SAFETY DATA SHEET  
according to Regulation (EC) No. 453/2010  
Dental Use  

Peak® SE Primer , Part 1 of 2

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

1.1. Product identifier

Product code : BI/15076  
Product name : Peak® SE Primer , Part 1 of 2  
Product description : Professional Dental Etchant

1.2. Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses : Professional Dental Etchant

1.3. Details of the supplier of the safety data sheet

Manufacturer  
Ultradent Products, Inc.  
505 W. Ultradent Drive (10200 South)  
South Jordan, UT 84095

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

1.4. Emergency telephone number

CHEMTREC (NORTH AMERICA) : (800) 424 - 9300  
(INTERNATIONAL) : +1(703) 527 - 3887

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation(EC) No 1272/2008 [CLP]

Health : Eye Irritation, Category 2  
Skin Irritation, Category 2  
Skin Sensitization, Category 1  
Acute Toxicity (Dermal), Category 3

Physical : Flammable Liquids, Category 2

2.2. Label elements

Classification according to Regulation(EC) No 1272/2008 [CLP]

Hazard pictogram(s) : 

| Flame | Exclamation mark |

Signal Word : DANGER

Hazard statement(s) : H225: Highly flammable liquid and vapour.  
H315: Causes skin irritation.  
H317: May cause an allergic skin reaction.
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Date Issued : 11/17/2006
SDS No : 69-001.10
Date Revised : 01/23/2017
Revision No : 10

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H319: Causes serious eye irritation.

Precautionary statement(s)


Storage : P273: Avoid release to the environment.

2.3. Other hazards

Conclusion: The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

SECTION 3: Composition / information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS</th>
<th>EINECS No.</th>
<th>Wt.%</th>
<th>Classification according to Regulation(EC) No 1272/2008 [CLP]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethyl Alcohol</td>
<td>64-17-5</td>
<td>200-578-6</td>
<td>&lt;40</td>
<td>Flam. Liq., Cat. 2; Eye Irr., Cat. 2; Skin Irr., Cat. 2; STOT SE, Cat. 3; H225; H319</td>
</tr>
<tr>
<td>2-hydroxyethyl Methacrylate</td>
<td>868-77-9</td>
<td>212-782-2</td>
<td>&lt;20</td>
<td>Eye Irr., Cat. 2B; Skin Sens., Cat. 1B; H317; H319</td>
</tr>
</tbody>
</table>

For full text of H-statements: see SECTION 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

Following eyes : Immediately flush eyes with plenty of water. Get medical attention, if irritation persists.

Following skin : Wash with soap and water. Get medical attention if irritation develops or persists.

Following ingestion : If swallowed Don't induce vomiting. Rinse mouth and seek medical advice if necessary.

Following inhalation : If inhaled, remove to fresh air. If breathing becomes difficult, call a physician.

4.2. Most important symptoms and effects, both acute and delayed

Eyes : Irritating to eyes.
Skin : May cause skin irritation and sensitization.
Ingestion: May be harmful if swallowed.
Inhalation: May be harmful if inhaled.

4.3. Indication of any immediate medical attention and special treatment needed
Notes to physician: Not Applicable

SECTION 5: Fire fighting measures

5.1. Extinguishing media
Extinguishing media: Foam, dry chemical, carbon dioxide (CO₂).

5.2. Special hazards arising from the substance or mixture
General hazard: This product has been classified as a Flammable Liquids Category 2.

5.3. Advice for firefighters
Fire fighting procedures: General: Evacuate all personnel; use protective equipment for fire-fighting. Use self-contained breathing apparatus when the product is involved in fire.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures
General procedures: Refer to Section 8 for Personal Protective Equipment.

6.2. Environmental precautions
Water spill: Do not allow to enter sewers or drains that may lead to waterways.

6.3. Methods and material for containment and cleaning up
Small Spill: Absorb liquid and place in sealed container for disposal. Vapors can travel to an ignition source.
Large Spill: Absorb with inert, damp non-combustible material, then flush area with water.

6.4. Reference to other sections
Reference to other sections: Not Applicable

SECTION 7: Handling and storage

7.1. Precautions for safe handling
Handling: Keep away from heat, sparks and flame.
Storage: See product labeling.

7.2. Conditions for safe storage, including any incompatibilities
Shelf life: See product labeling

7.3. Specific end use(s)
Specific end use(s): Professional Dental Etchant

SECTION 8: Exposure controls / personal protection

8.1. Control parameters
Control parameters: Ethyl Alcohol CAS: 64-17-5
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Control Parameters | Exposure Limits
--- | ---
OSHA PEL General Industry | 1000 ppm (1900 mg/m3) TWA
OSHA PEL - Construction Industry | 1000 ppm (900 mg/m3) TWA
OSHA PEL Shipyard Employment | 1000 ppm (1900 mg/m3) TWA
NIOSH REL | 1000 ppm (1900 mg/m3) TWA
ACGIH TLV | 1000 ppm (1880 mg/m3) STEL
CAL/OSHA PEL | 1000 ppm (1900 mg/m3) TWA

8.2. Exposure controls
Eye/face protection : Wear eye protection.
Skin protection : Wear suitable protective clothing and gloves.
Respiratory protection : Use only in well-ventilated areas.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties
Physical state : Liquid
Appearance : Clear, low viscosity liquid
Colour : Yellow
Odour : Methacrylate odor
pH : 0.9 - 1.5 (This value is when mixed with part 2 of 2)
Flash point : < 27°C
Specific gravity : 1.015

9.2. Other information
Additional information : No further relevant information available.

SECTION 10: Stability and reactivity

10.1. Reactivity
Reactivity : Stable when stored and handled under recommended conditions.

10.2. Chemical stability
Chemical stability : Polymerization occurs when exposed to visible light, ultraviolet light or extreme heat.

10.3. Possibility of hazardous reactions
Hazardous polymerization : None
Peak® SE Primer, Part 1 of 2

10.4. Conditions to avoid

Conditions to avoid: Heat, flames, ignition sources, direct light.

10.5. Incompatible materials

Incompatible materials: None known.

10.6. Hazardous decomposition products

Hazardous decomposition products: None known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute

Dermal LD<sub>50</sub>: > 800 mg/kg rat/rabbit
Notes: ~91% of the mixture consists of components of unknown toxicity (Dermal).

Oral LD<sub>50</sub>: > 4100 mg/kg Mouse/Rat/Guinea Pig
Notes: ~32% of the mixture consists of components of unknown toxicity (Oral).

Inhalation LC<sub>50</sub>: > 490 mg/l/4H Vapors Rat/Guinea Pig
Notes: ~23% of the mixture consists of components of unknown toxicity (Inhalation).

Other information: Device is biocompatible when used as directed by dental professionals per ISO 10993-1.

SECTION 12: Ecological information

12.1. Toxicity

Aquatic toxicity (acute): Do not allow to enter sewers or drains that may lead to waterways.

12.2. Persistence and degradability

Persistence and degradability: Not classified

12.3. Bioaccumulative potential

Bioaccumulative potential: Not classified

12.4. Mobility in soil

Mobility in soil: Not Available

12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment: Conclusion: The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

12.6. Other adverse effects

Environmental data: Do not flush to sewer.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

## SECTION 14: Transport information

### 14.1. UN number

UN number: 1987

### 14.2. UN proper shipping name

UN proper shipping name: Alcohols, n.o.s. (Ethyl alcohol mixture)

### 14.3. Transport hazard class(es)

- **Primary hazard class/division:** 3
- **Hazard classification:** 3

### 14.4. Packing group

Packing group: III

### 14.5. Environmental hazards

Marine pollutant #1: NAP

### 14.6. Special precautions for user

- **ADR - road:** NAP
- **RID - rail:** NAP
- **IMDG - sea:** NAP
- **IATA - air:** NAP

### 14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Transport in bulk: NAP

## SECTION 15: Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

**General information:** Substances of very high concern (SVHC) according to REACH, Article 57: Contains no SVHC substances.

**General comments:** Please refer to Medical Devices Directive 93/42/EEC.

### 15.2. Chemical safety assessment

Chemical safety assessment: See Section 11

**Additional information:** Ethyl Alcohol is only considered carcinogenic by IARC and CA Prop 65 when it is found in beverages. None of the other ingredients in the formulation of this product are considered to be carcinogenic by IARC, NTP, or CA Prop 65.

## SECTION 16: Other information

**Relevant H-statements (number and full text):**

- Eye Irr., Cat. 2B: Eye Irritation, Category 2B
- Eye Irr., Cat. 2: Eye Irritation, Category 2
- Flam. Liq., Cat. 2: Flammable Liquids, Category 2
- STOT SE, Cat. 3: Target Organ Toxicity (Single exposure), Respiratory Tract Category 3
- Skin Irr., Cat. 2: Skin Irritation, Category 2
- Skin Sens., Cat. 1B: Skin Sensitization, Category 1B
- H225: Highly flammable liquid and vapour.
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Peak® SE Primer , Part 1 of 2

H317: May cause an allergic skin reaction.
H319: Causes serious eye irritation.

Prepared by : Anu Kattoju
Revision summary : This SDS replaces the 03/19/2015 SDS. Revised: Section 1: MSDS No. Section 2: EMERGENCY OVERVIEW - IMMEDIATE CONCERNS 2.3. Other hazards. Section 4: INGESTION, INHALATION, SIGNS AND SYMPTOMS OF OVEREXPOSURE (INHALATION). Section 5: EXPLOSION HAZARDS, EXTINGUISHING MEDIA, FIRE EXPLOSION, FIRE FIGHTING EQUIPMENT, GENERAL HAZARD, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. Section 8: . Section 9: APPEARANCE, COLOR, COMMENTS, ODOR, PERCENT VOLATILE, pH, SPECIFIC GRAVITY. Section 10: CONDITIONS TO AVOID. Section 11: ACUTE (DERMAL LD₅₀ (rabbit), DERMAL LD₅₀ (rabbit), DERMAL LD₅₀ (rabbit), ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat), ORAL LD₅₀ (rat), ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat), INHALATION LC₅₀ (rat), INHALATION LC₅₀ (rat), INHALATION LC₅₀ (rat), ORAL LD₅₀ (rat) ACUTE, GENERAL COMMENTS. Section 12: CHEMICAL FATE INFORMATION, DISTRIBUTION, ECOTOXICOLOGICAL INFORMATION, ENVIRONMENTAL DATA, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE) (48-HOUR EC₅₀, 96-HOUR EC₅₀), SECTION 12: Ecological information. Section 14: VESSEL (IMO/IMDG) - MARINE POLLUTANT #1 ROAD AND RAIL (UK only) (CDG) - SPECIAL PROVISIONS SECTION 14: Transport information, ADR - road, IMDG - sea, IATA - air. Section 15: COMMENTS, GENERAL COMMENTS, RoHS. Section 16: GENERAL STATEMENTS.

General statements:

- NAP = Not Applicable
- NE = Not Established
- TLV = Threshold Limit Value
- PEL = Permissible exposure limits
- MAK = Maximum Workplace Concentration
- STEL = Short-term exposure limit
- STEV = Short-term exposure value
- TWA = Time Weighted Average
- PPE = Personal Protective Equipment
- AMU = Atomic Mass Unit

Manufacturer disclaimer:

FOR DENTAL USE ONLY: Use as directed. The information and recommendations are taken from sources (raw material SDS(s) and manufacturer's knowledge) believed to be accurate; however, the manufacturer, makes no warranty with respect to the accuracy of the information or the suitability of the recommendation and assumes no liability to any user thereof. Each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate.