

# SAFETY DATA SHEET

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

**ULTRADENT**  
PRODUCTS, INC.

Date Issued : 11/17/2006  
SDS No : 69-001.10  
Date Revised : 01/23/2017  
Revision No : 10

## 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]

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

**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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H319: Causes serious eye irritation.

**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 1975L0442-21/11/2003)

**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**

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

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.

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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 (CO<sub>2</sub>).

**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

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**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**

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

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**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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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 LD<sub>50</sub> (rabbit), DERMAL LD<sub>50</sub> (rabbit), DERMAL LD<sub>50</sub> (rabbit), ORAL LD<sub>50</sub> (rat), INHALATION LC<sub>50</sub> (rat), ORAL LD<sub>50</sub> (rat), ORAL LD<sub>50</sub> (rat), INHALATION LC<sub>50</sub> (rat), INHALATION LC<sub>50</sub> (rat), INHALATION LC<sub>50</sub> (rat), ORAL LD<sub>50</sub> (rat) ACUTE, GENERAL COMMENTS. **Section 12:** CHEMICAL FATE INFORMATION, DISTRIBUTION, ECOTOXICOLOGICAL INFORMATION, ENVIRONMENTAL DATA, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE) ( 48-HOUR EC<sub>50</sub>, 96-HOUR EC<sub>50</sub> ), 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 = Permittable 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.