

**SAFETY DATA SHEET**

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 11/17/2006

SDS No : 69-001.9

Date Revised : 03/19/2015

Revision No : 9

**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. 10200 S.  
 South Jordan, UT 84095

**Distributor**

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 Directive 1999/45/EC**

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

**Danger symbols** : F,Xi

**R phrases** : R36/38,R43,R11



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

**Health** : Eye Irritation, Category 2  
 Skin Irritation, Category 2  
 Skin Sensitization, Category 1

**Physical** : Flammable Liquids, Category 2

**2.2. Label elements****Classification according to Directive 1999/45/EC**

**Hazard pictogram(s)** :

|   |   |
|---|---|
| F   | Xi  |
|  |  |
| Highly flammable  | Irritant  |

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



**ULTRADENT**  
 PRODUCTS, INC.

Date Issued : 11/17/2006  
 SDS No : 69-001.9  
 Date Revised : 03/19/2015  
 Revision No : 9

**Peak® SE Primer , Part 1 of 2**

**R&S statement(s)** : R36/38: Irritating to eyes and skin.  
 R43: May cause sensitization by skin contact.  
 R11: Highly flammable.

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

**Hazard pictogram(s)** :    
 Flame Exclamation mark

**Signal Word** : WARNING

**Hazard statement(s)** : H225: Highly flammable liquid and vapour.  
 H315: Causes skin irritation.  
 H317: May cause an allergic skin reaction.

**Precautionary statement(s)**

**Prevention** : P280: Wear protective gloves/protective clothing/eye protection/face protection.

**Response** : P305: IF IN EYES:  
 P351: Rinse cautiously with water for several minutes.  
 P337+P313: If eye irritation persists: Get medical advice/attention.  
 P302+P352: IF ON SKIN: Wash with plenty of soap and water.  
 P332+P313: If skin irritation occurs: Get medical advice/attention.

**Storage** : P273: Avoid release to the environment.

**Disposal** : P501: Dispose of in compliance with governmental regulation. (EC 1975L0442-20/11/2003)

**2.3. Other hazards**

**Immediate concerns** : Flammable Liquid

**SECTION 3: Composition / information on ingredients**

**3.1. Substances**

Not Applicable

**3.2. Mixtures**

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



Date Issued : 11/17/2006  
 SDS No : 69-001.9  
 Date Revised : 03/19/2015  
 Revision No : 9

**Peak® SE Primer , Part 1 of 2**

| Chemical Name               | CAS      | EINECS No. | Wt. % | Classification according to Directive 67/548/EEC | Classification according to Regulation (EC) No 1272/2008 [CLP]            |
|-----------------------------|----------|------------|-------|--|---|
| Ethyl Alcohol               | 64-17-5  | 200-578-6  | < 40  | F; R11   | Flam. Liq., Cat. 2; H225  |
| 2-hydroxyethyl Methacrylate | 868-77-9 | 212-782-2  | < 20  | Xi; R43; R36/38                                  | Eye Irr., Cat. 2; Skin Irr., Cat. 2; Skin Sens., Cat. 1; H315; H317; H319 |

For full text of H-statements and R-phrases: 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 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. If exposed to excessive levels of dusts or fumes, remove to fresh air and get medical attention if cough or other symptoms develop.

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

- Eyes** : Irritating to eyes.
- Skin** : May cause skin irritation and sensitization.
- Ingestion** : No specific hazards are encountered under normal product use.
- Inhalation** : None expected for this product.

**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** : Please see Fire Fighting Equipment under Section 5.3.

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



**Date Issued :** 11/17/2006  
**SDS No :** 69-001.9  
**Date Revised :** 03/19/2015  
**Revision No :** 9

**Peak® SE Primer , Part 1 of 2**

**5.2. Special hazards arising from the substance or mixture**

**Explosion hazards** : Not Determined  
**Fire explosion** : Not Determined  
**Sensitive to static discharge** : Not Determined  
**Sensitivity to impact** : Not Determined

**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.  
**Fire fighting equipment** : Foam, dry chemical, carbon dioxide (CO<sub>2</sub>).

**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** : Not Determined

**8.2. Exposure controls**

**Eye/face protection** : Wear eye protection

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



**Date Issued :** 11/17/2006  
**SDS No :** 69-001.9  
**Date Revised :** 03/19/2015  
**Revision No :** 9

**Peak® SE Primer , Part 1 of 2**

**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** : Light yellow resin.  
**Odour** : Bitter  
**Flash point** : < 27°C

**9.2. Other information**

**Percent volatile** : Not Determined

**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

**10.4. Conditions to avoid**

**Conditions to avoid** : Avoid light exposure.

**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**

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

**SECTION 12: Ecological information**

**12.1. Toxicity**

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

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



**Date Issued :** 11/17/2006  
**SDS No :** 69-001.9  
**Date Revised :** 03/19/2015  
**Revision No :** 9

**Peak® SE Primer , Part 1 of 2**

**96-hour LC<sub>50</sub>** : Not Determined  
**48-hour EC<sub>50</sub>** : Not Determined  
**96-hour EC<sub>50</sub>** : Not Determined

**12.2. Persistence and degradability**

**Persistence and degradability** : Not Determined

**12.3. Bioaccumulative potential**

**Bioaccumulative potential** : Not Determined

**12.4. Mobility in soil**

**Mobility in soil** : Not Determined

**12.5. Results of PBT and vPvB assessment**

**Results of PBT and vPvB assessment** : Not Determined

**12.6. Other adverse effects**

**Environmental data** : Stable when stored and handled under recommended conditions.

**SECTION 13: Disposal considerations**

**13.1. Waste treatment methods**

**Disposal method** : Dispose of in compliance with governmental regulation.(EC 1975L0442-20/11/2003)

**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** : Not Applicable

**14.6. Special precautions for user**

**ADR - road** : N/A

**RID - rail** : N/A

**IMDG - sea** : N/A

**IATA - air** : N/A

**SAFETY DATA SHEET**

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 11/17/2006

SDS No : 69-001.9

Date Revised : 03/19/2015

Revision No : 9

**Peak® SE Primer , Part 1 of 2****14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**

Transport in bulk : N/A

**SECTION 15: Regulatory information****15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

RoHS : Please refer to Medical Devices Directive 93/42/EEC

**15.2. Chemical safety assessment**

Chemical safety assessment : See Section 11

**SECTION 16: Other information**

**Relevant R-phrases and/or H-statements (number and full text)** : R11: Highly flammable.  
 R36/38: Irritating to eyes and skin.  
 R43: May cause sensitization by skin contact.  
 Skin Sens., Cat. 1: Skin Sensitization, Category 1  
 H225: Highly flammable liquid and vapour.  
 H315: Causes skin irritation.  
 H317: May cause an allergic skin reaction.  
 H319: Causes serious eye irritation.

**Prepared by** : Anu Kattoju**Revision summary** : This SDS replaces the 02/26/2015 SDS. Revised: **Section 1:**  
**Section 2:** .**General statements** : N/A= Not Applicable**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.

# SAFETY DATA SHEET

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



Date Issued : 4/9/2014  
SDS No : 343-001.1

## 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** : Professional Use Dentin Etchant

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

**Relevant identified uses** : Professional Use Dental Etchant

#### 1.3. Details of the supplier of the safety data sheet

##### Manufacturer

Ultradent Products, Inc.  
505 W. 10200 S.  
South Jordan, UT 84095

##### Distributor

UP Dental GmbH  
Am Westhover Berg 30  
51149 Cologne Germany  
**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 Directive 1999/45/EC**

**Danger symbols** : F  
**R phrases** : R11

#### 2.2. Label elements

**Classification according to Directive 1999/45/EC**

**Hazard pictogram(s)** :   
 Highly flammable

**R&S statement(s)** : R11: Highly flammable.

#### 2.3. Other hazards

### SECTION 3: Composition / information on ingredients

#### 3.1. Substances

Not Applicable

#### 3.2. Mixtures



# SAFETY DATA SHEET

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



Date Issued : 4/9/2014  
SDS No : 343-001.1

## Peak® SE Primer, Part 2 of 2

| Chemical Name | CAS     | EINECS No. | Wt. % | Classification according to Directive 67/548/EEC |
|---------------|---------|------------|-------|--|
| Ethyl Alcohol | 64-17-5 | 200-578-6  | < 20  | F; R11   |

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

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

- Following eyes** : Hold eyelids apart and flush eyes with plenty of water for at least 10 minutes.
- Following skin** : Not needed for normal use.
- 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. If exposed to excessive levels of dusts or fumes, remove to fresh air and get medical attention if cough or other symptoms develop.

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

- Eyes** : Irritating to eyes.
- 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

### SECTION 5: Fire fighting measures

#### 5.1. Extinguishing media

- Extinguishing media** : Please see Fire Fighting Equipment under Section 5.3.

#### 5.2. Special hazards arising from the substance or mixture

- Explosion hazards** : Not Determined
- Fire explosion** : Not Determined
- Sensitive to static discharge** : Not Determined
- Sensitivity to impact** : Not Determined

#### 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.
- Fire fighting equipment** : Foam, dry chemical, carbon dioxide (CO<sub>2</sub>).

### SECTION 6: Accidental release measures

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



Date Issued : 4/9/2014  
 SDS No : 343-001.1

**Peak® SE Primer, Part 2 of 2**

**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 Use Dental Etchant

**SECTION 8: Exposure controls / personal protection**

**8.1. Control parameters**

**Control parameters** : Not Determined

**8.2. Exposure controls**

**Eye/face protection** : Use chemical splash goggles.

**Skin protection** : S37: 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**

**Physical state** : Liquid

**Appearance** : Clear

**Odour** : Ethanol

**Flash point** : 43°C

**9.2. Other information**

**Percent volatile** : Not Determined

**SECTION 10: Stability and reactivity**

# SAFETY DATA SHEET

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



Date Issued : 4/9/2014  
SDS No : 343-001.1

## Peak® SE Primer, Part 2 of 2

### 10.1. Reactivity

**Stable** : Yes

### 10.2. Chemical stability

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

### 10.3. Possibility of hazardous reactions

**Hazardous polymerization** : No

### 10.4. Conditions to avoid

**Conditions to avoid** : Not Determined

### 10.5. Incompatible materials

**Incompatible materials** : Not Determined

### 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>** : Not Determined

**Oral LD<sub>50</sub>** : Not Determined

**Inhalation LC<sub>50</sub>** : Not Determined

## SECTION 12: Ecological information

### 12.1. Toxicity

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

**96-hour LC<sub>50</sub>** : Not Determined

**48-hour EC<sub>50</sub>** : Not Determined

**96-hour EC<sub>50</sub>** : Not Determined

### 12.2. Persistence and degradability

**Persistence and degradability** : Not Determined

### 12.3. Bioaccumulative potential

**Bioaccumulative potential** : Not Determined

### 12.4. Mobility in soil

**Mobility in soil** : Not Determined

### 12.5. Results of PBT and vPvB assessment

**Results of PBT and vPvB assessment** : Not Determined

### 12.6. Other adverse effects

**Environmental data** : Avoid release to the environment.

# SAFETY DATA SHEET

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



Date Issued : 4/9/2014  
SDS No : 343-001.1

## Peak® SE Primer, Part 2 of 2

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

**Disposal method** : Dispose of in compliance with governmental regulation.(EC 1975L0442-20/11/2003)

### 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** : Not Determined

**Secondary hazard class/division** : Not Determined

**Hazard classification** : 3

#### 14.4. Packing group

**Packing group** : III

#### 14.5. Environmental hazards

**Marine pollutant #1** : Not Determined

**Marine pollutant #2** : Not Determined

#### 14.6. Special precautions for user

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

### SECTION 15: Regulatory information

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

**RoHS** : Please refer to Medical Devices Directive 93/42/EEC

#### 15.2. Chemical safety assessment

**Chemical safety assessment** : Not Determined

### SECTION 16: Other information

**Relevant R-phrases and/or H-statements (number and full text)** : R11: Highly flammable.  
R36: Irritating to eyes.

**Prepared by** : Anu Kattoju

**General statements** : NA = Not Applicable

**Manufacturer disclaimer** : FOR DENTAL USE ONLY: Use as directed. The information and recommendations are taken from sources (raw material MSDS(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

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



**Date Issued :** 4/9/2014  
**SDS No :** 343-001.1

**Peak® SE Primer, Part 2 of 2**

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recommendations in the specific context of the intended use and determine whether they are appropriate.