

SAFETY DATA SHEET

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

ULTRADENT
PRODUCTS, INC.

Date Issued : 01/18/2006
SDS No : 4-001.12
Date Revised : 09/27/2016
Revision No : 16

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

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 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 (Oral), Category 2
Acute Toxicity (Inhalation), Category 2
Acute Toxicity (Dermal), Category 1


2.2. Label elements

Classification according to Directive 1999/45/EC

Hazard pictogram(s) : T+ C



Very toxic



Corrosive

R& statement(s) : R26/27/28: Very toxic by inhalation, in contact with skin and if swallowed.
R35: Causes severe burns.

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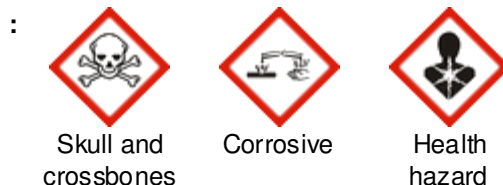
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Classification according to Regulation(EC) No 1272/2008 [CLP]

Hazard pictogram(s)



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.
H372: Causes damage to organs.
H290: May be corrosive to metals.

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): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P363: Wash contaminated clothing before reuse.
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

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

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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	Acute Tox. (O),Cat. 2; Acute Tox. (D),Cat. 1; Acute Tox. (I),Cat. 2; Skin Corr.,Cat. 1A; EYE DMG.,Cat. 1; STOT RE,Cat. 1; Cor. Metal,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

5.1. Extinguishing media

- Extinguishing media** : Foam, dry chemical, carbon dioxide (CO₂).

5.2. Special hazards arising from the substance or mixture

- Hazardous combustion products** : Not Established

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.

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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

8.1. Control parameters

Control parameters : Hydrofluoric Acid CAS: 7664-39-3

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Control Parameters	Exposure Limits
OSHA PEL- General Industry	3ppm (2 mg/m ³) TWA
OSHA PEL - Construction Industry	3 ppm (2mg/m ³) TWA
OSHA PEL - Shipyard Employment	3 ppm (2mg/m ³) TWA
NIOSH REL	3 ppm (2.5 mg/m ³) TWA 6ppm(5mg/m ³) Ceiling(15 minutes)
ACGIH TLV	0.5ppm TWA 2ppm Ceiling Skin; BEI
CAL/OSHA PELs	0.4 ppm (0.33 mg/m ³) TWA 1 ppm (0.83 mg/m ³) STEL Skin

Hydrofluoric Acid CAS 7664-39-3
International Control Parameters

Canada

Territory	Control Parameters
Alberta	= 1.6 mg/m ³ Ceiling F = 2ppm Ceiling F
British Columbia	= 2ppm Ceiling F
Ontario	0.5 ppm TWA F
Quebec	3 ppm Ceiling 2.6 mg/m ³ Ceiling

Australia: None

Mexico: = 2.5 mg/m³ Peak = 3 ppm Peak

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
- Appearance** : Medium viscosity
- Colour** : Yellow
- Odour** : Acidic, DO NOT SMELL
- pH** : < 1.0

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Specific gravity : 1.1 to 1.2

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

Dermal LD₅₀ : Acute Toxicity(Dermal) Category 1

Oral LD₅₀ : Acute Toxicity (Oral) Category 2

Inhalation LC₅₀ : Acute Toxicity (Inhalation) Dusts/Mists Category 2

STOT-repeated exposure : Category 1

Other information : 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.

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

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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)

SECTION 14: Transport information

14.1. UN number

UN number : 2922

14.2. UN proper shipping name

UN proper shipping name : Corrosive Liquid, Toxic n.o.s. (Hydrofluoric acid mixture)

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

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 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.

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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. (D), Cat. 1: Acute Toxicity (Dermal), Category 1
Acute Tox. (I), Cat. 2: Acute Toxicity (Inhalation), Category 2
Acute Tox. (O), Cat. 2: Acute Toxicity (Oral), Category 2
Cor. Metal, Cat. 1: Corrosive to Metals, Category 1
EYE DMG., Cat. 1: Eye Damage, Category 1
STOT RE, Cat. 1: Target Organ Toxicity (Repeated exposure), 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 04/10/2015 SDS. Revised: **Section 1:** MSDS No. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS 2.3. Other hazards. **Section 5:** EXPLOSION HAZARDS, EXTINGUISHING MEDIA, FIRE EXPLOSION, FIRE FIGHTING EQUIPMENT, HAZARDOUS COMBUSTION PRODUCTS, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 8:** . **Section 9:** APPEARANCE, pH, SPECIFIC GRAVITY. **Section 11:** ACUTE (ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat) ACUTE, GENERAL COMMENTS, STOT-REPEATED EXPOSURE. **Section 12:** CHEMICAL FATE INFORMATION, DISTRIBUTION, ENVIRONMENTAL DATA, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE) (48-HOUR EC₅₀, 96-HOUR EC₅₀), 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

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

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intended use and determine whether they are appropriate.