

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 20.11.2015



Version number 8

Revision: 20.11.2015

**SECTION 1: Identification of the substance/mixture and of the company/undertaking**

- **1.1 Product identifier**
- **Trade name: Monobond Plus**
- **1.2 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
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Ivoclar Vivadent AG  
Bendererstrasse 2  
FL-9494 Schaan  
PRINCIPALITY OF LIECHTENSTEIN
- 
- Tel: +423 235 35 35  
Fax: +423 235 33 60
- **Further information obtainable from:**  
Regulatory Affairs  
sds@ivoclarvivadent.com
- **1.4 Emergency telephone number:** +423 / 235 33 13 (Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein)

**SECTION 2: Hazards identification**

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
Flam. Liq. 2 H225 Highly flammable liquid and vapour.  
Skin Sens. 1 H317 May cause an allergic skin reaction.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**
-  
- GHS02 GHS07
- **Signal word** *Danger*
- **Hazard-determining components of labelling:**  
Methacrylated phosphoric acid ester
- **Hazard statements**  
H225 Highly flammable liquid and vapour.  
H317 May cause an allergic skin reaction.
- **Precautionary statements**  
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.  
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.  
P280 Wear protective gloves/protective clothing/eye protection/face protection.  
P233 Keep container tightly closed.  
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.  
P403+P235 Store in a well-ventilated place. Keep cool.
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.

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Trade name: **Monobond Plus**· **vPvB:** Not applicable.

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### SECTION 3: Composition/information on ingredients

#### · 3.2 Chemical characterisation: Mixtures

· **Description:** Mixture of substances listed below with nonhazardous additions.

#### · **Dangerous components:**

|                   |   |         |
|-------------------|---|---------|
| CAS: 64-17-5      | ethanol   | 50-100% |
| EINECS: 200-578-6 | Flam. Liq. 2, H225  |         |
| CAS: 85590-00-7   | Methacrylated phosphoric acid ester                         | 1-<2.5% |
|                   | Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317 |         |

· **Additional information:** For the wording of the listed risk phrases refer to section 16.

### SECTION 4: First aid measures

#### · 4.1 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.

· **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.

· **4.3 Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

### SECTION 5: Firefighting measures

#### · 5.1 Extinguishing media

##### · **Suitable extinguishing agents:**

CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

· **5.2 Special hazards arising from the substance or mixture** No further relevant information available.

##### · 5.3 Advice for firefighters

· **Protective equipment:** No special measures required.

· **Additional information** Cool endangered receptacles with water spray.

### SECTION 6: Accidental release measures

· **6.1 Personal precautions, protective equipment and emergency procedures** Not required.

· **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.

· **6.3 Methods and material for containment and cleaning up:** Pick up mechanically.

##### · 6.4 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.

### SECTION 7: Handling and storage

#### · 7.1 Precautions for safe handling

Only adequately trained personnel should handle this product.

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For use in dentistry only.

- **Information about fire - and explosion protection:** No special measures required.
- **7.2 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.
- **7.3 Specific end use(s)** No further relevant information available.

### SECTION 8: Exposure controls/personal protection

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

- **8.1 Control parameters**

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

|                      |
|----------------------|
| CAS: 64-17-5 ethanol |
|----------------------|

|  |
|--|
| WEL Long-term value: 1920 mg/m <sup>3</sup> , 1000 ppm |
|--|

- **Additional information:** The lists valid during the making were used as basis.

- **8.2 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.
- **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 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.

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· Eye protection: Safety glasses

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### SECTION 9: Physical and chemical properties

#### · 9.1 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/Melting range: | -114,5 °C |
| Boiling point/Boiling range: | 78 °C     |

· Flash point: 13 °C

· Ignition temperature: 425 °C

· Self-igniting: Product is not selfigniting.

· Danger of explosion: 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/cm <sup>3</sup> |
| · 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. |

· 9.2 Other information: No further relevant information available.

### SECTION 10: Stability and reactivity

· 10.1 Reactivity: No further relevant information available.

· 10.2 Chemical stability: Stable under normal handling and storage conditions.

· Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

· 10.3 Possibility of hazardous reactions: No dangerous reactions known.

· 10.4 Conditions to avoid: No further relevant information available.

· 10.5 Incompatible materials: No further relevant information available.

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- **10.6 Hazardous decomposition products:** None under normal conditions of storage and use.

### SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.

- **LD/LC50 values relevant for classification:**

|      |      |                   |
|------|------|-------------------|
| Oral | LD50 | >5000 mg/kg (rat) |
|------|------|-------------------|

- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation**  
May cause an allergic skin reaction.
- **Additional toxicological information:** No further relevant information available.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

### SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 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.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

### SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**  
Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- **European waste catalogue**

|           |  |
|-----------|--|
| 18 01 06* | chemicals consisting of or containing dangerous substances |
|-----------|--|

- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

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### SECTION 14: Transport information

|   |  |
|---|--|
| · 14.1 UN-Number<br>· ADR,RID,ADN, IMDG, IATA   | 1170   |
| · 14.2 UN proper shipping name<br>· ADR/RID/ADN<br>· IMDG<br>· IATA                             | 1170 ETHANOL (ETHYL ALCOHOL), solution<br>ETHANOL (ETHYL ALCOHOL), solution<br>ETHANOL, solution |
| · 14.3 Transport hazard class(es)<br>· ADR/RID/ADN  |  |
|                |  |
| · Class<br>· Label  | 3 (F1) Flammable liquids.<br>3   |
| · IMDG, IATA  |  |
|               |  |
| · Class<br>· Label  | 3 Flammable liquids.<br>3  |
| · 14.4 Packing group<br>· ADR,RID,ADN, IMDG, IATA   | II   |
| · 14.5 Environmental hazards:<br>· Marine pollutant:  | No   |
| · 14.6 Special precautions for user<br>· Danger code (Kemler):<br>· EMS Number:                 | Warning: Flammable liquids.<br>33<br>F-E,S-D   |
| · 14.7 Transport in bulk according to Annex II of<br>Marpol and the IBC Code                    | Not applicable.  |
| · Transport/Additional information:   |  |
| · ADR/RID/ADN<br>· Limited quantities (LQ)<br>· Transport category<br>· Tunnel restriction code | LQ4<br>2<br>D/E  |
| · UN "Model Regulation":  | UN1170, ETHANOL (ETHYL ALCOHOL) solution, 3, II  |

### SECTION 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- National regulations:
- Other regulations, limitations and prohibitive regulations  
The product is a medical device according to the Directive 93/42/EEC.

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· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

### SECTION 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*

*GHS: Globally Harmonised System of Classification and Labelling of Chemicals*

*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, Hazard Category 2*

*Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2*

*Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2*

*Skin Sens. 1: Sensitisation - Skin, Hazard Category 1*

· **\* Data compared to the previous version altered.**