

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



Date Issued : 05/06/2009
SDS No : 218-001.4
Date Revised : 10/19/2015
Revision No : 4

Opal® Etch

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

1.1. Product identifier

Product code : UX/10947
Product name : Opal® Etch
Product description : Phosphoric acid dentin 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

Opal® Orthodontics
 505 W 10200 S
 South Jordan, UT 84095

Distributor

MPG Service GmbH
 Gereonstrasse 34-36
 D-50670 Cologne, Germany
 Email: mpgservicekoeln@googlemail.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

Classification according to Directive 1999/45/EC

Hazard pictogram(s) : C



Corrosive

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


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

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Hazard pictogram(s)	:	
		Corrosive
Signal Word	:	DANGER
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. P330: Rinse mouth. 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	< 40	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** : 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.
- Fire fighting equipment** : The product is not combustible. Use appropriate media for adjacent fire. Cool containers with water.

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

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- 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

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) : 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

12.3. Bioaccumulative potential

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Bioaccumulative potential : Not Determined

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 : 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 : 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

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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)** : 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 10/21/2014 SDS. Revised: **Section 1:** . **Section 2:** . **Section 3:** Wt.%. **Section 5:** EXPLOSION HAZARDS, FIRE EXPLOSION, FIRE FIGHTING EQUIPMENT, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 8:** PERSONAL PROTECTIVE EQUIPMENT - SKIN. **Section 9:** pH, SOLUBILITY IN WATER. **Section 10:** HAZARDOUS POLYMERIZATION, STABLE. **Section 11:** ACUTE (ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat) ACUTE. **Section 12:** ECOTOXICOLOGICAL INFORMATION, ENVIRONMENTAL DATA, AQUATIC TOXICITY (ACUTE). **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:** SECTION 15: Regulatory information. **Section 16:** GENERAL STATEMENTS.
- General statements** : N/A= Not Applicable
- Manufacturer disclaimer** : FOR ORTHO 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.