

SAFETY DATA SHEETS

This SDS packet was issued with item:

077640089

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

077340425 077640147 077640154 077640162 077640188

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 09/06/2012

SDS No : 7-001.13

Date Revised : 03/18/2015

Revision No : 14

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. 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 : C
R phrases : R34

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

Health : Skin Corrosion, Category 1B

2.2. Label elements

This mixture contains Phosphoric Acid. This material is considered hazardous as defined by the OSHA Hazard Communication Standard (29 CFR 1819.1200)

Classification according to Directive 1999/45/EC

Hazard pictogram(s) : C



Corrosive

R&S statement(s) : R34: Causes burns.

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Ultra-Etch®**Classification according to Regulation (EC) No 1272/2008 [CLP]**

Hazard pictogram(s)

:



Corrosive

Signal Word

: WARNING

Hazard statement(s)

: 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.

P302+P352: IF ON SKIN: Wash with plenty of soap and water.

P332+P313: If skin irritation occurs: Get medical advice/attention.

P301: IF SWALLOWED:

P310: Immediately call a POISON CENTER or doctor/physician.

P331: Do NOT induce vomiting.

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

: Corrosive. Will cause eye burns and permanent tissue damage.

SECTION 3: Composition / information on ingredients**3.1. Substances**

Not Applicable

3.2. Mixtures

Chemical Name	CAS	EINECS No.	Wt. %	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No 1272/2008 [CLP]
Phosphoric Acid	7664-38-2	231-633-2	< 45	C; R34	Skin Corr., Cat. 1B; H314

For full text of H-statements and R-phrases: see SECTION 16.

SECTION 4: First aid measures**4.1. Description of first aid measures**

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- | | |
|-----------------------------|---|
| 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 | : Wash with soap and water. Get medical attention if irritation develops or persists. |
| 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 immediately. Never give anything by mouth to an unconscious person. |
| 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 | : Causes severe eye burns. |
| Skin | : Corrosive, causes skin burning. |
| Ingestion | : Harmful if swallowed. |
| Inhalation | : None expected for this product. |

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 | : Please see Fire Fighting Equipment under Section 5.3. |
|----------------------------|---|

5.2. Special hazards arising from the substance or mixture

- | | |
|--------------------------------------|------------------|
| Hazardous combustion products | : Not Determined |
| 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 | : Non-combustible. |

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

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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 : Not Applicable

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)

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

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Control parameters : Not Determined

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.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Gel

Colour : Blue

Odour : Odorless or no characteristic odor

pH : < 1

Solubility in water : Partially soluble in water.

9.2. Other information

Percent volatile : Not Determined

SECTION 10: Stability and reactivity

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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. 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

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.

SECTION 12: Ecological information

12.1. Toxicity

Toxicity : Not Determined

Aquatic toxicity (acute)

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

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Ultra-Etch®**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** : 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** : 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** : N/A**14.6. Special precautions for user****ADR - road** : N/A**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

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Ultra-Etch®**SECTION 16: Other information****Relevant R-phrases and/or H-statements (number and full text)**

: R34: Causes burns.
 Skin Corr., Cat. 1B: Skin Corrosion, Category 1B
 H314: Causes severe skin burns and eye damage.

Prepared by

: Anu Kattoju

Revision summary

: This SDS replaces the 02/25/2015 SDS. Revised: **Section 1:**
 . **Section 2:** . **Section 8:** PERSONAL PROTECTIVE EQUIPMENT -
 SKIN. **Section 10:** HAZARDOUS POLYMERIZATION.

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.

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 26.10.2018

Revision: 03.10.2018

1 Identification of the substance/mixture and of the company/undertaking

- **Product identifier**
- **Trade name:** Ultra-Etch® & Opal® Etch
- **Article number:** 10947
- **Index number:** SDS 7-001.17
- **Relevant identified uses of the substance or mixture and uses advised against**
Professional Dental Acid Etching Solution
- **Application of the substance / the mixture** Professional Dental Acid Etching Solution
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Ultradent Products Inc.
505 W. Ultradent Drive (10200 S)
South Jordan, UT 84095-3942
USA
onlineordersupport@ultradent.com
- 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
- **Further information obtainable from:** Customer Service
- **Emergency telephone number:**
CHEMTREC (NORTH AMERICA) : (800) 424-9300
(INTERNATIONAL) : +(703) 527-3887

2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**



GHS05 corrosion

Skin Corr. 1B H314 Causes severe skin burns and eye damage.



GHS07

Acute Tox. 4 H332 Harmful if inhaled.

- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**

The Regulation EC 1272/2008 on classification, labeling and packaging of substances and mixtures (CLP) shall not apply to a medical device in the finished state used in direct physical contact with the human body according to Art. 1.5 (d). Therefore, the product is exempted from the CLP labeling requirements, and no SDS is required by Regulation 1907/2006, Art. 2 (6c), REACH. Therefore, all given data, classification, and information on this SDS are provided solely on a voluntary basis.

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Trade name: Ultra-Etch® & Opal® Etch

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· **Hazard pictograms**

GHS05 GHS07

· **Signal word** *Danger*· **Hazard-determining components of labelling:**

Phosphoric Acid

Polyethylene Glycol

· **Hazard statements**

H332 Harmful if inhaled.

H314 Causes severe skin burns and eye damage.

· **Precautionary statements**

P101 If medical advice is needed, have product container or label at hand.

P102 Keep out of reach of children.

P103 Read label before use.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER/doctor.

P321 Specific treatment (see on this label).

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Other hazards**· **Results of PBT and vPvB assessment**· **PBT:** Not applicable.· **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterisation: Mixtures**· **Description:** Mixture of substances listed below with nonhazardous additions.· **Dangerous components:**

CAS: 7664-38-2 EINECS: 231-633-2	Phosphoric Acid ⚠ Acute Tox. 1, H330; ⚠ Met. Corr.1, H290; Skin Corr. 1B, H314; ⚠ Acute Tox. 4, H302	< 40%
CAS: 25322-68-3 NLP: 500-038-2	Polyethylene Glycol ⚠ Acute Tox. 2, H330	< 10%
	Dimethicone ⚠ Repr. 2, H361f; STOT RE 2, H373	< 1%

· **Additional information:** For the wording of the listed hazard phrases refer to section 16.

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Trade name: Ultra-Etch® & Opal® Etch

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4 First aid measures

- **Description of first aid measures**

- **General information:**

Immediately remove any clothing soiled by the product.

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

- **After inhalation:** This product is a viscous gel, therefore chance of inhalation is not possible.

- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.

- **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.

- **After swallowing:** If swallowed in large quantities seek medical attention.

- **Information for doctor:**

- **Most important symptoms and effects, both acute and delayed** No further relevant information available.

- **Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

5 Firefighting measures

- **Extinguishing media**

- **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.

- **Special hazards arising from the substance or mixture**

During heating or in case of fire poisonous gases are produced.

- **Advice for firefighters:**

- **Protective equipment:** Mouth respiratory protective device.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**

Mount respiratory protective device.

Wear protective equipment. Keep unprotected persons away.

- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.

- **Methods and material for containment and cleaning up:**

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Use neutralising agent.

Dispose contaminated material as waste according to item 13.

Ensure adequate ventilation.

- **Reference to other sections**

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7 Handling and storage

- **Handling:**

- **Precautions for safe handling:**

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

- **Information about fire - and explosion protection:** Keep respiratory protective device available.

- **Conditions for safe storage, including any incompatibilities**

- **Storage:**

- **Requirements to be met by storerooms and receptacles:** No special requirements.

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Trade name: Ultra-Etch® & Opal® Etch

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- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
See product labelling.
Keep container tightly sealed.
- **Specific end use(s)** Professional Dental Acid Etching Solution

8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Control parameters**

Ingredients with limit values that require monitoring at the workplace:	
7664-38-2 Phosphoric Acid	
WEL (Great Britain)	Short-term value: 2 mg/m ³ Long-term value: 1 mg/m ³

- **Additional information:** The lists valid during the making were used as basis.

- **Exposure controls**

- **Personal protective equipment:**

- **General protective and hygienic measures:**

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work..

Avoid contact with the eyes and skin.

- **Respiratory protection:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

- **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **Material of gloves**

The selection of suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

- **Penetration time of glove material**

The exact breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.

- **Eye protection:**



Tightly sealed goggles

- **Body protection:** Protective work clothing

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Trade name: Ultra-Etch® & Opal® Etch

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9 Physical and chemical properties

· Information on basic physical and chemical properties	
· General Information	
· Appearance:	
Form:	Gel
Colour:	Blue
· Odour:	Odourless
· Odour threshold:	Not determined.
· pH-value at 20 °C:	<1
· Change in condition	
Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	100 °C
· Flash point:	Not applicable.
· Flammability (solid, gas):	Not applicable.
· Decomposition temperature:	Not determined.
· Auto-ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapour pressure:	Not determined.
· Density at 20 °C:	1.3 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with water:	Not miscible or difficult to mix.
· Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
· Solvent content:	
Water:	< 60 %
VOC (EC)	0.00 %
Solids content:	<20.0 %
· Other information	Refractive Index 34-37 Brix

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions:** No dangerous reactions known.
- **Conditions to avoid:** No further relevant information available.

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Trade name: Ultra-Etch® & Opal® Etch

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- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity**
Harmful if inhaled.

- **LD/LC50 values relevant for classification:**

ATE (Acute Toxicity Estimates)

Oral	LD50	4,358 mg/kg (rat)
Inhalative	LC50/4 h	<0.88 mg/l

7664-38-2 Phosphoric Acid

Oral	LD50	1,530 mg/kg (rat)
Dermal	LD50	2,740 mg/kg (rabbit)
Inhalative	LC50/4 h	0.42225 mg/l (rabbit)

25322-68-3 Polyethylene Glycol

Oral	LD50	19,600 mg/kg (Guinea pig)
		17,300 mg/kg (mouse)
		>10,000 mg/kg (rat)
Dermal	LD50	>100 mg/l (Fish)
		>20,000 mg/kg (rabbit)
		>10,000 mg/l (Water Flea) (Toxicity to aquatic invertebrates)
Inhalative	LC50/4 h	1.65 mg/l (rat)
	LC50(Daphnia magna)	>10,000 mg/l (Water Flea) (Toxicity to aquatic invertebrates)

- **Primary irritant effect:**
- **Skin corrosion/irritation**
Causes severe skin burns and eye damage.
- **Serious eye damage/irritation**
Causes severe skin burns and eye damage.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.

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Trade name: Ultra-Etch® & Opal® Etch

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· **Additional ecological information:**

· **General notes:**

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

Must not reach sewage water or drainage ditch undiluted or unneutralised.

Rinse off of bigger amounts into drains or the aquatic environment may lead to decreased pH-values. A low pH-value harms aquatic organisms. In the dilution of the use-level the pH-value is considerably increased, so that after the use of the product the aqueous waste, emptied into drains, is only low water-dangerous.

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **Other adverse effects** No further relevant information available.

13 Disposal considerations

· **Waste treatment methods**

· **Recommendation**

Must not be disposed together with household garbage. Do not allow product to reach sewage system.


· **European waste catalogue**

HP 6	Acute Toxicity
HP 8	Corrosive

· **Uncleaned packaging:**

· **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

· UN-Number	UN1805
· ADR, IMDG, IATA	
· UN proper shipping name	1805 PHOSPHORIC ACID, SOLUTION mixture
· ADR	PHOSPHORIC ACID, SOLUTION mixture
· IMDG, IATA	
· Transport hazard class(es)	
· ADR, IMDG, IATA	
	
· Class	8 Corrosive substances.
· Label	8
· Packing group	
· ADR, IMDG, IATA	III
· Environmental hazards:	Not applicable.
· Special precautions for user	Warning: Corrosive substances.
· Danger code (Kemler):	80
· EMS Number:	F-A,S-B
· Segregation groups	Acids

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· Stowage Category	A
· Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	
· ADR	
· Limited quantities (LQ)	5L
· Excepted quantities (EQ)	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· Transport category	3
· Tunnel restriction code	E
· IMDG	
· Limited quantities (LQ)	5L
· Excepted quantities (EQ)	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· UN "Model Regulation":	UN 1805 PHOSPHORIC ACID, SOLUTION MIXTURE, 8, III

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **Directive 2012/18/EU**

· **Named dangerous substances - ANNEX I**

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006.

Product: None

Contained substance: None.

Substances in Candidate List (Art. 59 REACH): None.

Substances subject to authorisation (Annex XIV REACH): None

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012: None

Substances subject to the Rotterdam Convention: None.

Substances subject to the Stockholm Convention: None.

Healthcare controls: Information not available.

· **REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3**

· **Chemical safety assessment:**

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.

GB2

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Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 26.10.2018

Revision: 03.10.2018

Trade name: Ultra-Etch® & Opal® Etch

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16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Relevant phrases**

H290 May be corrosive to metals.

H302 Harmful if swallowed.

H314 Causes severe skin burns and eye damage.

H330 Fatal if inhaled.

H361f Suspected of damaging fertility.

H373 May cause damage to organs through prolonged or repeated exposure.

· **Department issuing SDS:** Regulatory Affairs

· **Contact:** Customer Service

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

VOC: Volatile Organic Compounds (USA, EU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Met. Corr. 1: Corrosive to metals – Category 1

Acute Tox. 4: Acute toxicity – Category 4

Acute Tox. 1: Acute toxicity – Category 1

Acute Tox. 2: Acute toxicity – Category 2

Skin Corr. 1B: Skin corrosion/irritation – Category 1B

Repr. 2: Reproductive toxicity – Category 2

STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2