SAFETY DATA SHEETS

This SDS packet was issued with item: 070215376

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

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Printing date 11/20/2015

vivadeni:

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



· Signal word Danger

- Hazard-determining components of labeling: ethanol
- Methacrylated phosphoric acid ester
- · Hazard statements

Highly flammable liquid and vapor.

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(Contd. of page 1) 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 = 0Fire = 3Reactivity = 0· HMIS-ratings (scale 0 - 4) HEALTH • Health = 0FIRE 3 Fire = 3**REACTIVITY** O *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 ethe	anol
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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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50-100%

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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:

CAS: 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

• Additional information: The lists that were valid during the creation were used as basis.

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•	Exposure	controls
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- · 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

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/vapo 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.	
· Vapor density	Not determined.	
· Evaporation rate	Not determined.	
· Solubility in / Miscibility with		
Water:	Soluble.	
· Partition coefficient (n-octanol/wate	e r): 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)

• 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)

CAS: 64-17-5 ethanol

· 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.

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

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· ADR/RID/ADN	
· Class · Label	3 (F1) Flammable liquids 3
· IMDG, IATA	
· Class · Label	3 Flammable liquids 3
· Packing group · DOT, ADR,RID,ADN, IMDG, IATA	II
• Environmental hazards: • Marine pollutant:	No
 Special precautions for user Danger code (Kemler): EMS Number: 	Warning: Flammable liquids 33 F-E,S-D
• Transport in bulk according to Annex I MARPOL73/78 and the IBC Code	l of 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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AЗ

· 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

· 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



· 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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Trade name: Monobond Plus

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.