1 Identification

· Product identifier
  · Trade name: **Monobond Etch & Prime**
  · Application of the substance / the mixture: Ceramic primer

· 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 6825
    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(s) identification

· Classification of the substance or mixture
  · Flam. Liq. 3 H226 Flammable liquid and vapor.
  · Acute Tox. 4 H302 Harmful if swallowed.
  · Skin Corr. 1C H314 Causes severe skin burns and eye damage.
  · Eye Dam. 1 H318 Causes serious eye damage.
  · Skin Sens. 1 H317 May cause an allergic skin reaction.
  · STOT SE 3 H335-H336 May cause respiratory irritation. May cause drowsiness or dizziness.

· Label elements
  · GHS label elements
    The product is classified and labeled according to the Globally Harmonized System (GHS).

· Hazard pictograms
  
  ![GHS02](image1) ![GHS05](image2) ![GHS07](image3)

· Signal word: Danger

· Hazard-determining components of labeling:
  Tetrabutylammonium Dihydrogen Trifluoride
  Methacrylated phosphoric acid ester

(Contd. on page 2)
43.0.9 butanol

**Hazard statements**
- Flammable liquid and vapor.
- Harmful if swallowed.
- Causes severe skin burns and eye damage.
- May cause an allergic skin reaction.
- May cause respiratory irritation. May cause drowsiness or dizziness.

**Precautionary statements**
- Wear protective gloves/protective clothing/eye protection/face protection.
- If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
- If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- Immediately call a POISON CENTER/doctor.
- If swallowed: Rinse mouth. Do NOT induce vomiting.
- If skin irritation or rash occurs: Get medical advice/attention.

**Classification system:**
- **NFPA ratings (scale 0 - 4)**
  - Health = 3
  - Fire = 3
  - Reactivity = 0
- **HMIS-ratings (scale 0 - 4)**
  - Health = *4
  - 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: 78-92-2 butanol 20-<25%
  - CAS: 99337-56-1 Tetrahydroammonium Dihydrogen Trifluoride 10-<10%
  - CAS: 85590-00-7 Methacrylated phosphoric acid ester 2.5-<10%
  - CAS: 16068-37-4 Bis(triethoxysilyl)ethane 1-<2.5%

### 4 First-aid measures

- **Description of first aid measures**
- **General information:** Immediately remove any clothing soiled by the product.
- **After inhalation:**
  - Supply fresh air and to be sure call for a doctor.
  - 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.
43. After swallowing:
   Rinse out mouth and then drink plenty of water.
   Seek immediate medical advice.

44. 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, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
   For safety reasons unsuitable extinguishing agents: Water with full jet
   Special hazards arising from the substance or mixture: No further relevant information available.

   Advice for firefighters
   Protective equipment: No special measures required.

6. Accidental release measures
   Personal precautions, protective equipment and emergency procedures
   Wear protective equipment. Keep unprotected persons away.

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

   Methods and material for containment and cleaning up:
   Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
   Use neutralizing agent.
   Dispose contaminated material as waste according to item 13.
   Ensure adequate ventilation.

   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.
   Ensure good ventilation/exhaustion at the workplace.
   Prevent formation of aerosols.

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

   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: 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.

- Control parameters

<table>
<thead>
<tr>
<th>Components with limit values that require monitoring at the workplace:</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS: 78-92-2 butanol</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PEL</th>
<th>Long-term value: 450 mg/m³, 150 ppm</th>
</tr>
</thead>
<tbody>
<tr>
<td>REL</td>
<td>Short-term value: 455 mg/m³, 150 ppm</td>
</tr>
<tr>
<td></td>
<td>Long-term value: 305 mg/m³, 100 ppm</td>
</tr>
<tr>
<td>TLV</td>
<td>Long-term value: 300 mg/m³, 100 ppm</td>
</tr>
</tbody>
</table>

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

- Exposure controls

- Personal protective equipment:

  - General protective and hygienic measures:
    Usual hygienic measures for dental practice and dental laboratories.
    Keep away from foodstuffs, beverages and feed.
    Wash hands before breaks and at the end of work.
    Immediately remove all soiled and contaminated clothing.
    Avoid contact with the eyes and skin.

  - Breathing equipment:
    In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

- Protection of hands:

  - Protective gloves
    After use of gloves apply skin-cleaning agents and skin cosmetics.

  - Material of gloves
    Fluorocarbon rubber (Viton)
    Butyl rubber, BR
    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:

  - Tightly sealed goggles


43.0.9

Color: Green

∙ Odor: Characteristic

∙ Odor threshold: Not determined.

∙ pH-value: Not determined.

∙ Change in condition
  Melting point/Melting range: Undetermined.
  Boiling point/Boiling range: Undetermined.

∙ Flash point: 34 °C (93 °F)

∙ Flammability (solid, gaseous): Not applicable.

∙ Auto igniting: Product is not selfigniting.

∙ Danger of explosion: Product is not explosive. However, formation of explosive air/vapor mixtures are possible.

∙ Flash point:
  Lower: 1.7 Vol %
  Upper: 9.8 Vol %

∙ Flash point: Not determined.

∙ Density: Not determined.

∙ Relative density: Not determined.

∙ Vapor density: Not determined.

∙ Evaporation rate: Not determined.

∙ Solubility in / Miscibility with Water: Fully miscible.

∙ 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:
  ∙ on the skin: Strong caustic effect on skin and mucous membranes.
  ∙ on the eye: Strong caustic effect.

∙ Sensitization: Sensitization possible through skin contact.
Additional toxicological information:
Swallowing will lead to a strong caustic effect on mouth and throat and to the danger of perforation of esophagus and stomach.

Carcinogenic categories

- 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.
    Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

- Uncleaned packagings:
  - Recommendation: Disposal must be made according to official regulations.

14 Transport information

- UN-Number
  - DOT, ADR, RID, ADN, IMDG, IATA: UN2924

- UN proper shipping name
  - DOT: Flammable liquids, corrosive, n.o.s. (Butanols, Tetrabutylammonium Dihydrogen Trifluoride)
  - ADR/RID/ADN: 2924 Flammable liquids, corrosive, n.o.s. (Butanols, Tetrabutylammonium Dihydrogen Trifluoride)
  - IMDG, IATA: FLAMMABLE LIQUID, CORROSIVE, N.O.S. (BUTANOLS, Tetrabutylammonium Dihydrogen Trifluoride)
**Trade name: Monobond Etch & Prime**

<table>
<thead>
<tr>
<th><strong>Transport hazard class(es)</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DOT</strong></td>
<td>![ DOT class 3 Flammable liquids ]</td>
</tr>
<tr>
<td><strong>Class</strong></td>
<td>3 Flammable liquids</td>
</tr>
<tr>
<td><strong>Label</strong></td>
<td>3, 8</td>
</tr>
<tr>
<td><strong>ADR/RID/ADN</strong></td>
<td>![ ADR/RID/ADN class 3 (FC) Flammable liquids ]</td>
</tr>
<tr>
<td><strong>Class</strong></td>
<td>3 (FC) Flammable liquids</td>
</tr>
<tr>
<td><strong>Label</strong></td>
<td>3+8</td>
</tr>
<tr>
<td><strong>IMDG</strong></td>
<td>![ IMDG class 3 Flammable liquids ]</td>
</tr>
<tr>
<td><strong>Class</strong></td>
<td>3 Flammable liquids</td>
</tr>
<tr>
<td><strong>Label</strong></td>
<td>3/8</td>
</tr>
<tr>
<td><strong>IATA</strong></td>
<td>![ IATA class 3 Flammable liquids ]</td>
</tr>
<tr>
<td><strong>Class</strong></td>
<td>3 Flammable liquids</td>
</tr>
<tr>
<td><strong>Label</strong></td>
<td>3 (8)</td>
</tr>
</tbody>
</table>

- **Packing group**
  - **DOT, ADR, RID, ADN, IMDG, IATA** III

- **Environmental hazards:** No

- **Special precautions for user** Warning: Flammable liquids

- **Danger code (Kemler):** 38

- **EMS Number:** F-E-S-C

- **Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** Not applicable.

- **Transport/Additional information:**

  - **ADR/RID/ADN**
    - **Excepted quantities (EQ)** Code: E1
      - Maximum net quantity per inner packaging: 30 ml
      - Maximum net quantity per outer packaging: 1000 ml

  - **IMDG**
    - **Limited quantities (LQ)** 5L

(Contd. on page 8)
Trade name: Monobond Etch & Prime

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):
    - CAS: 78-92-2 butanol

- TSCA (Toxic Substances Control Act):
  All ingredients are listed.

- 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.

  - Chemicals known to cause developmental toxicity:
    None of the ingredients is listed.

- Carcinogenic categories
  - EPA (Environmental Protection Agency)
    None of the ingredients is listed.

  - TLV (Threshold Limit Value established by ACGIH)
    None of the ingredients is listed.

  - 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
  - GHS05
  - GHS07

- Signal word
  - Danger

  - Hazard-determining components of labeling:
    - Tetrabutylammonium Dihydrogen Trifluoride
    - Methacrylated phosphoric acid ester
    - butanol
Safety Data Sheet
acc. to OSHA HCS

Printing date 09/21/2016
Version number 3
Reviewed on 09/21/2016

Trade name: Monobond Etch & Prime

(Contd. of page 8)

43.0.9

∙ Hazard statements
  Flammable liquid and vapor.
  Harmful if swallowed.
  Causes severe skin burns and eye damage.
  May cause an allergic skin reaction.
  May cause respiratory irritation. May cause drowsiness or dizziness.

∙ Precautionary statements
  Wear protective gloves/protective clothing/eye protection/face protection.
  If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
  If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.
  Continue rinsing.
  Immediately call a POISON CENTER/doctor.
  If swallowed: Rinse mouth. Do NOT induce vomiting.
  If skin irritation or rash occurs: Get medical advice/attention.

∙ 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.

∙ 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 09/21/2016 / 2

∙ 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
  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)
  HMIS: Hazardous Materials Identification System (USA)
  NIOSH: National Institute for Occupational Safety
  OSHA: Occupational Safety & Health
  TLV: Threshold Limit Value
  PEL: Permissible Exposure Limit
  REL: Recommended Exposure Limit
  Flam. Liq. 3: Flammable liquids – Category 3
  Acute Tox. 4: Acute toxicity – Category 4
  Skin Corr. 1C: Skin corrosion/irritation – Category 1C
  Eye Dam. 1: Serious eye damage/eye irritation – Category 1
  Skin Sens. 1: Skin sensitisation – Category 1
  STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

* Data compared to the previous version altered.