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

1.1 Product identifier
- Trade name: **Monobond-S**

1.2 Relevant identified uses of the substance or mixture and uses advised against
- No further relevant information available.
- Application of the substance / the preparation: Bonding agent

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
  - msds@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 Directive 67/548/EEC or Directive 1999/45/EC
  - R10: Flammable.

- Classification system:
  - The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

2.2 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 Preparations Directive 1999/45/EC usually if they are in the finished state and intended for the final user.

- Risk phrases:
  - 10 Flammable.

- Safety phrases:
  - 7 Keep container tightly closed.
  - 16 Keep away from sources of ignition - No smoking.
  - 60 This material and its container must be disposed of as hazardous waste.

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

SECTION 3: Composition/information on ingredients

3.2 Chemical characterization: Mixtures
- Description: Mixture of substances listed below with nonhazardous additions.

(Contd. on page 2)
Trade name: Monobond-S

SECTION 4: First aid measures

4.1 Description of first aid measures
- After inhalation: Supply fresh air; consult doctor in case of complaints.
- After skin contact:
  Rinse with water.
  Generally the product does not irritate the skin.
- After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.
- After swallowing:
  Rinse out mouth and then drink plenty of water.
  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
- Wear protective equipment. Keep unprotected persons away.

6.2 Environmental precautions:
- Dilute with plenty of water.
- Do not allow to enter sewers/ surface or ground water.

6.3 Methods and material for containment and cleaning up:
- Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

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
No special precautions are necessary if used correctly.

Information about fire - and explosion protection:
- Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.

7.2 Conditions for safe storage, including any incompatibilities
- Storage:
  - Requirements to be met by storerooms and receptacles: No special requirements.
  - Information about storage in one common storage facility: Not required.
- Further information about storage conditions: 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>Substance</th>
<th>Limit Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>64-17-5 ethanol</td>
<td>WEL: 1920 mg/m³, 1000 ppm</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.
    - Keep away from foodstuffs, beverages and feed.
    - Wash hands before breaks and at the end of work.
  - Respiratory protection:
    - In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
  - Protection of hands:
    - The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
    - After use of gloves apply skin-cleaning agents and skin cosmetics.
  - 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.
  - Eye protection: Safety glasses

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 at 20 °C: 4
Change in condition

- Melting point/Melting range: Undetermined.
- Boiling point/Boiling range: Undetermined.

Flash point: 25 °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: 15.0 Vol %

Vapour pressure at 20 °C: 59 hPa

Density at 20 °C: 0.913 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.

SECTION 10: Stability and reactivity

10.1 Reactivity
No further relevant information available.

10.2 Chemical stability
Stable under normal handling and storage conditions.

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

10.4 Conditions to avoid
No further relevant information available.

10.5 Incompatible materials
No further relevant information available.

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:
- Primary irritant effect:
  - on the skin: No irritant effect.
  - on the eye: No irritating effect.
- Sensitization: No sensitizing effects known.
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, IMDG, IATA
    1170
- 14.2 UN proper shipping name
  - ADR
    1170 ETHANOL (ETHYL ALCOHOL), solution
  - IMDG
    ETHANOL (ETHYL ALCOHOL), solution
  - IATA
    ETHANOL, solution
- 14.3 Transport hazard class(es)
  - ADR
    - Class
      3 (F1) Flammable liquids.
    - Label
      3
Trade name: Monobond-S

- IMDG, IATA

3 Flammable liquids.

- Class
- Label 3

- 14.4 Packing group
- ADR, IMDG, IATA
- 14.5 Environmental hazards:
- Marine pollutant: No

Warning: Flammable liquids.

- 14.6 Special precautions for user
- Danger code (Kemler): 30
- EMS Number: F-E,S-D

- 14.7 Transport in bulk according to Annex II of
  MARPOL73/78 and the IBC Code
- Transport in bulk: Not applicable.
  ADR
- Limited quantities (LQ) LQ7
- Transport category 3
- Tunnel restriction code D/E

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.

- 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
  R11 Highly flammable.
  * Data compared to the previous version altered.