

Safety Data Sheet
according to WHS Regulations

Printing date 18.10.2019

Version number 8

Revision: 18.10.2019

Hazardous according to criteria of Australian Safety and Compensation Council.

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 AG

Bendererstrasse 2

9494 Schaan

PRINCIPALITY OF LIECHTENSTEIN

Tel: +423 235 35 35 / Fax: +423 235 33 60

Importer:

Ivoclar Vivadent Pty. Ltd.

1- 5 Overseas Drive

Noble Park North VIC 3174

Tel: + 61 3 9795 9599 / Fax: + 61 3 9795 9645

· **Further information obtainable from:**

Regulatory Affairs

sds@ivoclarvivadent.com

· **Emergency telephone number:** 131 126 (Poisons Information Centre - 24 hours / 7 days)

2 Hazard(s) Identification

· **Classification of the substance or mixture**

Flam. Liq. 2 H225 Highly flammable liquid and vapour.

Skin Sens. 1 H317 May cause an allergic skin reaction.

· **Label elements**

· **GHS label elements**

The product is classified and labelled according to the Globally Harmonised System (GHS).

· **Hazard pictograms**



GHS02 GHS07

· **Signal word** Danger

· **Hazard-determining components of labelling:**

methacrylated phosphoric acid ester

· **Hazard statements**

Highly flammable liquid and vapour.

May cause an allergic skin reaction.

· **Precautionary statements**

Keep away from heat/sparks/open flames/hot surfaces. No smoking.

Keep container tightly closed.

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Avoid breathing dust/fume/gas/mist/vapours/spray.
 Wear protective gloves/protective clothing/eye protection/face protection.
 If skin irritation or rash occurs: Get medical advice/attention.
 Store in a well-ventilated place. Keep cool.

- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition and Information on Ingredients

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

· **Dangerous components:**

CAS: 64-17-5	ethanol Flam. Liq. 2, H225	50-100%
CAS: 85590-00-7	methacrylated phosphoric acid ester Skin Irrit. 2, H315; Eye Irrit. 2A, H319; Skin Sens. 1, H317	<2.5%

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

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.

5 Fire Fighting Measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, 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.
See Section 14 for Hazchem Code.

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.

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- **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 fire - and explosion protection:** 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 container tightly sealed.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls and personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Control parameters**

· **Ingredients with limit values that require monitoring at the workplace:**

CAS: 64-17-5 ethanol

NES Long-term value: 1880 mg/m³, 1000 ppm

WES Long-term value: 1880 mg/m³, 1000 ppm

- **Additional information:** The lists valid during the making were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Usual hygienic measures for dental practice and dental laboratories.
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
Keep away from foodstuffs, beverages and feed.
- **Respiratory protection:** 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

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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
· Colour:	Colourless
· Odour:	Alcohol-like
· Odour threshold:	Not determined.

· **pH-value:** Not determined.

· **Change in condition**

· Melting point/freezing point:	-114.5 °C
· Initial boiling point and boiling range:	78 °C

· **Flash point:** 13 °C

· **Ignition temperature:** 425 °C

· **Auto-ignition temperature:** Product is not selfigniting.

· **Explosive properties:** Product is not explosive. However, formation of explosive air/vapour mixtures are possible.

· **Explosion limits:**

· Lower:	3.5 Vol %
· Upper:	15 Vol %

· **Vapour pressure at 20 °C:** 59 hPa

· **Density at 20 °C:** 0.794 g/cm³

· **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.

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- **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 relevant for classification:**

Oral	LD50	>5000 mg/kg (rat)
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- **Skin corrosion/irritation** No irritant effect.
- **Serious eye damage/irritation** No irritating effect.
- **Respiratory or skin sensitisation** Sensitisation possible through skin contact.
- **Additional toxicological information:** No further relevant information available.

12 Ecological Information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour 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 (German Regulation) (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 together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

14 Transport information

- | | |
|--------------------------|------|
| · UN-Number | |
| · ADG, IMDG, IATA | 1170 |

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<ul style="list-style-type: none"> · <i>UN proper shipping name</i> · <i>ADG</i> · <i>IMDG</i> · <i>IATA</i> 	1170 ETHANOL (ETHYL ALCOHOL) solution ETHANOL (ETHYL ALCOHOL), solution ETHANOL, solution
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- *Transport hazard class(es)*

- *ADG*



<ul style="list-style-type: none"> · <i>Class</i> · <i>Label</i> 	3 (F1) Flammable liquids. 3
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- *IMDG, IATA*



<ul style="list-style-type: none"> · <i>Class</i> · <i>Label</i> 	3 Flammable liquids. 3
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- *Packing group*

- *ADG, IMDG, IATA* II

- *Environmental hazards:*

- *Marine pollutant:* No

- *Special precautions for user*

Warning: Flammable liquids.

- *Danger code (Kemler):*

33

- *Hazchem or Emergency Action Code:*

•2YE

- *EMS Number:*

F-E,S-D

- *Transport in bulk according to Annex II of Marpol and the IBC Code*

Not applicable.

- *Transport/Additional information:*

- *ADG*

- *Limited quantities (LQ)* LQ4

- *Transport category*

2

- *Tunnel restriction code*

D/E

- *UN "Model Regulation":*

UN 1170 ETHANOL (ETHYL ALCOHOL) SOLUTION,
3, II

15 Regulatory information

- *Safety, health and environmental regulations/legislation specific for the substance or mixture*

- *Australian Inventory of Chemical Substances*

CAS: 64-17-5 | ethanol

- *Standard for the Uniform Scheduling of Medicines and Poisons*

None of the ingredients is listed.

- *GHS label elements*

The product is classified and labelled according to the Globally Harmonised System (GHS).

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· **Hazard pictograms**

GHS02 GHS07

· **Signal word** *Danger*· **Hazard-determining components of labelling:***methacrylated phosphoric acid ester*· **Hazard statements***Highly flammable liquid and vapour.**May cause an allergic skin reaction.*· **Precautionary statements***Keep away from heat/sparks/open flames/hot surfaces. No smoking.**Keep container tightly closed.**Avoid breathing dust/fume/gas/mist/vapours/spray.**Wear protective gloves/protective clothing/eye protection/face protection.**If skin irritation or rash occurs: Get medical advice/attention.**Store in a well-ventilated place. Keep cool.*· **Directive 2012/18/EU**· **Named dangerous substances - ANNEX I** *None of the ingredients is listed.*· **Seveso category** *P5c FLAMMABLE LIQUIDS*· **Qualifying quantity (tonnes) for the application of lower-tier requirements** *5000 t*· **Qualifying quantity (tonnes) for the application of upper-tier requirements** *50000 t*· **National regulations:**· **Other regulations, limitations and prohibitive regulations***The product is a medical device according to the Directive 93/42/EEC.*· **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.

· **Relevant phrases***H225 Highly flammable liquid and vapour.**H315 Causes skin irritation.**H317 May cause an allergic skin reaction.**H319 Causes serious eye irritation.*· **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**IATA: International Air Transport Association**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)**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 – Category 2**Skin Irrit. 2: Skin corrosion/irritation – Category 2**Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A**Skin Sens. 1: Skin sensitisation – Category 1*