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.

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

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

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.
SECTION 3: Composition/information on ingredients

- 3.2 Chemical characterisation: Mixtures
- Description: Mixture of substances listed below with nonhazardous additions.
- Dangerous components:

<table>
<thead>
<tr>
<th>CAS</th>
<th>Substance</th>
<th>Percentage</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>64-17-5</td>
<td>Ethanol</td>
<td>50-100%</td>
<td>Flam. Liq. 2, H225</td>
</tr>
<tr>
<td>85590-00-7</td>
<td>Methacrylated phosphoric acid ester</td>
<td>1-&lt;2.5%</td>
<td>Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317</td>
</tr>
</tbody>
</table>

- 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: CO2, 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.
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:**

<table>
<thead>
<tr>
<th>CAS</th>
<th>WEL Long-term value: 1920 mg/m³, 1000 ppm</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS: 64-17-5 ethanol</td>
<td></td>
</tr>
</tbody>
</table>

- **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 breakthrough 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.
Trade name: **Monobond Plus**

- **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 self-igniting.
  - **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/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.

- **9.2 Other information**
  - No further relevant information available.

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### 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.

(Contd. on page 5)
Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 20.11.2015
Version number 8
Revision: 20.11.2015

Trade name: Monobond Plus

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:

<table>
<thead>
<tr>
<th>Route</th>
<th>LD50/LC50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>&gt;5000 mg/kg (rat)</td>
</tr>
</tbody>
</table>

- 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.
SECTION 14: Transport information

14.1 UN-Number
- ADR, RID, ADN, IMDG, IATA 1170

14.2 UN proper shipping name
- ADR/RID/ADN 1170 ETHANOL (ETHYL ALCOHOL), solution
- IMDG ETHANOL (ETHYL ALCOHOL), solution
- IATA ETHANOL, solution

14.3 Transport hazard class(es)
- ADR/RID/ADN
  - Class 3 (F1) Flammable liquids.
  - Label 3

14.4 Packing group
- ADR, RID, ADN, IMDG, IATA II

14.5 Environmental hazards:
- Marine pollutant: No

14.6 Special precautions for user
- Danger code (Kemler): Warning: Flammable liquids.
- EMS Number: F-E, S-D

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
- Not applicable.

Transport/Additional information:
- ADR/RID/ADN
  - Limited quantities (LQ) LQ4
  - Transport category 2
  - Tunnel restriction code 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.
Safety data sheet  
according to 1907/2006/EC, Article 31

Trade name: Monobond Plus

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)
  LD50: Lethal concentration, 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.