

SAFETY DATA SHEET

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

ULTRADENT
PRODUCTS, INC.

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)

Prevention

: P280: Wear protective gloves/protective clothing/eye protection/face protection.
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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Response : P241: Use explosion-proof [electrical/ventilating/lighting] equipment.
P242: Use non-sparking tools.

Storage : 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].

Disposal : P403+P235: Store in a well-ventilated place. Keep cool.
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	< 20	Flam. Liq.,Cat. 2; Skin Irr.,Cat. 2; Eye Irr.,Cat. 2; Acute Tox. (O),Cat. 4; STOT SE,Cat. 1; H225; H319

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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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 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, low viscosity liquid
- Odour** : Ethanol
- pH** : NAP (non-aqueous)
- Flash point** : 43°C
- Specific gravity** : 0.971

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.

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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 LD₅₀ : Not able to calculate ATE mix (dermal) due to lack of data on the components.

Oral LD₅₀ : > 20000 mg/kg Mouse

Notes : There are no components of unknown toxicity (oral).

Inhalation LC₅₀ : > 240000 mg/L/4H vapors Mouse

Notes : There are no components of unknown toxicity (inhalation).

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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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)

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 : None of the ingredients are listed as a carcinogen by IARC, NTP, or CA Prop 65.

SECTION 16: Other information

Relevant H-statements (number and full text) : Acute Tox. (O), Cat. 4: Acute Toxicity (Oral), Category 4
Eye Irr., Cat. 2: Eye Irritation, Category 2
Flam. Liq., Cat. 2: Flammable Liquids, Category 2
STOT SE, Cat. 1: Target Organ Toxicity (Single exposure), Category 1
Skin Irr., Cat. 2: Skin Irritation, Category 2
H225: Highly flammable liquid and vapour.
H319: Causes serious eye irritation.

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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 LD ₅₀ (rat), INHALATION LC ₅₀ (rat), ORAL LD ₅₀ (rat), ORAL LD ₅₀ (rat), INHALATION LC ₅₀ (rat), INHALATION LC ₅₀ (rat), INHALATION LC ₅₀ (rat), ORAL LD ₅₀ (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 EC ₅₀ , 96-HOUR EC ₅₀), 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 = 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
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.