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

Date Issued : 04/09/2014
SDS No : 343-001.3
Date Revised : 05/18/2017
Revision No : 2

Peak® SE Primer, Part 2 of 2

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

1.1. Product identifier
Product code : BJ/15077
Product name : Peak® SE Primer, Part 2 of 2
Product description : Adhesive Primer, Part 2

1.2. Relevant identified uses of the substance or mixture and uses advised against
Relevant identified uses : Professional Dental Adhesive Primer, Part 2

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]
The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Physical : Flammable Liquids, Category 2

2.2. Label elements
Classification according to Regulation(EC) No 1272/2008 [CLP]
Hazard pictogram(s) : Flame

Signal Word : DANGER
Hazard statement(s) : H225: Highly flammable liquid and vapour.
Precautionary statement(s)
P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233: Keep container tightly closed.
P240: Ground and bond container and receiving equipment.
P243: Take action to prevent static discharges.
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P242: Use non-sparking tools.

Response
P370+P378: In case of fire: Use Water spray, alcohol-resistant foam, dry chemical or carbon dioxide to extinguish.
P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

Storage
P403+P235: Store in a well-ventilated place. Keep cool.

Disposal

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; 20</td>
<td>Flam. Liq., Cat. 2; Skin Irr., Cat. 2; Eye Irr., Cat. 2; Acute Tox. (O), Cat. 4; STOT SE, Cat. 1; H225; 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
Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice/attention.

Following skin
Immediately wash skin with soap and plenty of water. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.

Following ingestion
If swallowed in small quantity the product is harmless, otherwise consult a doctor.

Following inhalation
No specific treatment is necessary since this material is not likely to be hazardous by inhalation.

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

Eyes
May cause eye irritation.

Skin
May cause slight irritation.

Ingestion
May be harmful if swallowed in large quantities.

Inhalation
None expected for this product.

4.3. Indication of any immediate medical attention and special treatment needed
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Notes to physician : NAP

SECTION 5: Fire fighting measures

5.1. Extinguishing media
Extinguishing media : Water spray, alcohol-resistant foam, dry chemical or carbon dioxide

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 : NAP

SECTION 7: Handling and storage

7.1. Precautions for safe handling
General procedures : Avoid contact with eyes, skin and clothing.
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 Adhesive Primer, Part 2

SECTION 8: Exposure controls / personal protection

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

8.2. Exposure controls

Eye/face protection : Wear eye protection.
Skin protection : Wear suitable gloves.
Respiratory protection : Good general ventilation should be sufficient to control airborne levels.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Liquid</td>
</tr>
<tr>
<td>Appearance</td>
<td>Clear, low viscosity liquid</td>
</tr>
<tr>
<td>Odour</td>
<td>Ethanol</td>
</tr>
<tr>
<td>pH</td>
<td>NAP (non-aqueous)</td>
</tr>
<tr>
<td>Flash point</td>
<td>43°C</td>
</tr>
<tr>
<td>Specific gravity</td>
<td>0.971</td>
</tr>
</tbody>
</table>

9.2. Other information

Additional information : No further relevant information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity : Stable

10.2. Chemical stability

Chemical stability : Stable when stored and handled under recommended conditions.

10.3. Possibility of hazardous reactions

Hazardous polymerization : None

10.4. Conditions to avoid

Conditions to avoid : Heat, flames and sparks. Extremes of temperature and direct sunlight.
### 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**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dermal LD(_{50})</strong></td>
<td>Not able to calculate ATE mix (dermal) due to lack of data on the components.</td>
<td></td>
</tr>
<tr>
<td><strong>Oral LD(_{50})</strong></td>
<td>&gt; 20000 mg/kg Mouse</td>
<td>There are no components of unknown toxicity (oral).</td>
</tr>
<tr>
<td><strong>Inhalation LC(_{50})</strong></td>
<td>&gt; 240000 mg/L/4H vapors Mouse</td>
<td>There are no components of unknown toxicity (inhalation).</td>
</tr>
</tbody>
</table>

**Germ cell mutagenicity**: The components in this product are not reported to produce mutagenic effects in humans.

**Carcinogenicity**: None of the components of this material are listed by IARC, NTP, or CA Prop 65 as carcinogens.

**Reproductive toxicity**: The components in this product are not reported to cause reproductive effects in humans.

**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**: No further relevant information available.

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods
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**SECTION 14: Transport information**

<table>
<thead>
<tr>
<th>14.1. UN number</th>
<th>UN number : 1987</th>
</tr>
</thead>
<tbody>
<tr>
<td>14.2. UN proper shipping name</td>
<td>UN proper shipping name : Alcohols, n.o.s. (Ethyl alcohol mixture)</td>
</tr>
<tr>
<td>14.3. Transport hazard class(es)</td>
<td>Hazard classification : 3</td>
</tr>
<tr>
<td>14.4. Packing group</td>
<td>Packing group : III</td>
</tr>
<tr>
<td>14.5. Environmental hazards</td>
<td>Marine pollutant #1 : NAP</td>
</tr>
<tr>
<td>14.6. Special precautions for user</td>
<td>ADR - road : NAP</td>
</tr>
<tr>
<td></td>
<td>RID - rail : NAP</td>
</tr>
<tr>
<td></td>
<td>IMDG - sea : NAP</td>
</tr>
<tr>
<td></td>
<td>IATA - air : NAP</td>
</tr>
</tbody>
</table>

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

Transport in bulk : NAP

**SECTION 15: Regulatory information**

<table>
<thead>
<tr>
<th>15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture</th>
<th>General information : Substances of very high concern (SVHC) according to REACH, Article 57: Contains no SVHC substances.</th>
</tr>
</thead>
<tbody>
<tr>
<td>General comments</td>
<td>Please refer to Medical Devices Directive 93/42/EEC.</td>
</tr>
<tr>
<td>15.2. Chemical safety assessment</td>
<td>Chemical safety assessment : See Section 11</td>
</tr>
<tr>
<td>Additional information</td>
<td>Additional information : None of the ingredients are listed as a carcinogen by IARC, NTP, or CA Prop 65.</td>
</tr>
</tbody>
</table>

**SECTION 16: Other information**

<table>
<thead>
<tr>
<th>Relevant H-statements (number and full text)</th>
<th>Acute Tox. (O), Cat. 4: Acute Toxicity (Oral), Category 4</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Eye Irr., Cat. 2: Eye irritation, Category 2</td>
</tr>
<tr>
<td></td>
<td>Flam. Liq., Cat. 2: Flammable Liquids, Category 2</td>
</tr>
<tr>
<td></td>
<td>STOT SE, Cat. 1: Target Organ Toxicity (Single exposure), Category 1</td>
</tr>
<tr>
<td></td>
<td>Skin Irr., Cat. 2: Skin irritation, Category 2</td>
</tr>
<tr>
<td></td>
<td>H225: Highly flammable liquid and vapour.</td>
</tr>
<tr>
<td></td>
<td>H319: Causes serious eye irritation.</td>
</tr>
</tbody>
</table>
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Prepared by:  Anu Kattoju
Revision summary: This SDS replaces the 09/03/2015 SDS. Revised: Section 1: GENERAL USE, MSDS No. Section 2: EMERGENCY OVERVIEW - IMMEDIATE CONCERNS. 2.3. Other hazards. Section 4: EYES, INHALATION, NOTES TO PHYSICIAN, SIGNS AND SYMPTOMS OF OVEREXPOSURE - EYES SKIN. Section 5: EXPLOSION HAZARDS, EXTINGUISHING MEDIA, FIRE EXPLOSION, FIRE FIGHTING EQUIPMENT, GENERAL HAZARD, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. Section 6: Section 7: GENERAL PROCEDURES. Section 8: PERSONAL PROTECTIVE EQUIPMENT - EYES AND FACE. Section 9: APPEARANCE, COMMENTS, PERCENT VOLATILE, pH, SPECIFIC GRAVITY. Section 11: ACUTE (ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat), ORAL LD₅₀ (rat), ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat), INHALATION LC₅₀ (rat), ORAL LD₅₀ (rat) ACUTE, GENERAL COMMENTS, CARCINOGENICITY, GERM CELL MUTAGENICITY, REPRODUCTIVE TOXICITY. Section 12: CHEMICAL FATE INFORMATION, DISTRIBUTION, 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, Primary hazard class/division, Secondary hazard class/division, 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

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.