

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.

(Contd. on page 2)

USA

Trade name: **Monobond Plus**

(Contd. of page 1)

· **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.

(Contd. on page 3)

Trade name: Monobond Plus

(Contd. of page 2)

- **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:**
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.

(Contd. on page 4)

Printing date 12/11/2012

Version number 6

Reviewed on 12/11/2012

Trade name: **Monobond Plus**

(Contd. of page 3)

- **Control parameters**

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

- **64-17-5 ethanol**

- **PEL** 1900 mg/m³, 1000 ppm

- **REL** 1900 mg/m³, 1000 ppm

- **TLV** Short-term value: 1880 mg/m³, 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:**

- **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)

(Contd. on page 5)

Safety Data Sheet

acc. to ISO/DIS 11014

SDS #1252

Printing date 12/11/2012

Version number 6

Reviewed on 12/11/2012

Trade name: **Monobond Plus**

(Contd. of page 4)

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.
· 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)
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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

(Contd. on page 6)

USA

Printing date 12/11/2012

Version number 6

Reviewed on 12/11/2012

Trade name: **Monobond Plus**

(Contd. of page 5)

- **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**

- **ADR, IMDG, IATA**

UN1170

1170

- **UN proper shipping name**

- **DOT, IATA**

- **ADR**

- **IMDG**

ETHANOL, solution

1170 ETHANOL (ETHYL ALCOHOL), solution

ETHANOL (ETHYL ALCOHOL), solution

- **Transport hazard class(es)**

- **DOT**



- **Class**

3 Flammable liquids.

(Contd. on page 7)

USA

Safety Data Sheet

acc. to ISO/DIS 11014

SDS #1252

Printing date 12/11/2012

Version number 6

Reviewed on 12/11/2012

Trade name: **Monobond Plus**

(Contd. of page 6)

· **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.

(Contd. on page 8)

USA

Safety Data Sheet
acc. to ISO/DIS 11014

SDS #1252

Printing date 12/11/2012

Version number 6

Reviewed on 12/11/2012

Trade name: **Monobond Plus**

(Contd. of page 7)

· 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.	

· 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.**