

## SAFETY DATA SHEETS

**This SDS packet was issued with item:**

077083538

**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).**

070215376 070483453 071455849 071455856 071455864 071455872 071455880 071455955 071455963 071455971  
071455989 071455997 071456003 071456011 071456029 077086259 077086663 077124506 077124514 077124522  
077124530 077125008 077125016 077125024 077125032 077125040 077125057 077125065 077125073 077125081  
077125099 077125107 077125115 077125123 077125131 077125149 077125156 077125164 077125172 077125180  
077125198 077125206 077125214 077125222 077125230 077125248 077125255 077125263 077125271 077125289  
077125297 077125305 077125313 077125321 077125339 077125503 077125511 077125529 077125537 077125545  
077125552 077125560 077125578 077125586 077125594 077125602 077125610 077125628 077125636 077125644  
077125651 077125669 077125677 077125685 077125693 077125701 077125719 077125727 077125735 077125743  
077125750 077125768 077125776 077125784 077125792 077125800 077125818 077125826 077125834 077126055  
077126188 077126196 077126204 077126212 077126238 077126246 077126253 077126261 077126279 077126287  
077126295 077126303 077126311 077126329 077126337 077126345 077126352 077126360 077126378 077126386  
077126394 077126402 077126410 077126428 077126436 077126444 077126451 077126550 077126568 077126576  
077126584 077126592 077126600 077126618 077126626 077126634 077126642 077126659 077126667 077126675  
077126683 077126691 077126709 077126717 077126725 077126733 077126741 077126758 077126766 077126774  
077142540 077142581 077142599 077142607 077142904 077142961 077143001 077143043 077143084 077143241  
077143266 077143282 077143290 077143316 077143324 077143340 077143365 077143381 077143407 077143423

**1 Identification**

- **Product identifier**
- **Trade name: *IPS Empress Direct***
- **Application of the substance / the mixture** *Light-curing resin-based dental restorative material*
- **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.*

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  - **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:**  
*urethane dimethacrylate*  
*Bis-GMA*
  - **Hazard statements**  
*Causes skin irritation.*  
*Causes serious eye irritation.*

# Safety Data Sheet

acc. to OSHA HCS

Printing date 03/25/2019

Version number 4

Reviewed on 01/24/2019

Trade name: **IPS Empress Direct**

(Contd. of page 1)

May cause an allergic skin reaction.

· **Precautionary statements**

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

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)**



· **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: 72869-86-4 | urethane dimethacrylate                  | 10-25%    |
| CAS: 13760-80-0 | ytterbium trifluoride                    | ≥2.5-<10% |
| CAS: 43048-08-4 | tricyclodocane dimethanol dimethacrylate | ≥2.5-<10% |
| CAS: 36425-15-7 | Bis-GMA                                  | ≥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:** Rinse with water.

· **After eye contact:**

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

· **After swallowing:** If symptoms persist consult doctor.

· **Information for doctor:**

· **Most important symptoms and effects, both acute and delayed** No further relevant information available.

· **Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

(Contd. on page 3)

## Safety Data Sheet acc. to OSHA HCS

Printing date 03/25/2019

Version number 4

Reviewed on 01/24/2019

Trade name: **IPS Empress Direct**

(Contd. of page 2)

### 5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**  
CO<sub>2</sub>, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

### 7 Handling and storage

- **Handling:**
- **Precautions for safe handling**  
Only adequately trained personnel should handle this product.  
For use in dentistry only.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store only in the original receptacle.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**  
Protect from exposure to the light.  
Protect from heat and direct sunlight.  
Keep receptacle tightly sealed.
- **Specific end use(s)** No further relevant information available.

### \* 8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**
- **Components with limit values that require monitoring at the workplace:**  
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists that were valid during the creation were used as basis.
- **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.  
Avoid contact with the eyes and skin.  
Keep away from foodstuffs, beverages and feed.

(Contd. on page 4)

## Safety Data Sheet

### acc. to OSHA HCS

Printing date 03/25/2019

Version number 4

Reviewed on 01/24/2019

**Trade name: IPS Empress Direct**

(Contd. of page 3)

- **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:**

|                        |                                    |
|------------------------|------------------------------------|
| <b>Form:</b>           | Pasty                              |
| <b>Color:</b>          | According to product specification |
| <b>Odor:</b>           | Characteristic                     |
| <b>Odor threshold:</b> | Not determined.                    |

- **pH-value:** Not determined.

- **Change in condition**

|                                     |               |
|-------------------------------------|---------------|
| <b>Melting point/Melting range:</b> | Undetermined. |
| <b>Boiling point/Boiling range:</b> | Undetermined. |

- **Flash point:** Not applicable.

- **Auto igniting:** Product is not selfigniting.

- **Danger of explosion:** Product does not present an explosion hazard.

- **Explosion limits:**

|               |                 |
|---------------|-----------------|
| <b>Lower:</b> | Not determined. |
| <b>Upper:</b> | Not determined. |

- **Vapor pressure:** Not determined.

|                                  |                                         |
|----------------------------------|-----------------------------------------|
| <b>Density at 20 °C (68 °F):</b> | 1.94 g/cm <sup>3</sup> (16.189 lbs/gal) |
| <b>Relative density</b>          | Not determined.                         |
| <b>Vapor density</b>             | Not determined.                         |
| <b>Evaporation rate</b>          | Not determined.                         |

(Contd. on page 5)

US

## Safety Data Sheet

acc. to OSHA HCS

Printing date 03/25/2019

Version number 4

Reviewed on 01/24/2019

**Trade name: *IPS Empress Direct***

(Contd. of page 4)

- |                                                   |                                            |
|---------------------------------------------------|--------------------------------------------|
| <b>· Solubility in / Miscibility with Water:</b>  | Nearly insoluble.                          |
| <b>· Partition coefficient (n-octanol/water):</b> | Not determined.                            |
| <b>· Viscosity:</b>                               |                                            |
| <b>Dynamic:</b>                                   | Not determined.                            |
| <b>Kinematic:</b>                                 | Not determined.                            |
| <b>· Other information</b>                        | 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:** No irritant effect.
- **on the eye:** Irritating effect.
- **Sensitization:** Sensitization possible through skin contact.
- **Additional toxicological information:** No further relevant information available.
- **Carcinogenic categories**

|                                            |
|--------------------------------------------|
| <b>· NTP (National Toxicology Program)</b> |
|--------------------------------------------|

|                                    |
|------------------------------------|
| None of the ingredients is listed. |
|------------------------------------|

|                                                                    |
|--------------------------------------------------------------------|
| <b>· OSHA-Ca (Occupational Safety &amp; Health Administration)</b> |
|--------------------------------------------------------------------|

|                                    |
|------------------------------------|
| 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 undiluted product or large quantities of it to reach ground water, water course or sewage system.

(Contd. on page 6)

## Safety Data Sheet

acc. to OSHA HCS

Printing date 03/25/2019

Version number 4

Reviewed on 01/24/2019

**Trade name: *IPS Empress Direct***

(Contd. of page 5)

- **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

### 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.

(Contd. on page 7)

US

## Safety Data Sheet

acc. to OSHA HCS

Printing date 03/25/2019

Version number 4

Reviewed on 01/24/2019

**Trade name: IPS Empress Direct**

(Contd. of page 6)

· **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: 13760-80-0 ytterbium trifluoride

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**



GHS07

· **Signal word** Warning

· **Hazard-determining components of labeling:**

urethane dimethacrylate

Bis-GMA

· **Hazard statements**

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

· **Precautionary statements**

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

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.

(Contd. on page 8)

US



**Safety Data Sheet**  
**acc. to OSHA HCS**

Printing date 03/25/2019

Version number 4

Reviewed on 01/24/2019

**Trade name: *IPS Empress Direct***

(Contd. of page 7)

· **Date of preparation / last revision** 03/25/2019 / 3· **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*· **\* Data compared to the previous version altered.**

US

**Safety Data Sheet**  
acc. to OSHA HCS

Printing date 11/20/2015

Version number 8

Reviewed on 11/20/2015


**1 Identification**

- **Product identifier**
- **Trade name: Monobond Plus**
- **Application of the substance / the mixture**  
Universal primer mediating a bond between metal, glass/oxid ceramics and resin
- **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 Sens. 1 H317 May cause an allergic skin reaction.  
Carc. 1A H350 May cause cancer.


---

  - **Label elements**
  - **GHS label elements**  
The product is classified and labeled according to the Globally Harmonized System (GHS).
  - **Hazard pictograms**
- 

GHS02



GHS07



GHS08
- **Signal word** Danger
  - **Hazard-determining components of labeling:**  
ethanol  
Methacrylated phosphoric acid ester
  - **Hazard statements**  
Highly flammable liquid and vapor.

(Contd. on page 2)

US

## Safety Data Sheet acc. to OSHA HCS

Printing date 11/20/2015

Version number 8

Reviewed on 11/20/2015

**Trade name: Monobond Plus**

(Contd. of page 1)

May cause an allergic skin reaction.

May cause cancer.

· **Precautionary statements**

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

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

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

Keep container tightly closed.

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

Store in a well-ventilated place. Keep cool.

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



· **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: 64-17-5    | ethanol                             | 50-100% |
| CAS: 85590-00-7 | Methacrylated phosphoric acid ester | 1-<2.5% |

### 4 First-aid measures

· **Description of first aid measures**

· **After inhalation:**

Supply fresh air; consult doctor in case of complaints.

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:** 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.

US

(Contd. on page 3)

## Safety Data Sheet acc. to OSHA HCS

Printing date 11/20/2015

Version number 8

Reviewed on 11/20/2015

Trade name: **Monobond Plus**

(Contd. of page 2)

### 5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**  
CO<sub>2</sub>, 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.
- **Additional information** Cool endangered receptacles with water spray.

### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

### 7 Handling and storage

- **Handling:**
- **Precautions for safe handling**  
Only adequately trained personnel should handle this product.  
For use in dentistry only.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store only in the original receptacle.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**  
Protect from exposure to the light.  
Protect from heat and direct sunlight.  
Keep receptacle tightly sealed.
- **Specific end use(s)** No further relevant information available.

### 8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**

· **Components with limit values that require monitoring at the workplace:**

**CAS: 64-17-5 ethanol**

PEL Long-term value: 1900 mg/m<sup>3</sup>, 1000 ppm

REL Long-term value: 1900 mg/m<sup>3</sup>, 1000 ppm

TLV Short-term value: 1880 mg/m<sup>3</sup>, 1000 ppm

- **Additional information:** The lists that were valid during the creation were used as basis.

(Contd. on page 4)

US

## Safety Data Sheet

acc. to OSHA HCS

Printing date 11/20/2015

Version number 8

Reviewed on 11/20/2015

Trade name: **Monobond Plus**

(Contd. of page 3)

- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
Usual hygienic measures for dental practice.  
Wash hands before breaks and at the end of work.  
Avoid contact with the eyes and skin.  
Keep away from foodstuffs, beverages and feed.
- **Breathing equipment:** 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:**

|                          |                 |
|--------------------------|-----------------|
| · <b>Form:</b>           | Fluid           |
| · <b>Color:</b>          | Colorless       |
| · <b>Odor:</b>           | Alcohol-like    |
| · <b>Odor threshold:</b> | Not determined. |

· **pH-value:** Not determined.

· **Change in condition**

|                                       |                     |
|---------------------------------------|---------------------|
| · <b>Melting point/Melting range:</b> | -114,5 °C (-174 °F) |
| · <b>Boiling point/Boiling range:</b> | 78 °C (172 °F)      |

· **Flash point:** 13 °C (55 °F)

· **Ignition temperature:** 425 °C (797 °F)

· **Auto igniting:** Product is not selfigniting.

· **Danger of explosion:** Product is not explosive. However, formation of explosive air/vapor mixtures are possible.

(Contd. on page 5)

US

## Safety Data Sheet

acc. to OSHA HCS

Printing date 11/20/2015

Version number 8

Reviewed on 11/20/2015

Trade name: **Monobond Plus**

(Contd. of page 4)

|                                                                            |                 |
|----------------------------------------------------------------------------|-----------------|
| · <b>Explosion limits:</b>                                                 |                 |
| <b>Lower:</b>                                                              | 3,5 Vol %       |
| <b>Upper:</b>                                                              | 15 Vol %        |
| · <b>Vapor pressure at 20 °C (68 °F):</b> 59 hPa (44 mm Hg)                |                 |
| · <b>Density at 20 °C (68 °F):</b> 0,794 g/cm <sup>3</sup> (6.626 lbs/gal) |                 |
| · <b>Relative density</b> Not determined.                                  |                 |
| · <b>Vapor density</b> Not determined.                                     |                 |
| · <b>Evaporation rate</b> Not determined.                                  |                 |
| · <b>Solubility in / Miscibility with Water:</b> Soluble.                  |                 |
| · <b>Partition coefficient (n-octanol/water):</b> Not determined.          |                 |
| · <b>Viscosity:</b>                                                        |                 |
| <b>Dynamic:</b>                                                            | Not determined. |
| <b>Kinematic:</b>                                                          | Not determined. |
| · <b>Other information</b> 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.

### 11 Toxicological information

- **Information on toxicological effects**
  - **Acute toxicity:**
- |                                                               |                   |
|---------------------------------------------------------------|-------------------|
| · <b>LD/LC50 values that are relevant for classification:</b> |                   |
| Oral LD50                                                     | >5000 mg/kg (rat) |
- **on the skin:** No irritant effect.
  - **on the eye:** No irritating effect.
  - **Sensitization:** Sensitization possible through skin contact.
  - **Additional toxicological information:** No further relevant information available.
  - **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

|              |         |   |
|--------------|---------|---|
| CAS: 64-17-5 | ethanol | I |
|--------------|---------|---|

- **NTP (National Toxicology Program)**

|                                    |
|------------------------------------|
| None of the ingredients is listed. |
|------------------------------------|

- **OSHA-Ca (Occupational Safety & Health Administration)**

|                                    |
|------------------------------------|
| None of the ingredients is listed. |
|------------------------------------|

(Contd. on page 6)

## Safety Data Sheet

acc. to OSHA HCS

Printing date 11/20/2015

Version number 8

Reviewed on 11/20/2015

Trade name: **Monobond Plus**

(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 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:**  
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

### 14 Transport information

- |                                                                                                                                                                |                                                                                                           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> <li>· <b>UN-Number</b></li> <li>· <b>DOT</b></li> <li>· <b>ADR,RID,ADN, IMDG, IATA</b></li> </ul>                           | <p>UN1170<br/>1170</p>                                                                                    |
| <ul style="list-style-type: none"> <li>· <b>UN proper shipping name</b></li> <li>· <b>ADR/RID/ADN</b></li> <li>· <b>IMDG</b></li> <li>· <b>IATA</b></li> </ul> | <p>1170 ETHANOL (ETHYL ALCOHOL), solution<br/>ETHANOL (ETHYL ALCOHOL), solution<br/>ETHANOL, solution</p> |
| <ul style="list-style-type: none"> <li>· <b>Transport hazard class(es)</b></li> <li>· <b>DOT</b></li> </ul>                                                    | <p>3 Flammable liquids<br/>3</p>                                                                          |



- **Class**
- **Label**

(Contd. on page 7)

US

## Safety Data Sheet

acc. to OSHA HCS

Printing date 11/20/2015

Version number 8

Reviewed on 11/20/2015

Trade name: **Monobond Plus**

(Contd. of page 6)

## · ADR/RID/ADN



· Class 3 (F1) Flammable liquids  
 · Label 3

## · IMDG, IATA



· Class 3 Flammable liquids  
 · Label 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):

33

## · EMS Number:

F-E,S-D

## · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

## · UN "Model Regulation":

UN1170, Ethanol (Ethyl alcohol) solution, 3, II

### 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):

CAS: 64-17-5 ethanol

CAS: 2530-85-0 3-trimethoxysilylpropyl methacrylate

## · 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.

(Contd. on page 8)

US



## Safety Data Sheet

acc. to OSHA HCS

Printing date 11/20/2015

Version number 8

Reviewed on 11/20/2015

**Trade name: Monobond Plus**

(Contd. of page 7)

· **Chemicals known to cause developmental toxicity:**

CAS: 64-17-5 ethanol

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**

CAS: 64-17-5 ethanol

A3

· **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

GHS08

· **Signal word Danger**

· **Hazard-determining components of labeling:**

ethanol

Methacrylated phosphoric acid ester

· **Hazard statements**

Highly flammable liquid and vapor.

May cause an allergic skin reaction.

May cause cancer.

· **Precautionary statements**

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

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

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

Keep container tightly closed.

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

Store in a well-ventilated place. Keep cool.

· **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 11/20/2015 / 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

(Contd. on page 9)

US

**Safety Data Sheet**  
**acc. to OSHA HCS**

Printing date 11/20/2015

Version number 8

Reviewed on 11/20/2015

**Trade name: Monobond Plus**

(Contd. of page 8)

*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)*  
*LC50: Lethal concentration, 50 percent*  
*LD50: Lethal dose, 50 percent*  
*PBT: Persistent, Bioaccumulative and Toxic*  
*vPvB: very Persistent and very Bioaccumulative*  
*Flam. Liq. 2: Flammable liquids, Hazard Category 2*  
*Skin Sens. 1: Sensitisation - Skin, Hazard Category 1*  
*Carc. 1A: Carcinogenicity, Hazard Category 1A*  
· **\* Data compared to the previous version altered.**

US

**Safety Data Sheet**  
acc. to OSHA HCS

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**
- 

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

(Contd. on page 2)

# Safety Data Sheet

## acc. to OSHA HCS

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 = 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.

(Contd. on page 3)

US

## Safety Data Sheet acc. to OSHA HCS

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:**  
CO<sub>2</sub>, 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)

## Safety Data Sheet

### acc. to OSHA HCS

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 chemical properties

#### · General Information

##### · Appearance:

|                        |                 |
|------------------------|-----------------|
| <b>Form:</b>           | Fluid           |
| <b>Color:</b>          | Yellowish       |
| <b>Odor:</b>           | Characteristic  |
| <b>Odor threshold:</b> | Not determined. |

· **pH-value:** Not determined.

##### · Change in condition

|                                     |               |
|-------------------------------------|---------------|
| <b>Melting point/Melting range:</b> | Undetermined. |
| <b>Boiling point/Boiling range:</b> | 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)

## Safety Data Sheet

acc. to OSHA HCS

Printing date 03/25/2019

Version number 8

Reviewed on 01/28/2019

Trade name: **Heliobond**

(Contd. of page 4)

|                                                   |                                            |
|---------------------------------------------------|--------------------------------------------|
| · <b>Explosion limits:</b>                        |                                            |
| <b>Lower:</b>                                     | Not determined.                            |
| <b>Upper:</b>                                     | Not determined.                            |
| · <b>Vapor pressure:</b>                          | Not determined.                            |
| · <b>Density at 20 °C (68 °F):</b>                | 1.14 g/cm <sup>3</sup> (9.513 lbs/gal)     |
| · <b>Relative density</b>                         | Not determined.                            |
| · <b>Vapor density</b>                            | Not determined.                            |
| · <b>Evaporation rate</b>                         | Not determined.                            |
| · <b>Solubility in / Miscibility with Water:</b>  | Not miscible or difficult to mix.          |
| · <b>Partition coefficient (n-octanol/water):</b> | Not determined.                            |
| · <b>Viscosity:</b>                               |                                            |
| <b>Dynamic:</b>                                   | Not determined.                            |
| <b>Kinematic:</b>                                 | Not determined.                            |
| · <b>Other information</b>                        | 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**
- |                                                                    |
|--------------------------------------------------------------------|
| · <b>NTP (National Toxicology Program)</b>                         |
| None of the ingredients is listed.                                 |
| · <b>OSHA-Ca (Occupational Safety &amp; Health Administration)</b> |
| None of the ingredients is listed.                                 |

(Contd. on page 6)

## Safety Data Sheet acc. to OSHA HCS

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.

### 14 Transport information

- |                                                                                  |                                                                                |
|----------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| · <b>UN-Number</b>                                                               | · <b>DOT, ADR/RID/ADN, ADN, IMDG, IATA</b> Void                                |
| · <b>UN proper shipping name</b>                                                 | · <b>DOT, ADR/RID/ADN, ADN, IMDG, IATA</b> Void                                |
| · <b>Transport hazard class(es)</b>                                              | · <b>DOT, ADR/RID/ADN, ADN, IMDG, IATA</b>                                     |
| · <b>Class</b>                                                                   | Void                                                                           |
| · <b>Packing group</b>                                                           | · <b>DOT, ADR/RID/ADN, IMDG, IATA</b> Void                                     |
| · <b>Environmental hazards:</b>                                                  | · <b>Marine pollutant:</b> No                                                  |
| · <b>Special precautions for user</b>                                            | Not applicable.                                                                |
| · <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b> | Not applicable.                                                                |
| · <b>Transport/Additional information:</b>                                       | Product is not classified as a dangerous good for transport (ADR, IMDG, IATA). |
| · <b>UN "Model Regulation":</b>                                                  | Void                                                                           |

US  
(Contd. on page 7)



# Safety Data Sheet

## acc. to OSHA HCS

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)

## Safety Data Sheet acc. to OSHA HCS

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)*

*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

**Safety Data Sheet**  
acc. to OSHA HCS

Printing date 04/20/2015

Version number 6

Reviewed on 03/27/2015


**1 Identification**

- **Product identifier**
- **Trade name:** ***Tetric EvoCeram***
- **Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** *Light-curing resin-based dental restorative material*
- **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.

---

  - **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:**  
*urethane dimethacrylate*  
*Bis-GMA*

(Contd. on page 2)

# Safety Data Sheet

acc. to OSHA HCS

Printing date 04/20/2015

Version number 6

Reviewed on 03/27/2015

Trade name: **Tetric EvoCeram**

(Contd. of page 1)

- **Hazard statements**

Causes skin irritation.  
Causes serious eye irritation.  
May cause an allergic skin reaction.

- **Precautionary statements**

Wear protective gloves/protective clothing/eye protection/face protection.  
Wash contaminated clothing before reuse.  
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 = 0  
Reactivity = 0

- **HMIS-ratings (scale 0 - 4)**



HEALTH 1 Health = 1  
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:**

|            |                                        |          |
|------------|----------------------------------------|----------|
| 72869-86-4 | urethane dimethacrylate                | 2.5-<10% |
| 1565-94-2  | Bis-GMA                                | 2.5-<10% |
| 13760-80-0 | ytterbium trifluoride                  | 2.5-<10% |
| 41637-38-1 | ethoxylated bisphenol A dimethacrylate | 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:** 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)

## Safety Data Sheet acc. to OSHA HCS

Printing date 04/20/2015

Version number 6

Reviewed on 03/27/2015

**Trade name: Tetric EvoCeram**

(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:**  
CO<sub>2</sub>, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

### 7 Handling and storage

- **Handling:**
- **Precautions for safe handling**  
Only adequately trained personnel should handle this product.  
For use in dentistry only.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store only in the original receptacle.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**  
Protect from exposure to the light.  
Protect from heat and direct sunlight.  
Keep receptacle tightly sealed.
- **Specific end use(s)** No further relevant information available.

### 8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**
- **Components with limit values that require monitoring at the workplace:**  
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists that were valid during the creation were used as basis.

(Contd. on page 4)

US

## Safety Data Sheet acc. to OSHA HCS

Printing date 04/20/2015

Version number 6

Reviewed on 03/27/2015

**Trade name: Tetric EvoCeram**

(Contd. of page 3)

- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
Usual hygienic measures for dental practice.  
Wash hands before breaks and at the end of work.  
Avoid contact with the eyes and skin.  
Keep away from foodstuffs, beverages and feed.
- **Breathing equipment:** 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.
- **Eye protection:** Safety glasses

### 9 Physical and chemical properties

- |                                                                |                                               |
|----------------------------------------------------------------|-----------------------------------------------|
| · <b>Information on basic physical and chemical properties</b> |                                               |
| · <b>General Information</b>                                   |                                               |
| · <b>Appearance:</b>                                           |                                               |
| <b>Form:</b>                                                   | Pasty                                         |
| <b>Color:</b>                                                  | According to product specification            |
| · <b>Odor:</b>                                                 | Characteristic                                |
| · <b>Odour threshold:</b>                                      | Not determined.                               |
| · <b>pH-value:</b>                                             | Not applicable.                               |
| · <b>Change in condition</b>                                   |                                               |
| <b>Melting point/Melting range:</b>                            | Undetermined.                                 |
| <b>Boiling point/Boiling range:</b>                            | Undetermined.                                 |
| · <b>Flash point:</b>                                          | Not applicable.                               |
| · <b>Flammability (solid, gaseous):</b>                        | Not determined.                               |
| · <b>Auto igniting:</b>                                        | Product is not selfigniting.                  |
| · <b>Danger of explosion:</b>                                  | Product does not present an explosion hazard. |
| · <b>Explosion limits:</b>                                     |                                               |
| <b>Lower:</b>                                                  | Not determined.                               |
| <b>Upper:</b>                                                  | Not determined.                               |

(Contd. on page 5)

## Safety Data Sheet

acc. to OSHA HCS

Printing date 04/20/2015

Version number 6

Reviewed on 03/27/2015

Trade name: **Tetric EvoCeram**

(Contd. of page 4)

|                                                   |                                            |
|---------------------------------------------------|--------------------------------------------|
| · <b>Vapor pressure:</b>                          | Not applicable.                            |
| · <b>Density at 20 °C (68 °F):</b>                | 2.1 g/cm <sup>3</sup> (17.525 lbs/gal)     |
| · <b>Relative density</b>                         | Not determined.                            |
| · <b>Vapour density</b>                           | Not applicable.                            |
| · <b>Evaporation rate</b>                         | Not applicable.                            |
| · <b>Solubility in / Miscibility with Water:</b>  | Nearly insoluble.                          |
| · <b>Partition coefficient (n-octanol/water):</b> | Not determined.                            |
| · <b>Viscosity:</b>                               |                                            |
| · <b>Dynamic:</b>                                 | Not applicable.                            |
| · <b>Kinematic:</b>                               | Not applicable.                            |
| · <b>Other information</b>                        | 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**  
Keep away from heat and direct sunlight.  
Protect from exposure to the light.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** None under normal conditions of storage and use.

### 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** Irritating effect.
- **Sensitization:** Sensitization possible through skin contact.
- **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.

(Contd. on page 6)

## Safety Data Sheet

acc. to OSHA HCS

Printing date 04/20/2015

Version number 6

Reviewed on 03/27/2015

Trade name: **Tetric EvoCeram**

(Contd. of page 5)

- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**  
*Water hazard class 1 (Self-assessment): slightly hazardous for water*  
*Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.*
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

### 13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**  
*Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.*
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

### 14 Transport information

- |                                                                                             |                                                                                       |
|---------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|
| · <b>UN-Number</b><br>· <b>DOT, ADR, ADN, IMDG, IATA</b>                                    | Void                                                                                  |
| · <b>UN proper shipping name</b><br>· <b>DOT, ADR, ADN, IMDG, IATA</b>                      | Void                                                                                  |
| · <b>Transport hazard class(es)</b><br>· <b>DOT, ADR, ADN, IMDG, IATA</b><br>· <b>Class</b> | Void                                                                                  |
| · <b>Packing group</b><br>· <b>DOT, ADR, IMDG, IATA</b>                                     | Void                                                                                  |
| · <b>Environmental hazards:</b><br>· <b>Marine pollutant:</b>                               | No                                                                                    |
| · <b>Special precautions for user</b>                                                       | Not applicable.                                                                       |
| · <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>            | Not applicable.                                                                       |
| · <b>Transport/Additional information:</b>                                                  | <i>Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).</i> |
| · <b>UN "Model Regulation":</b>                                                             | -                                                                                     |

US

(Contd. on page 7)



# Safety Data Sheet

acc. to OSHA HCS

Printing date 04/20/2015

Version number 6

Reviewed on 03/27/2015

Trade name: **Tetric EvoCeram**

(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)**

13760-80-0 ytterbium trifluoride

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**



GHS07

· **Signal word** Warning

· **Hazard-determining components of labeling:**

urethane dimethacrylate

Bis-GMA

· **Hazard statements**

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

· **Precautionary statements**

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

Wash contaminated clothing before reuse.

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

(Contd. on page 8)

## Safety Data Sheet acc. to OSHA HCS

Printing date 04/20/2015

Version number 6

Reviewed on 03/27/2015

**Trade name: Tetric EvoCeram**

(Contd. of page 7)

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** 04/20/2015 / 5

· **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)

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Eye Irrit. 2A: Serious eye damage/eye irritation, Hazard Category 2A

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

· **\* Data compared to the previous version altered.**

US