

# 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.

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*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)**



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:**

|                 |                                     |         |
|-----------------|-------------------------------------|---------|
| 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.*

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## 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.

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- **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:

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

· **pH-value:** Not determined.

#### · Change in condition

|                              |                     |
|------------------------------|---------------------|
| Melting point/Melting range: | -114,5 °C (-174 °F) |
| Boiling point/Boiling range: | 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.

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|                                                   |                                            |
|---------------------------------------------------|--------------------------------------------|
| · <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**

|                                                             |
|-------------------------------------------------------------|
| · <b>IARC (International Agency for Research on Cancer)</b> |
|-------------------------------------------------------------|

|              |         |   |
|--------------|---------|---|
| CAS: 64-17-5 | ethanol | 1 |
|--------------|---------|---|

- **NTP (National Toxicology Program)**

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

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

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

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### 12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**  
Water hazard class 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

- |                                                                                     |                                        |
|-------------------------------------------------------------------------------------|----------------------------------------|
| · <b>UN-Number</b>                                                                  |                                        |
| · <b>DOT</b>                                                                        | UN1170                                 |
| · <b>ADR,RID,ADN, IMDG, IATA</b>                                                    | 1170                                   |
| · <b>UN proper shipping name</b>                                                    |                                        |
| · <b>ADR/RID/ADN</b>                                                                | 1170 ETHANOL (ETHYL ALCOHOL), solution |
| · <b>IMDG</b>                                                                       | ETHANOL (ETHYL ALCOHOL), solution      |
| · <b>IATA</b>                                                                       | ETHANOL, solution                      |
| · <b>Transport hazard class(es)</b>                                                 |                                        |
| · <b>DOT</b>                                                                        |                                        |
|  |                                        |
| · <b>Class</b>                                                                      | 3 Flammable liquids                    |
| · <b>Label</b>                                                                      | 3                                      |

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## · 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.

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• **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

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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.**

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