

**Safety Data Sheet**  
acc. to ISO/DIS 11014

Printing date 12/11/2012

Version number 6

Reviewed on 12/11/2012

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

· **Product identifier**

· **Trade name: Monobond Plus**

· **Relevant identified uses of the substance or mixture and uses advised against**

No further relevant information available.

· **Application of the substance / the preparation**

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 MSDS Assistance:

US: 1-800-533-6825

Canada: 1-800-263-8182

**2 Hazards identification**

· **Classification of the substance or mixture**

· **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**

Irritant

May cause sensitisation by skin contact.

Highly flammable

Highly flammable.

· **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: **Monobond Plus**

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· **Code letter and hazard designation of product:**



Irritant  
Highly flammable

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

Methacrylated phosphoric acid ester

· **Risk phrases:**

Highly flammable.

May cause sensitisation by skin contact.

· **Safety phrases:**

Keep container tightly closed and in a well-ventilated place.

Keep away from sources of ignition - No smoking.

Do not breathe vapour/spray.

Avoid contact with skin.

Wear suitable gloves.

This material and its container must be disposed of as hazardous waste.

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



Health = 0

Fire = 3

Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**



Health = 0

Fire = 3

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:**

64-17-5	ethanol	50-100%
2530-85-0	3-trimethoxysilylpropyl methacrylate	≤ 2.5%
85590-00-7	Methacrylated phosphoric acid ester	≤ 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.

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- **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.

### 5 Firefighting 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.

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· **Control parameters**

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

**64-17-5 ethanol**

PEL	1900 mg/m <sup>3</sup> , 1000 ppm
REL	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.

· **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>Odour threshold:</b>	Not determined.

· **pH-value:** Not determined.

· **Change in condition**

· **Melting point/Melting range:** -114.5 °C (-174 °F)

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<b>Boiling point/Boiling range:</b>	78 °C (172 °F)
· <b>Flash point:</b>	13 °C (55 °F)
· <b>Ignition temperature:</b>	425 °C (797 °F)
· <b>Auto igniting:</b>	Product is not selfigniting.
· <b>Danger of explosion:</b>	Product is not explosive. However, formation of explosive air/vapor mixtures are possible.
· <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>Vapour 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:**

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

Oral	LD50	>5000 mg/kg (rat)
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- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** Sensitization possible through skin contact.
- **Additional toxicological information:**  
The product shows the following dangers according to internally approved calculation methods for preparations:  
Irritant

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· **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 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

· **UN-Number**

· **DOT**

UN1170

· **ADR, IMDG, IATA**

1170

· **UN proper shipping name**

· **DOT, IATA**

ETHANOL, solution

· **ADR**

1170 ETHANOL (ETHYL ALCOHOL), solution

· **IMDG**

ETHANOL (ETHYL ALCOHOL), solution

· **Transport hazard class(es)**

· **DOT**



· **Class**

3 Flammable liquids.

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· **Label** 3

· **ADR**



· **Class** 3 (F1) Flammable liquids

· **Label** 3

· **IMDG, IATA**

· **Class** 3 Flammable liquids.

· **Label** 3

· **Packing group**

· **DOT, ADR, 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.

### 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):**

64-17-5 ethanol

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.

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

64-17-5	ethanol
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· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

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

64-17-5	ethanol	
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A3

· **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  
Highly flammable

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

Methacrylated phosphoric acid ester

· **Risk phrases:**

Highly flammable.  
May cause sensitisation by skin contact.

· **Safety phrases:**

Keep container tightly closed and in a well-ventilated place.  
Keep away from sources of ignition - No smoking.  
Do not breathe vapour/spray.  
Avoid contact with skin.  
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.

· **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.**