

Safety Data Sheet
acc. to OSHA HCS

Printing date 05/07/2015

Version number 7

Reviewed on 03/09/2015

1 Identification


- **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 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

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- **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.

- **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:**

64-17-5	ethanol	50-100%
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.

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

5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.
- **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:**

64-17-5 ethanol

PEL Long-term value: 1900 mg/m³, 1000 ppm

REL Long-term value: 1900 mg/m³, 1000 ppm

TLV Short-term value: 1880 mg/m³, 1000 ppm

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· **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:**

Form: Fluid

Color: Colorless

· **Odor:** Alcohol-like

· **Odour 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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- | | |
|--|-----------------|
| · Explosion limits: | |
| Lower: | 3.5 Vol % |
| Upper: | 15 Vol % |
| · Vapor pressure at 20 °C (68 °F): 59 hPa (44 mm Hg) | |
| · Density at 20 °C (68 °F): 0.794 g/cm ³ (6.626 lbs/gal) | |
| · Relative density Not determined. | |
| · Vapour density Not determined. | |
| · Evaporation rate Not determined. | |
| · Solubility in / Miscibility with Water: Soluble. | |
| · Partition coefficient (n-octanol/water): Not determined. | |
| · Viscosity: | |
| Dynamic: | Not determined. |
| Kinematic: | Not determined. |
| · Other information No further relevant information available. | |

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability** Stable under normal handling and storage conditions.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** None under normal conditions of storage and use.

11 Toxicological information

- **Information on toxicological effects**
 - **Acute toxicity:**
- | | |
|---|-------------------|
| · LD/LC50 values that are relevant for classification: | |
| Oral LD50 | >5000 mg/kg (rat) |
- **Primary irritant effect:**
 - **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)**

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.

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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

- | | |
|--|--|
| <ul style="list-style-type: none"> · UN-Number · DOT · ADR, IMDG, IATA | <p style="margin: 0;">UN1170</p> <p style="margin: 0;">1170</p> |
| <ul style="list-style-type: none"> · UN proper shipping name · ADR · IMDG · IATA | <p style="margin: 0;">1170 ETHANOL (ETHYL ALCOHOL), solution</p> <p style="margin: 0;">ETHANOL (ETHYL ALCOHOL), solution</p> <p style="margin: 0;">ETHANOL, solution</p> |
| <ul style="list-style-type: none"> · Transport hazard class(es) · DOT | <div style="text-align: center; margin: 10px 0;">  </div> |
| <ul style="list-style-type: none"> · Class · Label | <p style="margin: 0;">3 Flammable liquids</p> <p style="margin: 0;">3</p> |

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· **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.

· **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):**

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

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

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

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** 05/07/2015 / 6

· **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
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