

SAFETY DATA SHEETS

This SDS packet was issued with item:

077086663

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

Safety Data Sheet
acc. to OSHA HCS

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.

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Trade name: **Syntac Adhesive**

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· **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 = 0
Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**



Health = *2
Fire = 0
Reactivity = 0

· **Other hazards**

· **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**

· **Description:** Mixture of the substances listed below with nonhazardous additions.

· **Dangerous components:**

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.

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- **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.
- **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.

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Trade name: Syntac Adhesive

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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

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Trade name: **Syntac Adhesive**

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9 Physical and chemical properties

· **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/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.

· **Incompatible materials:** No further relevant information available.

· **Hazardous decomposition products:** None under normal conditions of storage and use.

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Trade name: **Syntac Adhesive**

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11 Toxicological information

· **Information on toxicological effects**

· **Acute toxicity:**

· **LD/LC50 values that are relevant for classification:**

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.

· **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.

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Trade name: Syntac Adhesive

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

14 Transport information

- | | |
|--|---|
| · UN-Number | Void |
| · DOT, ADR, ADN, IMDG, IATA | Void |
| · UN proper shipping name | Void |
| · DOT, ADN, IMDG, IATA | Void |
| · ADR | 2922 CORROSIVE LIQUID, TOXIC, N.O.S. (glutaral) |
| · Transport hazard class(es) | |
| · DOT, ADR, ADN, IMDG, IATA | Void |
| · Class | Void |
| · Packing group | |
| · DOT, ADR, IMDG, IATA | Void |
| · Environmental hazards: | |
| · Marine pollutant: | No |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |

15 Regulatory information

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

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

None of the ingredients is listed.

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

None of the ingredients is listed.

· **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.

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Trade name: Syntac Adhesive

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· **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/EC 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.**

USA

1 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 L4W4Y3
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 components:**

1565-94-2	Bis-GMA	⚠ H315; H319	50-100%
109-16-0	triethyleneglycol dimethacrylate	⚠ H315; H319; H317; H335	25-50%

3 Hazards identification

- **Classification of the substance or mixture**
 - **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
 Irritant
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/EC usually if they are in the finished state and intended for the final user.

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acc. to ISO/DIS 11014

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Trade name: **Heliobond**

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· **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 = 0
Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**



HEALTH 1 Health = 1
FIRE 0 Fire = 0
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 eye 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).

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Trade name: Heliobond

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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.

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Trade name: Heliobond

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- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:** Safety glasses

9 Physical and chemical properties

· 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-octanol/water):** 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.

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Trade name: Heliobond

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- **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.
- **Persistence and degradability** 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.

14 Transport information

- | | |
|--|-----------------|
| · UN-Number | Void |
| · DOT, ADR, ADN, IMDG, IATA | Void |
| · UN proper shipping name | Void |
| · DOT, ADR, ADN, IMDG, IATA | Void |
| · Transport hazard class(es) | Void |
| · DOT, ADR, ADN, IMDG, IATA | Void |
| · Class | Void |
| · Packing group | Void |
| · DOT, ADR, IMDG, IATA | Void |
| · Environmental hazards: | No |
| · 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. |

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acc. to ISO/DIS 11014

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Trade name: **Heliobond**

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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:**

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.

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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

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**
- 

GHS07
- **Signal word** *Warning*
 - **Hazard-determining components of labeling:**
Bis-GMA
triethylene glycol dimethacrylate
 - **Hazard statements**
Causes skin irritation.

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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 = 2
Fire = 0
Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**



HEALTH 2 Health = 2
FIRE 0 Fire = 0
REACTIVITY 0 Reactivity = 0

· **Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**

· **Description:** Mixture of the substances listed below with nonhazardous additions.

· **Dangerous components:**

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.

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- **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.

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- **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 chemical properties**

· **General Information**

· **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.

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· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapor pressure:	Not determined.
· Density at 20 °C (68 °F):	1.14 g/cm ³ (9.513 lbs/gal)
· Relative density	Not determined.
· Vapor density	Not determined.
· Evaporation rate	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. |

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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.

14 Transport information

- | | |
|--|--|
| · UN-Number | · DOT, ADR/RID/ADN, ADN, IMDG, IATA Void |
| · UN proper shipping name | · DOT, ADR/RID/ADN, ADN, IMDG, IATA Void |
| · Transport hazard class(es) | · DOT, ADR/RID/ADN, ADN, IMDG, IATA |
| · Class | 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 of MARPOL73/78 and the IBC Code | Not applicable. |
| · Transport/Additional information: | Product is not classified as a dangerous good for transport (ADR, IMDG, IATA). |
| · UN "Model Regulation": | Void |

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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.

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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)

HMS: 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

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