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

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 Product name : UX/10947

: 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 Regu	lation (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)



2

R&S statement(s)

: R34: Causes burns.

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®

Classification according to Regu	llation (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

according to Regulation (EC) No. 453/2010

Dental Use



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Ultra-Etch®

	•
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 immediat	te medical attention and special treatment needed
Notes to physician	: Corrosive
SECTION 5: Fire fighting measure	ures
5.1. Extinguishing media	
Extinguishing media	: Please see Fire Fighting Equipment under Section 5.3.
5.2. Special hazards arising fro	m the substance or mixture
Hazardous combustion produc	ts : 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 processitions prot	active equipment and emergency procedures
Concept and address	Pofer to Section 8 for Personal Protective Equipment
I S DROE SI NEW OF STREET	

6.2. Environmental precautions

according to Regulation (EC) No. 453/2010

Dental Use



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Ultra-Etch®

Water spill	: Do not allow to enter sewers or drains that may lead to waterways.
6.3. Methods and material for co	ntainment 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 storag	je
7.1. Precautions for safe handlin	g
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 chemic	al properties
9.1. Information on basic physic	al and chemical properties
Physical state	: Gel
Colour	: Blue
Odour	: Odorless or no characteristic odor
рН	: < 1
Solubility in water	: Partially soluble in water.
9.2. Other information	
Percent volatile	: Not Determined
SECTION 10: Stability and react	ivity

according to Regulation (EC) No. 453/2010

Dental Use



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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 rea	actions		
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 infor	mation		
11 1 Information on toxicologic	al 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 informat	tion		
12.1 Toxicity			
Toxicity	: Not Determined		
Aquatic toxicity (acute)			
96-hour LC _{E0}	: Not Determined		
48-hour EC ₅₀	: Not Determined		
96-hour EC ₅₀	: Not Determined		
12.2. Persistence and degradabil	ity		
Persistence and degradability	: Not Determined		
12.3. Bioaccumulative potential			
Bioaccumulative potential	: Not Determined		

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®	
12.4. Mobility in soil		
Mobility in soil : Not Determined		
12.5. Results of PBT and vPvB a	issessment	
Results of PBT and vPvB assessment	: Not Determined	
12.6. Other adverse effects		
Environmental data	: Not defined	
SECTION 13: Disposal consider	ations	
13.1. Waste treatment methods Disposal method	Dispose of in compliance with governmental regulation.(EC 1975L0442-20/11/2003)	
SECTION 14: Transport information	ition	
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 us	er	
ADR - road	: N/A	
RID - rail	: N/A	
IMDG - sea	: N/A	
IATA - air	: N/A	
14.7. Transport in bulk accordin	ig to Annex II of MARPOL73/78 and the IBC Code	
Transport in bulk	: N/A	
SECTION 15: Regulatory inform	lation	
15.1. Safety, health and environ	nmental regulations/legislation specific for the substance or mixture	
RoHS	Please refer to Medical Devices Directive 93/42/EEC	
15.2. Chemical safety assessme	ent	
Chemical safety assessment	: See Section 11	

according to Regulation (EC) No. 453/2010

Dental Use



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Ultra-Etch®

SECTION 16: Other information

Relevant R-phrases and/or H- statements (number and full text) Prepared by Revision summary	 : R34: Causes burns. Skin Corr., Cat. 1B: Skin Corrosion, Category 1B H314: Causes severe skin burns and eye damage. : Anu Kattoju : 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

RODUCTS, INC.

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@utradent.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.



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.

(Contd. on page 2)

GB2

Printing date 26.10.2018

Revision: 03.10.2018

Trade name: Ultra-Etch[®] & Opal[®] Etch

· Hazard picto	(Contd. of page 1)
	\land
GHS05	
011505	
· Signal word	Danger
· Hazard-dete	rmining components of labelling:
Phosphoric 1	Acid
Polyethylene	e Glycol
· Hazard state	ements
H332 Harmj	ful if inhaled.
H314 Cause	s severe skin burns and eye damage.
· Precautiona	ry 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 hazar	ds
\cdot Results of P	BT and vPvB assessment
• PBT: Not ap	plicable.
• vPvB: Not a	pplicable.

3 Composition/information on ingredients

• Chemical characterisation: Mixtures

• Description: Mixture of substances listed below with nonhazardous additions.

 Dangerous compone 	ents:	
CAS: 7664-38-2	Phosphoric Acid	< 40%
EINECS: 231-633-2		
CAS: 25322-68-3	Polyethylene Glycol	< 10%
NLP: 500-038-2	🛞 Acute Tox. 2, H330	
	Dimethicone	< 1%
	🚸 Repr. 2, H361f; STOT RE 2, H373	
• Additional informat	ion: For the wording of the listed hazard phrases refer to section 16.	

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Printing date 26.10.2018

Revision: 03.10.2018

Trade name: Ultra-Etch[®] & Opal[®] Etch

(Contd. of page 2)

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.

(Contd. on page 4)

GB2

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Trade name: Ultra-Etch[®] & Opal[®] Etch

- · 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/m³

Long-term value: 1 mg/m³

- 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 \cdot *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:



· Body protection: Protective work clothing

(Contd. on page 5)

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Trade name: Ultra-Etch[®] & Opal[®] Etch

(Contd. of page 4)

9 Physical and chemical properties	
• Information on basic physical and chem • General Information	nical properties
· Appearance:	
Form:	Gel
Colour:	Blue
· Odour:	Odourless Net the second secon
· Odour threshold:	Not determined.
· pH-value at 20 °C:	<]
• Change in condition Melting point/freezing point: Initial boiling point and boiling range	Undetermined. : 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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(Contd. of page 5)

Trade name: Ultra-Etch[®] & Opal[®] Etch

· 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/l7664-38-2 Phosphoric Acid Oral LD50 1,530 mg/kg (rat) LD50 Dermal 2,740 mg/kg (rabbit) Inhalative LC50/4 h 0.42225 mg/l (rabbit) 25322-68-3 Polyethylene Glycol LD50 Oral 19,600 mg/kg (Guinea pig) 17,300 mg/kg (mouse) >10,000 mg/kg (rat)LC50 Fish >100 mg/l (Fish) Dermal LD50 >20,000 mg/kg (rabbit) 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 eve 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 (carcinogenity, 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:

 $\cdot \textit{Bioaccumulative potential No further relevant information available}.$

• *Mobility in soil* No further relevant information available.

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Trade name: Ultra-Etch[®] & Opal[®] Etch

· 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 pHvalue 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.*

UN-Number	
ADR, IMDG, IATA	UN1805
UN proper shipping name	
ADR	1805 PHOSPHORIC ACID, SOLUTION mixture
IMDG, IATA	PHOSPHORIC ACID, SOLUTION mixture
Transport hazard class(es)	
ADR, IMDG, IATA	
Class	8 Corrosive substances
Label	8 Corrosive substances.
Luber	0
Packing group	111
ADK, IMDG, IATA	111
Environmental hazards:	Not applicable.
Special precautions for user	Warning: Corrosive substances.
Danger code (Kemler):	80
EMS Number:	F-A,S-B
~ .	4 • 1

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Trade name: Ultra-Etch[®] & Opal[®] Etch

	(Contd. of page
· Stowage Category	A
· Transport in bulk according to Annex II oj and the IBC Code	f Marpol Not applicable.
· Transport/Additional information:	
· ADR	
· Limited quantities (LQ)	5L
\cdot Excepted quantities ($\widetilde{E}O$)	Code: El
	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 1000 ml
· Transport category	3
· Tunnel restriction code	Ε
·IMDG	
· Limited quantities (LQ)	5L
\cdot Excepted quantities ($\widetilde{E}Q$)	Code: El
	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, 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 authorisarion (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.

(Contd. on page 9)

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Trade name: Ultra-Etch[®] & Opal[®] Etch

(Contd. of page 8)

16 C	Other information
T sp	his information is based on our present knowledge. However, this shall not constitute a guarantee for any pecific product features and shall not establish a legally valid contractual relationship.
• R	elevant phrases
H	1290 May be corrosive to metals.
H	1302 Harmful if swallowed.
H	1314 Causes severe skin burns and eye damage.
H	1330 Fatal if inhaled.
H	1361f Suspected of damaging fertility.
H	1373 May cause damage to organs through prolonged or repeated exposure.
$\begin{array}{c} \cdot \mathbf{D} \\ \cdot \mathbf{C} \\ \cdot \mathbf{A} \\ A \\ C \\ A \\ C \\ I \\ I \\ G \\ F \end{array}$	Pepartment Issuing SDS: Kegulatory Affairs Contact: Customer Service bbreviations and acronyms: DR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the Internationa arriage of Dangerous Goods by Road) MDG: International Maritime Code for Dangerous Goods ITA: International Air Transport Association HS: Globally Harmonised System of Classification and Labelling of Chemicals INFCS: Furopean Inventory of Fxisting Commercial Chemical Substances
E	LINCS: European List of Notified Chemical Substances
С.	AS: Chemical Abstracts Service (division of the American Chemical Society)
	OC: Volatile Organic Compounds (USA, EU)
	CSU: Leinal concentration, SU percent
P	B. Persistent Bioaccumulative and Toxic
vl	DB: very Persistent and very Bioaccumulative
M	let. Corr.1: Corrosive to metals – Category 1
A	cute Tox. 4: Acute toxicity – Category 4
A	cute Tox. 1: Acute toxicity – Category 1
A	cute Tox. 2: Acute toxicity – Category 2
SP P	KIN CORP. 1B: SKIN CORPOSION/IPPILIATION – Category IB
S	epr. 2. Reproductive toxicity – Category 2 TOT RF 2: Specific target organ toxicity (repeated exposure) – Category 2
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