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

- **Product identifier**

  - **Trade name:** Peak™ SE Primer (Part 1 of 2)
  - **Article number:** 15076
  - **Index number:** SDS 69-001.11
  - **Relevant identified uses of the substance or mixture and uses advised against:** Professional Dental Etchant
  - **Application of the substance / the mixture:** Professional Dental Etchant

- **Details of the supplier of the safety data sheet**

  - **Manufacturer/Supplier:**
    Ultradent Products Inc.
    505 W. Ultradent Drive (10200 S)
    South Jordan, UT 84095-3942
    USA
    onlineordersupport@ultradent.com

  - **EC Responsible Person:**
    Ultradent Products GmbH
    Am Westhover Berg 30
    51149 Cologne Germany
    Email: infoDE@ultradent.com
    Emergency Phone: +49(0)2203-35-92-0

- **Further information obtainable from:** Customer Service

- **Emergency telephone number:**
  - CHEMTREC (NORTH AMERICA) : (800) 424-9300
  - (INTERNATIONAL) : +(703) 527-3887

2 Hazards identification

- **Classification of the substance or mixture**

  - **Classification according to Regulation (EC) No 1272/2008**

    - GHS02 flame
      - Flam. Liq. 3 H226 Flammable liquid and vapour.

    - GHS05 corrosion
      - Skin Corr. 1A H314 Causes severe skin burns and eye damage.
      - Eye Dam. 1 H318 Causes serious eye damage.

    - GHS07
      - Skin Sens. 1 H317 May cause an allergic skin reaction.

- **Label elements**

  - **Labelling according to Regulation (EC) No 1272/2008**

    The Regulation EC 1272/2008 on classification, labeling and packaging of substances and mixtures (CLP) shall not apply to a medical device in the finished state used in direct physical contact with the human body according to Art. 1.5 (d). Therefore, the product is exempted from the CLP labeling requirements, and no SDS is required by Regulation 1907/2006, Art. 2 (6c), REACH. Therefore, all given data, classification, and information on this SDS (Contd. on page 2)
Trade name: Peak™ SE Primer (Part 1 of 2)

are provided solely on a voluntary basis.

- **Hazard pictograms** GHS02, GHS05, GHS07
- **Signal word** Danger

- **Hazard-determining components of labelling:**
  - Trade Secret
  - 2-Hydroxyethyl Methacrylate
  - Organophosphine Oxide

- **Hazard statements**
  - H226 Flammable liquid and vapour.
  - H314 Causes severe skin burns and eye damage.
  - H317 May cause an allergic skin reaction.

- **Precautionary statements**
  - P101 If medical advice is needed, have product container or label at hand.
  - P102 Keep out of reach of children.
  - P103 Read label before use.
  - P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
  - P233 Keep container tightly closed.
  - P260 Do not breathe dusts or mists.
  - P264 Wash thoroughly after handling.
  - P272 Contaminated work clothing should not be allowed out of the workplace.
  - P280 Wear protective gloves / eye protection / face protection.
  - P301+P330+P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
  - P303+P361+P333 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
  - P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
  - P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
  - P310 Immediately call a POISON CENTER/doctor.
  - P321 Specific treatment (see on this label).
  - P362+P364 Take off contaminated clothing and wash it before reuse.
  - P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
  - P363 Wash contaminated clothing before reuse.
  - P370+P378 In case of fire: Use for extinction: CO2, powder or water spray.
  - P403+P235 Store in a well-ventilated place. Keep cool.
  - P405 Store locked up.
  - P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

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

### 3 Composition/information on ingredients

- **Chemical characterisation:** Mixtures
- **Description:** Mixture of substances listed below with nonhazardous additions.

<table>
<thead>
<tr>
<th>CAS: 64-17-5</th>
<th>Ethyl Alcohol</th>
<th>&gt;25-≤50%</th>
</tr>
</thead>
<tbody>
<tr>
<td>EINECS: 200-578-6</td>
<td>✅ Flam. Liq. 2, H225</td>
<td></td>
</tr>
</tbody>
</table>

(Contd. on page 3)
4 First aid measures

- **Description of first aid measures**
- **General information:** Immediately remove any clothing soiled by the product.
- **After inhalation:** Seek medical treatment in case of complaints.
- **After skin contact:**
  Immediately wash with water and soap and rinse thoroughly.
  If skin irritation continues, consult a doctor.
- **After eye contact:**
  Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing:**
  Do NOT induce vomiting.
  Rinse mouth with water.
  Drink plenty of water and provide fresh air. Call for a doctor immediately.
- **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:**
  Carbon dioxide
  Dry Chemical
  Foam
- **Special hazards arising from the substance or mixture**
  During heating or in case of fire poisonous gases are produced.
- **Advice for firefighters:**
  General: Evacuate all personnel; use protective equipment for fire-fighting. Use self-contained breathing apparatus when the product is involved in fire.
- **Protective equipment:**
  Wear fully protective suit.
  Mouth respiratory protective device.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
  Mount respiratory protective device.
  Wear protective equipment. Keep unprotected persons away.
51.1.24

- Environmental precautions:
  Dilute with plenty of water.
  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 neutralising 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:
    Ensure good ventilation/exhaustion at the workplace.
    Prevent formation of aerosols.
  - Information about fire - and explosion protection:
    Keep ignition sources away - Do not smoke.
    Protect against electrostatic charges.
    Keep respiratory protective device available.

- 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.

- Specific end use(s) Professiona Dental Etchant

8 Exposure controls/personal protection

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

- Control parameters

<table>
<thead>
<tr>
<th>Ingredients with limit values that require monitoring at the workplace:</th>
</tr>
</thead>
<tbody>
<tr>
<td>64-17-5 Ethyl Alcohol</td>
</tr>
<tr>
<td>WEL (Great Britain) Long-term value: 1920 mg/m³, 1000 ppm</td>
</tr>
</tbody>
</table>

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

- Exposure controls
  - Personal protective equipment:
    - General protective and hygienic measures:
      Keep away from foodstuffs, beverages and feed.
      Immediately remove all soiled and contaminated clothing.
      Wash hands before breaks and at the end of work.
      Avoid contact with the eyes.
      Avoid contact with the eyes and skin.

- 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.
Trade name: Peak™ SE Primer (Part 1 of 2)

· **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 of the glove material:

· **Material of gloves**

The selection of 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.

· **Eye protection:**

![Tightly sealed goggles]

· **Body protection:** Protective work clothing

---

### 9 Physical and chemical properties

<table>
<thead>
<tr>
<th>· <strong>Information on basic physical and chemical properties</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>· <strong>General Information</strong></td>
</tr>
<tr>
<td>· <strong>Appearance:</strong></td>
</tr>
<tr>
<td>- <strong>Form:</strong> Liquid</td>
</tr>
<tr>
<td>- <strong>Colour:</strong> Yellow</td>
</tr>
<tr>
<td>- <strong>Odour:</strong> Methacrylate</td>
</tr>
<tr>
<td>- <strong>Odour threshold:</strong> Not determined.</td>
</tr>
<tr>
<td>· <strong>pH-value at 20 °C:</strong> 0.9-1.5-When mixed with part 2</td>
</tr>
<tr>
<td>· <strong>Change in condition</strong></td>
</tr>
<tr>
<td>- <strong>Melting point/freezing point:</strong> Undetermined.</td>
</tr>
<tr>
<td>- <strong>Initial boiling point and boiling range:</strong> Undetermined.</td>
</tr>
<tr>
<td>· <strong>Flash point:</strong> &lt;27 °C</td>
</tr>
<tr>
<td>· <strong>Flammability (solid, gas):</strong> Not applicable.</td>
</tr>
<tr>
<td>· <strong>Decomposition temperature:</strong> Not determined.</td>
</tr>
<tr>
<td>· <strong>Auto-ignition temperature:</strong> Product is not selfigniting.</td>
</tr>
<tr>
<td>· <strong>Explosive properties:</strong> Product is not explosive. However, formation of explosive air/vapour mixtures are possible.</td>
</tr>
<tr>
<td>· <strong>Explosion limits:</strong></td>
</tr>
<tr>
<td>- <strong>Lower:</strong> Not determined.</td>
</tr>
<tr>
<td>- <strong>Upper:</strong> Not determined.</td>
</tr>
<tr>
<td>· <strong>Vapour pressure at 20 °C:</strong> 552 hPa</td>
</tr>
</tbody>
</table>

(Contd. on page 6)
· Density at 20 °C: 1.015 g/cm³
· Relative density Not determined.
· Vapour 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.

· Solvent content:
  VOC (EC) <65%
· Solids content: <20.0 %
· Other information No further relevant information available.

### 10 Stability and reactivity

· Reactivity Polymerization occurs when exposed to visible light, ultraviolet light or extreme heat.
· Chemical stability
  · Thermal decomposition / conditions to be avoided: Stable under recommended storage conditions
  · Possibility of hazardous reactions: No dangerous reactions known.
  · Conditions to avoid:
    Direct Light
    Heat
    Flames
  · Incompatible materials: No further relevant information available.
  · Hazardous decomposition products: No dangerous decomposition products known.

### 11 Toxicological information

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

· LD/LC50 values relevant for classification:

  **64-17-5 Ethyl Alcohol**

<table>
<thead>
<tr>
<th>Route</th>
<th>Value</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>LD₅₀</td>
<td>5,600 mg/kg (Guinea pig)</td>
</tr>
<tr>
<td></td>
<td>LD₅₀</td>
<td>3,400 mg/kg (mouse)</td>
</tr>
<tr>
<td></td>
<td>LC₅₀</td>
<td>7,060 mg/kg (rat)</td>
</tr>
<tr>
<td>Inhalative</td>
<td>LC₅₀ Fish</td>
<td>&gt;10,000 mg/l (Fish)</td>
</tr>
<tr>
<td></td>
<td>LC₅₀/4 h</td>
<td>39 mg/l (mouse)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>20,000 mg/l (rat)</td>
</tr>
</tbody>
</table>

  **868-77-9 2-Hydroxyethyl Methacrylate**

<table>
<thead>
<tr>
<th>Route</th>
<th>Value</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>LD₅₀</td>
<td>3,275 mg/kg (mouse)</td>
</tr>
<tr>
<td></td>
<td>LD₅₀</td>
<td>&gt;5,000 mg/kg (rat)</td>
</tr>
<tr>
<td></td>
<td>LC₅₀ Fish</td>
<td>&gt;100 mg/l (Fish)</td>
</tr>
<tr>
<td>Dermal</td>
<td>LD₅₀</td>
<td>&gt;3,000 mg/kg (rabbit)</td>
</tr>
</tbody>
</table>
Trade name: Peak™ SE Primer (Part 1 of 2)

<table>
<thead>
<tr>
<th>162881-26-7 Organophosphine Oxide</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Oral</strong></td>
</tr>
<tr>
<td><strong>LC50 Fish</strong></td>
</tr>
<tr>
<td><strong>Dermal</strong></td>
</tr>
</tbody>
</table>

**Primary irritant effect:**
- **Skin corrosion/irritation**
  Causes severe skin burns and eye damage.
- **Serious eye damage/irritation**
  Causes serious eye damage.
- **Respiratory or skin sensitisation**
  May cause an allergic skin reaction.
- **CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)**
- **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.

**12 Ecological information**

**Toxicity**

**Aquatic toxicity:**
- **64-17-5 Ethyl Alcohol**
  Algae Toxicity: 1,000 mg/l (Algae)
- **868-77-9 2-Hydroxyethyl Methacrylate**
  EC50: 345 mg/l (Algae)
- **162881-26-7 Organophosphine Oxide**
  EC50 (static): >1.175 mg/kg (daphnia) (Toxicity to aquatic invertebrates)
  Aquatic Toxicity: 20.008 mg/l (daphnia) (Daphnia Magna Reproduction Test)
  Toxicity to Aquatic Plants (static): >0.26 mg/l (Plant) (Toxicity to algae)

**Persistence and degradability**
No further relevant information available.

**Behaviour 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 (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.
  Must not reach sewage water or drainage ditch undiluted or unneutralised.
  Rinse off of bigger amounts into drains or the aquatic environment may lead to decreased pH-values. A low pH-value harms aquatic organisms.
  In the dilution of the use-level the pH-value is considerably increased, so that after the use of the product the aqueous waste, emptied into drains, is only low water-dangerous.
- **Results of PBT and vPvB assessment**
  - **PBT:** Not applicable.
  - **vPvB:** Not applicable.
Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 19.10.2020
Revision: 18.09.2020

Trade name: Peak™ SE Primer (Part 1 of 2)

- Other adverse effects: No further relevant information available.

13 Disposal considerations

- Waste treatment methods
- Recommendation: Do not allow product to reach sewage system.

**European waste catalogue**

<table>
<thead>
<tr>
<th>HP3</th>
<th>Flammable</th>
</tr>
</thead>
<tbody>
<tr>
<td>HP8</td>
<td>Corrosive</td>
</tr>
<tr>
<td>HP13</td>
<td>Sensitising</td>
</tr>
</tbody>
</table>

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

14 Transport information

- UN-Number: UN2920
- ADR, IMDG, IATA
- UN proper shipping name
- ADR: 2920 CORROSIVE LIQUID, FLAMMABLE, N.O.S. (PHOSPHORUS PENTOXIDE, Ethyl Alcohol)
- IMDG, IATA: CORROSIVE LIQUID, FLAMMABLE, N.O.S. (PHOSPHORUS PENTOXIDE, Ethyl Alcohol)

- Transport hazard class(es)

**ADR**

<table>
<thead>
<tr>
<th>Class</th>
<th>8 Corrosive substances.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Label</td>
<td>8+3</td>
</tr>
</tbody>
</table>

**IMDG**

<table>
<thead>
<tr>
<th>Class</th>
<th>8 Corrosive substances.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Label</td>
<td>8/3</td>
</tr>
</tbody>
</table>

**IATA**

<table>
<thead>
<tr>
<th>Class</th>
<th>8 Corrosive substances.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Label</td>
<td>8 (3)</td>
</tr>
</tbody>
</table>

(Contd. of page 7)
Trade name: Peak™ SE Primer (Part 1 of 2)

<table>
<thead>
<tr>
<th>· Packing group</th>
<th>· ADR, IMDG, IATA</th>
<th>II</th>
</tr>
</thead>
<tbody>
<tr>
<td>· Environmental hazards:</td>
<td></td>
<td>Not applicable.</td>
</tr>
<tr>
<td>· Special precautions for user</td>
<td>Hazard identification number (Kemler code):</td>
<td>Warning: Corrosive substances. 83</td>
</tr>
<tr>
<td>· EMS Number:</td>
<td></td>
<td>F-E-S-C</td>
</tr>
<tr>
<td>· Segregation groups</td>
<td></td>
<td>Acids</td>
</tr>
<tr>
<td>· Stowage Category</td>
<td></td>
<td>E</td>
</tr>
<tr>
<td>· Stowage Code</td>
<td></td>
<td>SW1 Protected from sources of heat. SW2 Clear of living quarters.</td>
</tr>
<tr>
<td>· Transport in bulk according to Annex II of Marpol and the IBC Code</td>
<td>Not applicable.</td>
<td></td>
</tr>
<tr>
<td>· ADR/Additional information:</td>
<td>Transport category</td>
<td>2</td>
</tr>
<tr>
<td>· ADR</td>
<td></td>
<td>Tunnel restriction code D/E</td>
</tr>
<tr>
<td>· Limited quantities (LQ)</td>
<td></td>
<td>1L Code: E2</td>
</tr>
<tr>
<td>· Excepted quantities (EQ)</td>
<td></td>
<td>Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml</td>
</tr>
<tr>
<td>· IMDG</td>
<td></td>
<td>1L Code: E2</td>
</tr>
<tr>
<td>· Limited quantities (LQ)</td>
<td></td>
<td>Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml</td>
</tr>
<tr>
<td>· UN &quot;Model Regulation&quot;:</td>
<td></td>
<td>UN 2920 CORROSIVE LIQUID, FLAMMABLE, N.O.S. (PHOSPHORUS PENTOXIDE, ETHYL ALCOHOL), 8 (3), II</td>
</tr>
</tbody>
</table>

15 Regulatory information

| · Safety, health and environmental regulations/legislation specific for the substance or mixture |
| · Directive 2012/18/EU |
| · Named dangerous substances - ANNEX I None of the ingredients is listed. |
| · Seveso category P5c FLAMMABLE LIQUIDS |
| · Qualifying quantity (tonnes) for the application of lower-tier requirements 5,000 t |
| · Qualifying quantity (tonnes) for the application of upper-tier requirements 50,000 t |
| · REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3 |

| · DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II |
| None of the ingredients is listed. |

| · Chemical safety assessment: |
| Device is biocompatible when used as directed by dental professionals per ISO 10993-1 |
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.
  H314 Causes severe skin burns and eye damage.
  H315 Causes skin irritation.
  H317 May cause an allergic skin reaction.
  H318 Causes serious eye damage.
  H319 Causes serious eye irritation.
  H413 May cause long lasting harmful effects to aquatic life.

· Department issuing SDS: Environmental, Health & Safety
· Contact: Customer Service
· 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)
  VOC: Volatile Organic Compounds (USA, EU)
  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 – Category 2
  Flam. Liq. 3: Flammable liquids – Category 3
  Skin Corr. 1A: Skin corrosion/irritation – Category 1A
  Skin Irrit. 2: Skin corrosion/irritation – Category 2
  Eye Dam. 1: Serious eye damage/eye irritation – Category 1
  Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
  Skin Sens. 1: Skin sensitisation – Category 1
  Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4