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 6925
    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 identification

- **Classification of the substance or mixture**
  - Flammable Liquids - Category 2 H225 Highly flammable liquid and vapour.
  - Skin Sensitizer - Category 1 H317 May cause an allergic skin reaction.
  - Carcinogenicity - Category 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**
  - GHS02
  - GHS07
  - GHS08
- **Signal word** Danger
- **Hazard-determining components of labeling**:
  - ethanol
  - Methacrylated phosphoric acid ester
- **Hazard statements**
  - Highly flammable liquid and vapour.

(Contd. on page 2)
Trade name: Monobond Plus

May cause an allergic skin reaction.
May cause cancer.

- **Precautionary statements**
  Obtain special instructions before use.
  Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
  Avoid breathing dust/fume/gas/mist/vapourspray.
  Wear protective gloves/protective clothing/eye protection/face protection.
  Use explosion-proof [electrical/ventilating/lighting] equipment.
  Ground and bond container and receiving equipment.
  Keep container tightly closed.
  Use non-sparking tools.
  Take actions to prevent static discharges.
  Contaminated work clothing should not be allowed out of the workplace.
  Do not handle until all safety precautions have been read and understood.
  IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. Specific treatment (see on this label).
  IF exposed or concerned: Get medical advice/attention.
  If skin irritation or rash occurs: Get medical advice/attention.
  In case of fire: Use for extinction: CO2, powder or water spray.
  Take off contaminated clothing and wash it before reuse.
  Store locked up.
  Store in a well-ventilated place. Keep cool.
  Dispose of contents/container in accordance with local/regional/national/international regulations.

- **Classification system:**
  - **NFPA ratings (scale 0 - 4)**
    - Health = 0
    - Fire = 3
    - Reactivity = 0
  - **HMIS-ratings (scale 0 - 4)**
    - Health = 0
    - Fire = 3
    - 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 ethanol 60-100% w/w
  - CAS: 85590-00-7 Methacrylated phosphoric acid ester ≤1% w/w

### 4 First aid measures

- **Description of first aid measures**
- **After inhalation:**
  Supply fresh air; consult doctor in case of complaints.
Trade name: Monobond Plus

(Contd. of page 2)

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 Firefighting 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.
Trade name: **Monobond Plus**

### Control parameters

#### Components with limit values that require monitoring at the workplace:

<table>
<thead>
<tr>
<th>CAS</th>
<th>64-17-5 ethanol</th>
</tr>
</thead>
<tbody>
<tr>
<td>EL</td>
<td>Short-term value: 1000 ppm</td>
</tr>
<tr>
<td>EV</td>
<td>Long-term value: 1,900 mg/m³, 1,000 ppm</td>
</tr>
</tbody>
</table>

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

### Exposure controls

#### Personal protective equipment:

- **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

### Physical and chemical properties

#### Information on basic physical and chemical properties

- **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
- **Boiling point/Boiling range:** 78 °C
Trade name: Monobond Plus

· Flash point: 13 °C
· Ignition temperature: 425 °C
· Auto igniting: Product is not selfigniting.
· Danger of explosion: Product is not explosive. However, formation of explosive air/vapor mixtures are possible.

· Explosion limits:
  Lower: 3,5 Vol %
  Upper: 15 Vol %
· Vapor pressure at 20 °C: 59 hPa
· Density at 20 °C: 0,794 g/cm³
  Relative density: Not determined.
  Vapor 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.
· 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:
  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
Trade name: Monobond Plus

- NTP (National Toxicology Program)
  None of the ingredients is listed.
- OSHA-Ca (Occupational Safety & Health Administration)
  None of the ingredients is listed.

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.

14 Transport information

- UN-Number
  - DOT: UN1170
  - TDG, IMDG, IATA: 1170
- UN proper shipping name
  - DOT, IATA: ETHANOL, solution
  - ADR/RID/ADN: 1170 ETHANOL (ETHYL ALCOHOL), solution
  - IMDG: ETHANOL (ETHYL ALCOHOL), solution
- Transport hazard class(es)
  - DOT
    - Class: 3 Flammable liquids
### 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.
Trade name: Monobond Plus

- **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 A3
  - 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**
    - GHS02
    - GHS07
    - GHS08

- **Signal word** Danger

- **Hazard-determining components of labeling:**
  - Ethanol
  - Methacrylated phosphoric acid ester

- **Hazard statements**
  - Highly flammable liquid and vapour.
  - May cause an allergic skin reaction.
  - May cause cancer.

- **Precautionary statements**
  - Obtain special instructions before use.
  - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
  - Avoid breathing dust/fume/gas/mist/vapours/spray.
  - Wear protective gloves/protective clothing/eye protection/face protection.
  - Use explosion-proof [electrical/ventilating/lighting] equipment.
  - Ground and bond container and receiving equipment.
  - Keep container tightly closed.
  - Use non-sparking tools.
  - Take actions to prevent static discharges.
  - Contaminated work clothing should not be allowed out of the workplace.
  - Do not handle until all safety precautions have been read and understood.
  - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. Specific treatment (see on this label).
  - IF exposed or concerned: Get medical advice/attention.
  - If skin irritation or rash occurs: Get medical advice/attention.
  - In case of fire: Use for extinction: CO2, powder or water spray.
  - Take off contaminated clothing and wash it before reuse.
  - Store locked up.
  - Store in a well-ventilated place. Keep cool.
  - Dispose of contents/container in accordance with local/regional/national/international regulations.

- **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.

(Contd. on page 9)
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:
- IMDG: International Maritime Code for Dangerous Goods
- DOT: US Department of Transportation
- IATA: International Air Transport Association
- ACGIH: American Conference of Governmental Industrial Hygienists
- 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
- Flammable Liquids - Category 2: Flammable liquids, Hazard Category 2
- Skin Sensitizer - Category 1: Sensitisation - Skin, Hazard Category 1
- Carcinogenicity - Category 1A: Carcinogenicity, Hazard Category 1A

* Data compared to the previous version altered.