

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 01/18/2006

SDS No : 4-001.11

Date Revised : 04/10/2015

Revision No : 15

Ultradent® Porcelain Etch

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

1.1. Product identifier

Product code : PE/ 10324
Product name : Ultradent® Porcelain Etch
Product description : Acid Etching solution

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

Relevant identified uses : Professional Dental Acid Etching Solution

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 : T+,C
R phrases : R26/27/28,R35

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

Health : Skin Corrosion, Category 1A
 Acute Toxicity (Inhalation), Category 1
 Acute Toxicity (Oral), Category 1

2.2. Label elements

Classification according to Directive 1999/45/EC

Hazard pictogram(s) : T+ C

 Very toxic

 Corrosive

R&S statement(s) : R26/27/28: Very toxic by inhalation, in contact with skin and if swallowed.

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R35: Causes severe burns.

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

:

Skull and
crossbones

Corrosive

Signal Word

: DANGER

Hazard statement(s)

: H331: Toxic if inhaled.
 H301: Toxic if swallowed.
 H311: Toxic in contact with skin.
 H314: Causes severe skin burns and eye damage.

Precautionary statement(s)**Prevention**

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

Response

: P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P315: Get immediate medical advice/attention.
 P303+P361+P353: IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
 P313: Get medical advice/attention.
 P301: IF SWALLOWED:
 P310: Immediately call a POISON CENTER or doctor/physician.
 P331: Do NOT induce vomiting.
 P330: Rinse mouth.
 P342+P311: If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

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**

: Toxic by inhalation, ingestion, and skin contact.

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]
Hydrofluoric Acid	7664-39-3	231-634-8	< 10	C,+T; R26/27/28; R35	Skin Corr.,Cat. 1A; Acute Tox. (I),Cat. 1; Acute Tox. (O),Cat. 1; H300; H310; H314; H330

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

: Remove contact lenses before flushing. With eyelids held open, flush immediately with lukewarm water for at least 15 minutes. DO NOT use an eye ointment. If a physician is not immediately available, apply 1-2 drops of 0.5% Pontocaine Hydrochloride solution. Get immediate medical attention.

Following skin

: Flush skin with large amounts of water and remove contaminated clothing, watches, etc. After the water rinse, rub "Calcium Gluconate" thoroughly into the skin. Seek medical attention for all burns, regardless of how minor they may seem.

Following ingestion

: DO NOT INDUCE VOMITING -SEEK MEDICAL ADVICE IMMEDIATELY! Rinse mouth thoroughly and give large amounts of milk or water if person is conscious. After ingestion of fluorides, give milk or Calcium Gluconate orally. Transport to hospital if there is any suspicion of ingestion.

Following inhalation

: Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.

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

Eyes

: Causes severe eye burns.

Skin

: Contact causes severe skin irritatin and possible burns.

Ingestion

: Toxic if swallowed.

Inhalation

: Toxic if inhaled

4.3. Indication of any immediate medical attention and special treatment needed

Notes to physician

: Toxic by inhalation, skin contact and ingestion.

SECTION 5: Fire fighting measures

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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 (CO₂).

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Special protective equipment : Wear suitable protective clothing, gloves and eye/face protection.

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 : Dilute with water and mop up, or absorb with inert dry material and place in an appropriate waste disposal container. If necessary: Neutralize the residue with a dilute solution of sodium carbonate.

Large spill : Absorb with fly ash or cement powder. Neutralize with soda ash or caustic soda. Collect carefully in tightly closed containers. DO NOT TOUCH SPILLED MATERIAL.

6.4. Reference to other sections

Reference to other sections : Not Applicable

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Handling : Will attack glass and most ceramics. May attack some metals. Use personal protective equipment in a well-ventilated area.

Storage : Keep container tightly closed in a cool place.

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 Acid Etching Solution

SECTION 8: Exposure controls / personal protection

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8.1. Control parameters

Control parameters : Not Determined

8.2. Exposure controls

Eye/face protection : Use chemical splash goggles and face shield (ANSI Z87.1 or approved equivalent).

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 : Gel

Colour : Yellow

Odour : Acidic, DO NOT SMELL

9.2. Other information

Percent volatile : Not Determined

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 : Avoid strong bases, Metals, Metal oxides, Inorganic acids, Organic anhydrides, Glass, and Intense Heat.

10.5. Incompatible materials

Incompatible materials : Not Determined

10.6. Hazardous decomposition products

Hazardous decomposition products : Fluorine gas. Hydrogen is formed in contact with metals. Heating may liberate hazardous corrosive vapors.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute

Notes : Device is a strong acid and is extremely toxic. It is to be used only as directed with PPE, and only by licensed dental professionals.

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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 LC₅₀	: Not Determined
48-hour EC₅₀	: Not Determined
96-hour EC₅₀	: Not Determined

12.2. Persistence and degradability

Persistence and degradability	: Not Determined
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12.3. Bioaccumulative potential

Bioaccumulative potential	: Not Determined
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12.4. Mobility in soil

Mobility in soil	: Not Determined
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12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment	: Not Determined
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12.6. Other adverse effects

Environmental data	: Not Available
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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	: 2922
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14.2. UN proper shipping name

UN proper shipping name	: Corrosive Liquid, Toxic n.o.s. (Hydrofluoric acid mixture)
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14.3. Transport hazard class(es)

Primary hazard class/division	: 8(6.1)
Hazard classification	: 8(6.1)

14.4. Packing group

Packing group	: II
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14.5. Environmental hazards

Marine pollutant #1	: N/A
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14.6. Special precautions for user

ADR - road	: N/A
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RID - rail : N/A

IMDG - sea : N/A

IATA - air : N/A

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) : R26/27/28: Very toxic by inhalation, in contact with skin and if swallowed.
R35: Causes severe burns.
Acute Tox. (I), Cat. 1: Acute Toxicity (Inhalation), Category 1
Acute Tox. (O), Cat. 1: Acute Toxicity (Oral), Category 1
Skin Corr., Cat. 1A: Skin Corrosion, Category 1A
H300: Fatal if swallowed.
H310: Fatal in contact with skin.
H314: Causes severe skin burns and eye damage.
H330: Fatal if inhaled.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 01/27/2015 SDS. Revised: **Section 1:** . **Section 2:** . **Section 6:** SPECIAL PROTECTIVE EQUIPMENT. **Section 8:** PERSONAL PROTECTIVE EQUIPMENT - SKIN. **Section 10:** HAZARDOUS POLYMERIZATION, STABLE. **Section 11:** ACUTE (ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat) ACUTE. **Section 15:** SECTION 15: Regulatory information. **Section 16:** GENERAL STATEMENTS.

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.

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Silane

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

1.1. Product identifier

Product code : SI/10325
Product name : Silane
Product description : Bonding Agent

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

Relevant identified uses : Professional Dental Bonding Agent

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 : R11, R36

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

Health : Eye Irritation, Category 2

Environmental : Flammable Liquids, Category 2

2.2. Label elements

Classification according to Directive 1999/45/EC

Hazard pictogram(s) :

F+	Xi
	
Extremely flammable	Irritant

R&S statement(s) : R11: Highly flammable.
 R36: Irritating to eyes.

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Silane**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.
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.
P315: Get immediate medical advice/attention.
P302+P352: IF ON SKIN: Wash with plenty of soap and water.
P362+P364: Take off contaminated clothing and wash it before reuse.
P301: IF SWALLOWED:
P331: Do NOT induce vomiting.
P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P313: 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

Physical hazards

: 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]
Methacryloxy propyl trimethoxy silane	7803-62-5	232-263-4	< 10	F+; R12; R17	Flam. Gas, Cat. 1; H220; H280; H332
Isopropyl Alcohol	67-63-0	200-661-7	< 95	F+; R11; R36/37/38; R22	Eye Irr., Cat. 2; Flam. Liq., Cat. 2; STOT SE, Cat. 3; H225; H319; H336

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 for at least 15 minutes. Get immediate medical 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** : Give large volumes of water. Do not induce vomiting. Consult a physician if ingested in large amounts.
- Following inhalation** : Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.

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

- Eyes** : Severe eye irritation
- Skin** : May cause slight irritation.
- Ingestion** : Irritating to mouth, throat, and stomach.
- Inhalation** : High concentrations in immediate area can displace oxygen and can cause dizziness, unconsciousness, and even death with longer exposure. Keep people away from such vapors without self-contained breathing apparatus.

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

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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 (CO₂).

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Special protective equipment : Wear suitable protective clothing, gloves and eye/face protection.

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 : Wipe up small amounts with chemical resistant or damp rag which is washed with large amounts of water after each use. After cleaning, flush away traces with water.

Large spill : Collect in tightly closed containers.

6.4. Reference to other sections

Reference to other sections : Not Applicable

Additional information : Refer particularly to local circumstances and regulations.

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 Bonding Agent

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Control parameters : Not Determined

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8.2. Exposure controls

- Engineering controls** : Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits.
- Eye/face protection** : Wear safety glasses with side shields (or goggles) and a face shield.
- 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** : Volatile Liquid
- Colour** : Colorless
- Odour** : Rubbing alcohol
- Melting temperature** : -89°C
- Boiling temperature** : 82°C
- Solubility in water** : Fully miscible

9.2. Other information

- Percent volatile** : Not Determined

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 ignition sources

10.5. Incompatible materials

- Incompatible materials** : Strong oxidizers, acids, and Isocyanates

10.6. Hazardous decomposition products

- Hazardous decomposition products** : Complete combustion generates carbon dioxide. Incomplete combustion generates toxic and highly flammable carbon monoxide.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute

- Notes** : Device is biocompatible when used as directed by dental professionals

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per ISO 10993-1.

SECTION 12: Ecological information

12.1. Toxicity

Toxicity : None Expected.

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 : Does not bioaccumulate.

12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment : Not Determined

12.6. Other adverse effects

Environmental data : Not defined

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. (Isopropyl alcohol mixture)

14.3. Transport hazard class(es)

Primary hazard class/division : 3

Hazard classification : 3

14.4. Packing group

Packing group : II

14.5. Environmental hazards

Marine pollutant #1 : N/A

14.6. Special precautions for user

ADR - road : N/A

RID - rail : N/A

IMDG - sea : N/A

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IATA - air : N/A

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.
 R12: Extremely flammable.
 R17: Spontaneously flammable in air.
 R22: Harmful if swallowed.
 R36/37/38: Irritating to eyes, respiratory system and skin.
 Eye Irr., Cat. 2: Eye Irritation, Category 2
 Flam. Gas, Cat. 1: Flammable Gases, Category 1
 Flam. Liq., Cat. 2: Flammable Liquids, Category 2
 STOT SE, Cat. 3: Target Organ Toxicity (Single exposure), Category 3
 H220: Extremely flammable gas.
 H225: Highly flammable liquid and vapour.
 H280: Contains gas under pressure; may explode if heated.
 H319: Causes serious eye irritation.
 H332: Harmful if inhaled.
 H336: May cause drowsiness or dizziness.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 08/07/2014 SDS. Revised: **Section 1:** Date-Revised.

General statements : N/A= Not Applicable

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