritation or rash occurs: Get medical advice/attention.

If experiencing respiratory symptoms: Call a POISON CENTER/doctor.

· National regulations:

· Other regulations, limitations and prohibitive regulations

The product is a medical device according to the 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.

· 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.

Date of preparation / last revision 01/14/2019 / 9

· 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

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit Acute Tox. 4: Acute toxicity – Category 4

Skin Irrit. 2: Skin corrosion/irritation – Category 2

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

Resp. Sens. 1: Respiratory sensitisation - Category 1

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.



Printing date 03/25/2019 Version number 8 Reviewed on 01/28/2019

1 Identification

- · Product identifier
- · Trade name: Heliobond
- · Application of the substance / the mixture Light-curing primer agent
- · 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 SDS Assistance: US: 1-800-533-6825 Canada: 1-800-263-8182

2 Hazard(s) 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.

STOT SE 3 H335 May cause respiratory irritation.

- · Label elements
- · GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

· Hazard pictograms



- · Signal word Warning
- · Hazard-determining components of labeling:

Bis-GMA

triethylene glycol dimethacrylate

· Hazard statements

Causes skin irritation.

(Contd. on page 2)

Printing date 03/25/2019 Version number 8 Reviewed on 01/28/2019

Trade name: Heliobond

(Contd. of page 1)

Causes serious eye irritation.

May cause an allergic skin reaction.

May cause respiratory irritation.

· Precautionary statements

Wear protective gloves/protective clothing/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.

If skin irritation or rash occurs: Get medical advice/attention.

If eye irritation persists: Get medical advice/attention.

Wash contaminated clothing before reuse.

Additional information:

Medical devices are exempt from the labeling provisions of GHS according to the Hazard Communication Standard (HCS).

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



Health = 2Fire = 0Reactivity = 0

· HMIS-ratings (scale 0 - 4)



2 Health = 2 Fire = 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:		
ſ	CAS: 36425-15-7	Bis-GMA	50-100%
	CAS: 109-16-0	triethylene glycol dimethacrylate	25-50%

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: Immediately 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.

(Contd. on page 3)

Printing date 03/25/2019 Version number 8 Reviewed on 01/28/2019

Trade name: Heliobond

(Contd. of page 2)

· Indication of any immediate medical attention and special treatment needed No further relevant information available.

5 Fire-fighting 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:

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

Ensure adequate ventilation.

· 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.

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

- 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.

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.

(Contd. on page 4)

Printing date 03/25/2019 Version number 8 Reviewed on 01/28/2019

Trade name: Heliobond

(Contd. of page 3)

- · Exposure controls
- · 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.

Do not inhale gases / fumes / aerosols.

Avoid contact with the eyes and skin.

Keep away from foodstuffs, beverages and feed.

- · 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. 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.

- · 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

Information on basic physical and General Information	chemical properties	
Appearance:		
Form:	Fluid	
Color:	Yellowish	
Odor:	Characteristic	
Odor 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.	

(Contd. on page 5)

Printing date 03/25/2019 Version number 8 Reviewed on 01/28/2019

Not determined.

Not determined.

Trade name: Heliobond

· Explosion limits: Lower:

Upper:

(Contd. of page 4)

• Vapor pressure: Not determined.
 • Density at 20 °C (68 °F): 1.14 g/cm³ (9.513 lbs/gal)

Relative density
 Vapor density
 Evaporation rate
 Not determined.
 Not determined.

· Solubility in / Miscibility with

Water: Not miscible or difficult to mix.

· 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.

· 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:
- on the skin: Irritant to skin and mucous membranes.
- · on the eye: 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
- · NTP (National Toxicology Program)

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

US

Printing date 03/25/2019 Version number 8 Reviewed on 01/28/2019

Trade name: Heliobond

(Contd. of page 5)

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 2 (Self-assessment): hazardous for water

Do not allow product 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, ADR/RID/ADN, ADN, IMDG, IAT	TA Void
UN proper shipping name DOT, ADR/RID/ADN, ADN, IMDG, IAT	FA Void
Transport hazard class(es)	
DOT, ADR/RID/ADN, ADN, IMDG, IAT Class	Γ A Void
Packing group DOT, ADR/RID/ADN, IMDG, IATA	Void
Environmental hazards: Marine pollutant:	No
Special precautions for user	Not applicable.
Transport in bulk according to Annex II MARPOL73/78 and the IBC Code	of Not applicable.
Transport/Additional information:	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).
UN ''Model Regulation'':	Void

Printing date 03/25/2019 Version number 8 Reviewed on 01/28/2019

Trade name: Heliobond

(Contd. of page 6)

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.

· GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

· Hazard pictograms



GHS07

- · Signal word Warning
- · Hazard-determining components of labeling:

Bis-GMA

triethylene glycol dimethacrylate

· Hazard statements

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

May cause respiratory irritation.

· Precautionary statements

Wear protective gloves/protective clothing/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.

(Contd. on page 8)

Printing date 03/25/2019 Version number 8 Reviewed on 01/28/2019

Trade name: Heliobond

(Contd. of page 7)

If skin irritation or rash occurs: Get medical advice/attention.

If eye irritation persists: Get medical advice/attention.

Wash contaminated clothing before reuse.

· National regulations:

· Other regulations, limitations and prohibitive regulations

The product is a medical device according to the 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.

· 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.

Date of preparation / last revision 03/25/2019 / 7

· 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

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

 ${\it Skin Irrit.~2: Skin corrosion/irritation-Category~2}$

Eye Irrit. 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.

US



Printing date 01/14/2019 Version number 11 Reviewed on 01/14/2019

1 Identification

- · Product identifier
- · Trade name: Syntac Primer
- · Application of the substance / the mixture Enamel-Dentin Bonding Agent
- · 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 SDS Assistance: US: 1-800-533-6825 Canada: 1-800-263-8182

2 Hazard(s) identification

· Classification of the substance or mixture

Flam. Liq. 2 H225 Highly flammable liquid and vapor.

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.

STOT SE 3 H335-H336 May cause respiratory irritation. May cause drowsiness or dizziness.

- · Label elements
- · GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

· Hazard pictograms





GHS02

GHS07

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

 $triethylene\ glycol\ dimethacrylate$

acetone

maleic acid

(Contd. on page 2)

Printing date 01/14/2019 Version number 11 Reviewed on 01/14/2019

Trade name: Syntac Primer

(Contd. of page 1)

polyethylene glycol dimethacrylate

· Hazard statements

Highly flammable liquid and vapor.

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

May cause respiratory irritation. May cause drowsiness or dizziness.

· Precautionary statements

Keep away from heat/sparks/open flames/hot surfaces. No smoking.

Keep container tightly closed.

Avoid breathing mist/vapours/spray.

Wear protective gloves / eye protection.

If skin irritation or rash occurs: Get medical advice/attention.

If eye irritation persists: Get medical advice/attention.

Additional information:

Medical devices are exempt from the labeling provisions of GHS according to the Hazard Communication Standard (HCS).

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



Health = 1 Fire = 3Reactivity = 0

· HMIS-ratings (scale 0 - 4)



- · 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:		
CAS: 67-64-1	acetone	25-50%
CAS: 109-16-0	triethylene glycol dimethacrylate	10-25%
CAS: 25852-47-5	polyethylene glycol dimethacrylate	2.5-<10%
CAS: 110-16-7	maleic acid	2.5-<10%

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: Immediately rinse with water.
- After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.

(Contd. on page 3)

Printing date 01/14/2019 Version number 11 Reviewed on 01/14/2019

Trade name: Syntac Primer

(Contd. of page 2)

· 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:

CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

- For safety reasons unsuitable extinguishing agents: Water with full jet
- Special hazards arising from the substance or mixture No further relevant information available.
- Advice for firefighters
- · Protective equipment: No special measures required.
- · Additional information

Fumes are heavier than air.

Cool endangered receptacles with water spray.

6 Accidental release measures

· Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

· Environmental precautions:

Dilute with plenty of water.

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).

Ensure adequate ventilation.

· 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.

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

· Information about protection against explosions and fires:

Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

- · Conditions for safe storage, including any incompatibilities
- · Storage:
- · Requirements to be met by storerooms and receptacles:

Store in a cool location.

Store only in the original receptacle.

(Contd. on page 4)

Printing date 01/14/2019 Version number 11 Reviewed on 01/14/2019

Trade name: Syntac Primer

(Contd. of page 3)

- · Information about storage in one common storage facility: Not required.
- Further information about storage conditions:

Keep receptacle tightly sealed.

Store in cool, dry conditions in well sealed receptacles.

· 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:

CAS: 67-64-1 acetone

PEL Long-term value: 2400 mg/m³, 1000 ppm REL Long-term value: 590 mg/m³, 250 ppm

TLV Short-term value: (1782) NIC-1187 mg/m³, (750) NIC-500 ppm Long-term value: (1188) NIC-594 mg/m³, (500) NIC-250 ppm

BEI

· Ingredients with biological limit values:

CAS: 67-64-1 acetone

BEI 50 mg/L

Medium: urine Time: end of shift

Parameter: Acetone (nonspecific)

- · 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 and dental laboratories.

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

Keep away from foodstuffs, beverages and feed.

Avoid contact with the eyes and skin.

Do not inhale dust / smoke / mist.

· Breathing equipment:

Not necessary if room is well-ventilated.

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

After use of gloves apply skin-cleaning agents and skin cosmetics.

· Material of gloves

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· 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.

(Contd. on page 5)

Printing date 01/14/2019 Version number 11 Reviewed on 01/14/2019

Trade name: Syntac Primer

(Contd. of page 4)

· Eye protection:



Tightly sealed goggles

· **Body protection:** Protective work clothing

9 Physical and chemical properties

Information on basic physical and chemical properties

· General Information

· Appearance:

Form: Fluid
Color: Colorless
Odor: Acetone-like
Odor threshold: Not determined.

pH-value: Not determined.

· Change in condition

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

Flash point: < 21 °C (< 70 °F)

· Flammability (solid, gaseous): Not applicable.

· Auto igniting: Product is not selfigniting.

• Danger of explosion: Product is not explosive. However, formation of explosive air/vapor

mixtures are possible.

· Explosion limits:

 Lower:
 2.6 Vol %

 Upper:
 13.0 Vol %

· Vapor pressure: Not determined.

• Density at 20 °C (68 °F): 0.957 g/cm³ (7.986 lbs/gal) • Relative density Not determined.

Vapor density
 Evaporation rate
 Not determined.
 Not determined.

· Solubility in / Miscibility with

Water: Fully miscible.

· 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.
- · Chemical stability Stable under normal handling and storage conditions.
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

(Contd. on page 6)

Printing date 01/14/2019 Version number 11 Reviewed on 01/14/2019

Trade name: Syntac Primer

(Contd. of page 5)

- 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:
- · on the skin: Irritant to skin and mucous membranes.
- · on the eye: Irritating effect.
- · Sensitization: Sensitization possible through skin contact.
- · Additional toxicological information: No further relevant information available.
- · Carcinogenic categories
- · NTP (National Toxicology Program)

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

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.
- $\cdot \textit{Additional ecological information:}$
- · 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.

US

Printing date 01/14/2019 Version number 11 Reviewed on 01/14/2019

Trade name: Syntac Primer

(Contd. of page 6)

Transport information	
UN-Number DOT, ADR/RID/ADN, IMDG, IATA	UN1090
UN proper shipping name ADR/RID/ADN IMDG, IATA	1090 ACETONE ACETONE
Transport hazard class(es)	
DOT	
Class	3 Flammable liquids
· Label	3
ADR/RID/ADN	
Class	3 (F1) Flammable liquids
· Label · IMDG, IATA	3
Class - Label	3 Flammable liquids 3
Packing group	
DOT, ADR/RID/ADN, IMDG, IATA	II
Environmental hazards:	
Marine pollutant:	No
Special precautions for user	Warning: Flammable liquids
Danger code (Kemler): EMS Number:	33 F-E,S-E
Transport in bulk according to Annex I	
MARPOL73/78 and the IBC Code	Not applicable.
Transport/Additional information:	
· ADR/RID/ADN	
Excepted quantities (EQ)	Code: E2
	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity ner outer nackaoino: 500 ml
· IMDG	Maximum net quantity per outer packaging: 500 ml

Printing date 01/14/2019 Version number 11 Reviewed on 01/14/2019

Trade name: Syntac Primer

	(Contd. of page 7
· Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· UN ''Model Regulation'':	UN1090, Acetone, 3, II

15 Regulatory information

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

CAS: 67-64-1 acetone

Ι

· TLV (Threshold Limit Value established by ACGIH)

CAS: 67-64-1 acetone

A4

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

None of the ingredients is listed.

· GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

· Hazard pictograms





GHS02

GHS07

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

triethylene glycol dimethacrylate acetone maleic acid polyethylene glycol dimethacrylate

(Contd. on page 9)

Printing date 01/14/2019 Version number 11 Reviewed on 01/14/2019

Trade name: Syntac Primer

(Contd. of page 8)

· Hazard statements

Highly flammable liquid and vapor.

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

May cause respiratory irritation. May cause drowsiness or dizziness.

· Precautionary statements

Keep away from heat/sparks/open flames/hot surfaces. No smoking.

Keep container tightly closed.

Avoid breathing mist/vapours/spray.

Wear protective gloves / eye protection.

If skin irritation or rash occurs: Get medical advice/attention.

If eye irritation persists: Get medical advice/attention.

· National regulations:

· Other regulations, limitations and prohibitive regulations

The product is a medical device according to the 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.

· 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.

· Date of preparation / last revision 01/14/2019 / 10

· 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

 $DOT: \ US \ Department \ of \ Transportation$

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

BEI: Biological Exposure Limit

Flam. Liq. 2: Flammable liquids – Category 2

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 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.