

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



Highly flammable

Xi



Irritant

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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

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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.

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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 ₂).

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General procedures	: Refer to Section 8 for Personal Protective Equipment.
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6.2. Environmental precautions

Water spill	: Do not allow to enter sewers or drains that may lead to waterways.
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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
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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
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7.3. Specific end use(s)

Specific end use(s)	: Professional Dental Etchant
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SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Control parameters	: Not Determined
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8.2. Exposure controls

Eye/face protection	: Wear eye protection
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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.

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96-hour LC₅₀ : Not Determined

48-hour EC₅₀ : Not Determined

96-hour EC₅₀ : 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

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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.