

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 09/06/2012

SDS No : 7-001.16

Date Revised : 03/27/2017

Revision No : 17

Ultra-Etch®**SECTION 1 : Identification of the substance/preparation and of the company/undertaking****1.1. Product identifier**

Product code : UX/10947
 Product name : Ultra-Etch®
 Product description : Phosphoric acid dental etchant

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. 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 : Skin Corrosion, Category 1B
 Acute Toxicity (Inhalation), Category 4

2.2. Label elements**Classification according to Regulation(EC) No 1272/2008 [CLP]**

Hazard pictogram(s) :



Corrosive



Exclamation mark

Signal Word : DANGER

Hazard statement(s) : H314: Causes severe skin burns and eye damage.
 H332: Harmful if inhaled.

Precautionary statement(s)

Prevention : P280: Wear protective gloves/protective clothing/eye protection/face protection.
 P260: Do not breathe dust/fume.
 P261: Avoid breathing dust/fumes/gas/mist/vapours/spray.

SAFETY DATA SHEET

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



Date Issued : 09/06/2012
SDS No : 7-001.16
Date Revised : 03/27/2017
Revision No : 17

Ultra-Etch®

Response	<p>P271: Use only outdoors or in a well-ventilated area.</p> <p>: P301: IF SWALLOWED: P330: Rinse mouth. P331: Do NOT induce vomiting. 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. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P312: Call a POISON CENTER or doctor/physician if you feel unwell. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p>
Storage	<p>: P273: Avoid release to the environment. P405: Store locked up.</p>
Disposal	<p>: P501: Dispose of in compliance with governmental regulation. (EC 1975L0442-21/11/2003)</p>

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]
Phosphoric Acid	7664-38-2	231-633-2	< 40	Skin Corr.,Cat. 1B; H314
Cobalt aluminate blue spinel	1345-16-0	310-193-6	< 1	Skin Irr.,Cat. 2; Eye Irr.,Cat. 2; STOT SE,Cat. 3; H315; H319; H335
Siloxane	NAP	NAP	< 1	STOT SE,Cat. 2; Rep. Tox.,Cat. 2; H361f; H373

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 with plenty of water. After initial flushing, remove any contact lenses and continue flushing for at least 15 minutes. Have eyes examined and tested by medical personnel.
Following skin	: Remove contaminated clothing. Wash with soap and water.
Following ingestion	: If swallowed, rinse mouth with water, Do NOT Induce Vomiting. Give victim a glass of water or milk. Call a physician or poison control center if you feel unwell.
Following inhalation	: Remove to open air. In the event of breathing difficulties get medical

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



Date Issued : 09/06/2012
 SDS No : 7-001.16
 Date Revised : 03/27/2017
 Revision No : 17

Ultra-Etch®

advice/attention immediately.

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

Eyes : Causes severe eye burns.
Skin : Corrosive, causes skin burning.
Ingestion : Harmful if swallowed.
Inhalation : May be harmful if inhaled.

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

Notes to physician : Corrosive

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

Hazardous combustion products : Phosphine, oxides of phosphorous, hydrogen gas

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 : Clean up spills immediately, observing precautions in Protective Equipment section.

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 : Use suitable protective equipment.

Storage : See product labeling.

7.2. Conditions for safe storage, including any incompatibilities

Shelf life : See product labeling

7.3. Specific end use(s)

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



Date Issued : 09/06/2012
 SDS No : 7-001.16
 Date Revised : 03/27/2017
 Revision No : 17

Ultra-Etch®

Specific end use(s) : Professional Dental Acid Etching Solution

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Control parameters : Phosphoric Acid CAS: 7664-38-2

Control Parameters	Exposure Limits
OSHA PEL General Industry	1 mg/m ³
OSHA PEL Construction Industry	1 mg/m ³
OSHA PEL Shipyard Industry	1 mg/m ³
NIOSH REL	1 mg/m ³ TWA 2 mg/m ³ STEL
ACGIH TLV	1 mg/m ³ TWA 2 mg/m ³ STEL
CAL/OSHA PEL	1 mg/m ³

Cobalt Zinc Aluminate Blue Spinel CAS 68186-87-8

ACGIH TWA Respirable Fraction: 1 mg/m³ (Aluminum) 0.02 mg/m³ (Cobalt)

Siloxane

REL: 5ppm

8.2. Exposure controls

Eye/face protection : Wear eye protection .

Skin protection : Wear suitable protective clothing and gloves.

Respiratory protection : Good general ventilation should be sufficient to control airborne levels. In case of insufficient ventilation, wear suitable respiratory equipment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Gel
Appearance : Medium viscosity
Colour : Blue
Odour : Odorless or no characteristic odor
pH : < 1
Specific gravity : 1.3
Solubility in water : Partially Soluble

9.2. Other information

Additional information : No further relevant information available

SECTION 10: Stability and reactivity

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



Date Issued : 09/06/2012
SDS No : 7-001.16
Date Revised : 03/27/2017
Revision No : 17

Ultra-Etch®

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 : Strong bases, metals, excess heat, exposure to moist air or water

10.5. Incompatible materials

Incompatible materials : Strong caustics, most metals.

10.6. Hazardous decomposition products

Hazardous decomposition products : Phosphine, oxides of phosphorous, hydrogen gas

Additional information : Reacts with bases to form phosphate salts and is corrosive (especially when hot) to many metals and alloys. Liberates explosive hydrogen gas when reacting with chlorides and stainless steel, and reacts violently with sodium tetrahydroborate. Forms flammable gases with sulfides, mercaptans, cyanides, and aldehydes. Also forms toxic fumes with cyanides, sulfides, fluorides, organic peroxides, and halogenated organics.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute

Dermal LD₅₀ : > 6100 mg/kg Rabbit

Notes : < 1% of the mixture consists of components of unknown toxicity (Dermal).

Oral LD₅₀ : > 3400 mg/kg Rat

Notes : < 1% of the mixture consists of components of unknown toxicity (Oral).

Inhalation LC₅₀ : > 1.9 mg/l/4H Inhalation Category 4 Dust/Mist Rat

Notes : ~1% of the mixture consists of components of unknown toxicity (Inhalation).

Carcinogenicity : Cobalt Zinc Aluminate Blue Spinel may cause cancer according to the SDS.

Reproductive toxicity : WARNING! This product contains a chemical known to cause birth defects or other reproductive harm. Siloxane

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

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



Date Issued : 09/06/2012
 SDS No : 7-001.16
 Date Revised : 03/27/2017
 Revision No : 17

Ultra-Etch®

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

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

SECTION 14: Transport information

14.1. UN number

UN number : 1760

14.2. UN proper shipping name

UN proper shipping name : Corrosive liquid, n.o.s. (Phosphoric acid mixture)

14.3. Transport hazard class(es)

Primary hazard class/division : 8

Hazard classification : 8

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.

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



Date Issued : 09/06/2012
 SDS No : 7-001.16
 Date Revised : 03/27/2017
 Revision No : 17

Ultra-Etch®

General comments : Please refer to Medical Devices Directive 93/42/EEC.

15.2. Chemical safety assessment

Chemical safety assessment : See Section 11

Additional information : WARNING! This product contains a chemical known to cause birth defects or other reproductive harm: Siloxane
 WARNING! Cobalt Zinc Aluminate Blue Spinel may cause cancer according to the SDS.

SECTION 16: Other information

Relevant H-statements (number and full text) : Eye Irr., Cat. 2: Eye Irritation, Category 2
 Rep. Tox., Cat. 2: Reproductive Toxicity, Category 2
 STOT SE, Cat. 2: Target Organ Toxicity (Single exposure), Category 2
 STOT SE, Cat. 3: Target Organ Toxicity (Single exposure), Respiratory Tract Category 3
 Skin Corr., Cat. 1B: Skin Corrosion, Category 1B
 Skin Irr., Cat. 2: Skin Irritation, Category 2
 H314: Causes severe skin burns and eye damage.
 H315: Causes skin irritation.
 H319: Causes serious eye irritation.
 H335: May cause respiratory irritation.
 H361f: Suspected of damaging fertility.
 H373: May cause damage to organs (lungs) through prolonged or repeated exposure.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 12/22/2015 SDS. Revised: **Section 1**: MSDS No. **Section 2**: EMERGENCY OVERVIEW - IMMEDIATE CONCERNS 2.3. Other hazards. **Section 4**: INHALATION, SIGNS AND SYMPTOMS OF OVEREXPOSURE - INHALATION. **Section 5**: EXTINGUISHING MEDIA, FIRE FIGHTING EQUIPMENT. **Section 6**: **Section 8**: PERSONAL PROTECTIVE EQUIPMENT - RESPIRATORY. **Section 9**: APPEARANCE, COMMENTS, PERCENT VOLATILE, SPECIFIC GRAVITY. **Section 11**: ACUTE (DERMAL LD₅₀ (rabbit), DERMAL LD₅₀ (rabbit), DERMAL LD₅₀ (rabbit), ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat), ORAL LD₅₀ (rat), ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat), INHALATION LC₅₀ (rat), INHALATION LC₅₀ (rat), ORAL LD₅₀ (rat) ACUTE, GENERAL COMMENTS, CARCINOGENICITY, REPRODUCTIVE TOXICITY. **Section 12**: CHEMICAL FATE INFORMATION, DISTRIBUTION, ECOTOXICOLOGICAL INFORMATION, 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

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



Date Issued : 09/06/2012
SDS No : 7-001.16
Date Revised : 03/27/2017
Revision No : 17

Ultra-Etch®

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.