




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**
- **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.**
 2785 Skymark Avenue, Unit 1, Mississauga, Ontario L4W4Y3
 CANADA
 Tel. +1 800 263 8182
 Fax +1 905 238 5711
- **Information department:** Quality Assurance / Regulatory Affairs
- **Emergency telephone number:**
 24 Hour Emergency Assistance:
 Emergency-Call USA - Infotrac: 1-800-535-5053
 Emergency-Call Canada - Canutec: 1-613-996-6666
- **General MSDS Assistance:**
 US: 1-800-533-6825
 Canada: 1-800-263-8182



2 Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **Description:** Mixture of the substances listed below with nonhazardous additions.

- **Dangerous components:**

64-17-5	ethanol	 H225	50-100%
2530-85-0	3-trimethoxysilylpropyl methacrylate	 H315; H319; H335; H227	≤ 2.5%
85590-00-7	Methacrylated phosphoric acid ester	 H315; H319; H317	≤ 2.5%

3 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.
- **Information concerning particular hazards for human and environment:**
 The product has to be labelled due to the calculation procedure of international guidelines.
- **Classification system:**
 The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

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· **Label elements**

· **Labelling according to EU guidelines:**

The product has been classified and marked in accordance with directives on hazardous materials.

· **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 fumes/aerosol.

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.

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:**

Rinse out mouth and then drink plenty of water.

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 Firefighting 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**
Wear protective equipment. Keep unprotected persons away.
- **Environmental precautions:**
Dilute with plenty of water.
Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
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** Ensure good ventilation/exhaustion at the workplace.
- **Information about protection against explosions and fires:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store in a cool location.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
Keep receptacle tightly sealed.
Store in cool, dry conditions in well sealed receptacles.
- **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	1900 mg/m ³ , 1000 ppm
REL	1900 mg/m ³ , 1000 ppm
TLV	Short-term value: 1880 mg/m ³ , 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.

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

· **Breathing equipment:** Not necessary if room is well-ventilated.

· **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Not suitable are gloves made of the following materials:**

Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates.

· **Eye protection:**



Tightly sealed goggles

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.

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· Danger of explosion:	Product is not explosive. However, formation of explosive air/vapor mixtures are possible.
· 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.
· Segregation coefficient (n-octanol/water):	Not determined.
· Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
· Other information	No further relevant information available.

10 Stability and reactivity

- **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	>6000 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

12 Ecological information

- **Toxicity**
- **Acquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.

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- **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

- **DOT regulations:**



- **Hazard class:** 3
- **Identification number:** UN1170
- **Packing group:** II
- **Proper shipping name (technical name):** ETHANOL, solution
- **Label:** 3

- **Land transport ADR/RID (cross-border):**



- **ADR/RID class:** 3 (F1) Flammable liquids
- **Danger code (Kemler):** 33
- **UN-Number:** 1170
- **Packaging group:** II
- **Label:** 3
- **UN proper shipping name:** 1170 ETHANOL (ETHYL ALCOHOL), solution

- **Maritime transport IMDG:**



- **IMDG Class:** 3
- **UN Number:** 1170
- **Label:** 3
- **Packaging group:** II

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- **EMS Number:** F-E,S-D
- **Marine pollutant:** No
- **Propper shipping name:** ETHANOL (ETHYL ALCOHOL), solution

· **Air transport ICAO-TI and IATA-DGR:**

- **ICAO/IATA Class:** 3
- **UN/ID Number:** 1170
- **Label:** 3
- **Packaging group:** II
- **Propper shipping name:** ETHANOL, solution

- **Special precautions for user Warning:** Flammable liquids
- **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.

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

64-17-5 ethanol

· **Carcinogenic categories**· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **NTP (National Toxicology Program)**

None of the ingredients is listed.

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

64-17-5 ethanol

A3

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

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

None of the ingredients is listed.

· **Product related hazard informations:**

The product has been classified and marked in accordance with directives on hazardous materials.

· **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 fumes/aerosol.

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.

USA