

DENTSPLY International

DENTSPLY PROFESSIONAL

Safety Data Sheet

Safety Data Sheet (in compliance with Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010)

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product Identifier:

Trade Name (as labeled): DELTON® EZ Etch 34% Tooth Conditioning Gel
Part/Item Number: 2103

1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against:

Recommended Use: DELTON EZ Etch 34% Tooth Conditioning Gel indicated to use to surface condition enamel (and dentin where the total etch technique is desired) prior to restoration with adhesive restorative materials.

Restrictions on Use: For Professional Use Only.

1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name: DENTSPLY Professional
Manufacturer/Supplier Address: 1301 Smile Way
York, PA 17404
Manufacturer/Supplier Telephone Number: 800-989-8826 or 717-767-8502 (Product Information)
Email address: ProfessionalMSDS@dentsply.com

1.4 Emergency Telephone Number:

Transportation Emergency Number: 800-424-9300 Chemtrec

2. HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture:

GHS Classification:		
Health	Environmental	Physical
Skin Corrosive Category 1B (H314) Eye Damage Category 1 (H318)	Not Hazardous	Not Hazardous

EU Classification: Corrosive (C) R34

2.2 Label Elements:



Signal Word: Danger

Hazard Phrases	Precautionary Phrases
H314 Causes severe skin burn and eye damage.	P260 Do not breathe mists. P264 Wash thoroughly after handling. P280 Wear protective gloves, protective clothing, eye protection, and face protection. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P303 + P361 + P353 IF ON SKIN (or hair): Remove immediately all contaminated clothing. Rinse skin with water or shower. P363 Wash contaminated clothing before reuse. P304 + P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P310 Immediately call a POISON CENTER or doctor. P301 + 330 + 331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. P405 Store locked up. P501 Dispose of contents and container in accordance with local and national regulations.

2.3 Other Hazards: None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixture:

Hazardous Components	C.A.S. #	EINECS #	Classification	WT %
Phosphoric Acid	7664-38-2	231-633-2	C, R34 Skin Corr. Cat 1B, H314	30-40
Amorphous Precipitated Silica	112945-52	231-545-4	Not applicable	1-10

The exact concentration is being withheld as a trade secret.

Refer to Section 16 for the full text of the GHS and EU Classifications.

4. FIRST AID MEASURES

4.1 Description of First Aid Measures:

Eye	Immediately flush eyes with plenty of water for at least 30 minutes while holding the eyelids apart. Remove contact lenses, if present and easy to do. Get immediate medical attention.
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Skin	Remove contaminated clothing. Wash skin thoroughly with soap and water for at least 30 minutes. Seek immediate medical attention. Launder clothing before re-use.
Inhalation	Remove victim to fresh air. Give artificial respiration if needed. If breathing is difficult, oxygen should be administered by qualified personnel. Get medical attention if symptoms of exposure persist.
Ingestion	Do not induce vomiting. If conscious, rinse mouth with a small amount of water and give one glass of water to dilute. Never give anything by mouth to an unconscious or drowsy person. Get medical attention.

4.2 Most Important Symptoms and Effects, Both Acute and Delayed:

Causes severe eye and skin irritation and burns. If swallowed, may cause burns to mouth, throat, and stomach. May be fatal if swallowed in large amounts. Inhalation of mists may cause severe irritation and burns to respiratory tract.

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:

If contact occurs seek immediate medical attention.

Note to Physicians (Treatment, Testing, and Monitoring): Treat symptomatically.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media:

Use media appropriate for surrounding fire. Cool fire exposed containers and structures with water.

5.2 Special Hazards Arising from the Substance or Mixture:

Reacts with most metals to form flammable hydrogen gas. Combustion produces phosphorous oxides.

5.3 Advice for Fire-Fighters:

Fire Fighting Procedures:	Use water to cool fire-exposed containers. Fight fire from safe distance or protected location.
Precautions for Fire Fighters:	Do not enter fire area without proper protection. Firefighters should wear full emergency equipment and an approved positive pressure self-contained breathing apparatus.

Recommended Protective Equipment for Fire Fighters:

EYES/FACE	HANDS	RESPIRATORY	THERMAL
			

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

Evacuate spill area and keep unprotected personnel away. Avoid contact with skin, eyes or clothing. Avoid breathing mists. Wear appropriate protective clothing.

Recommended Personal Protective Equipment for Containment and Clean-up:			
EYES/FACE	HANDS	RESPIRATORY	SKIN
			

6.2 Environmental Precautions:

Prevent entry into sewers and waterways. Report releases as required by local, state, and national authorities.

6.3 Methods and Material for Containment and Cleaning up:

Contain and collect using an inert absorbent material and place in appropriate containers for disposal. Rinse spill area with water. Prevent spill from entering sewers and water courses. Report releases as required by local, state and federal authorities.

6.4 Reference to Other Sections:

Refer to Section 8 for Personal Protective Equipment and Section 13 for Disposal information.

7. HANDLING AND STORAGE

7.1 Precautions for Safe Handling:

Avoid contact with the eyes, skin and clothing. Avoid breathing mists. Wear protective clothing and equipment as described in Section 8. Use with adequate ventilation. Wash thoroughly with soap and water after handling. Keep containers closed when not in use.

Do not reuse containers. Empty containers retain product residues that can be hazardous. Follow all SDS precautions when handling empty containers.

7.2 Conditions for Safe Storage, Including Any Incompatibilities:

Store in a cool, dry, well-ventilated area away from incompatible materials. Protect from physical damage.

7.3 Specific End Use (s): For professional use only.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:

Occupational Exposure Limits:

Phosphoric Acid	United States	1 ppm TWA ACGIH TLV 1 ppm TWA OSHA PEL
	Germany	2 mg/m3 DFG MAK (Inhalable fraction)
	United Kingdom	1 mg/m3 TWA UK WEL, 2 mg/m3 STEL
	European Union	1 mg/m3 TWA, 2 mg/m3/ STEL
Amorphous Precipitated Silica	United States	20 mcppcf TWA OSHA PEL
	Germany	4 mg/m3 (inhalable)
	United Kingdom	6 mg/m3 (inhalable) 2.4 mg/m3 (respirable aerosol)
	European Union	None established

Biological Exposure Limits: None Established

8.2 Exposure Controls:

Appropriate Engineering Controls: Use with adequate local exhaust ventilation to maintain exposure levels below the occupational exposure limits.

Individual Protection Measures (PPE):

Specific Eye/face Protection: Chemical safety goggles and a face shield should be worn.

Specific Skin Protection: Wear impervious gloves such as natural rubber or neoprene.

Specific Respiratory Protection: None should be needed for normal use. If the exposure limits are exceeded, an approved supplied air respirator appropriate for the form and concentration of the contaminants should be used. Selection and use of respiratory equipment must be in accordance with applicable regulations and good industrial hygiene practice.

Specific Thermal Hazards: None required.

Recommended Personal Protective Equipment

EYES/FACE	HANDS	RESPIRATORY	SKIN
			

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

Appearance:	Slightly viscous, blue paste	Explosive limits:	LEL: Not applicable UEL: Not applicable
Odor:	Acrid odor	Vapor pressure (mmHg):	Not available

Odor threshold:	Not available	Vapor density:	Not available
pH:	<1	Relative density:	1.3 g/cm3
Melting/freezing point:	Not available	Solubility(ies):	95% soluble in water.
Initial boiling point and boiling range:	108°C (226°F)	Partition coefficient: n-octanol/water:	Not determined
Flash point:	Not flammable	Auto-ignition temperature:	Not applicable
Evaporation rate:	Not available	Decomposition temperature:	Not determined
Flammability (solid, gas):	Not applicable	Viscosity:	Not applicable
Explosive Properties:	Not explosive	Oxidizing Properties:	Not an oxidizer

9.2 Other Information: None available

10. STABILITY AND REACTIVITY

10.1 Reactivity: Not normally reactive.
10.2 Chemical Stability: Stable under normal storage and handling conditions.
10.3 Possibility of Hazardous Reactions: Reacts with most common metals to form flammable hydrogen gas.
10.4 Conditions to Avoid: Avoid temperatures greater than 50°C for extended periods.
10.5 Incompatible materials: Avoid caustics, alcohols, aldehydes, cyanides, combustible materials, ketones, metals, phenols, esters, sulfides and halogenated organics
10.6 Hazardous Decomposition Products: Thermal decomposition may produce phosphorus oxides.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

<u>Potential Health Effects:</u>
<u>Eyes:</u> May cause severe irritation or burns with redness, tearing, and blurred vision. Permanent eye damage is possible.
<u>Skin:</u> May cause severe irritation and burns with redness and pain. Repeated exposure to dilute acid solutions may cause dermatitis.
<u>Ingestion:</u> Ingestion may cause irritation or burns to the mouth, throat and stomach with abdominal pain, and nausea. Severe exposures may cause burns, shock, circulatory collapse or death.
<u>Inhalation:</u> This product is a gel. No adverse effects are expected under normal conditions of use.
<u>Chronic Health Effects:</u> None known.
<u>Irritation:</u> No data available.

<u>Corrosivity:</u> Phosphoric acid: Corrosive to rabbit skin and rabbit eyes.
<u>Sensitisation:</u> No data available. This product is not expected to cause sensitization.
<u>Carcinogenicity:</u> None of the components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU CLP Directive.
<u>Mutagenicity:</u> Phosphoric acid was negative in an in vitro mammalian cell gene mutation assay, in an in vitro mammalian chromosome aberration test and AMES test. The surfactant was negative in an in vitro genetic study.
<u>Medical Conditions Aggravated by Exposure:</u> Individuals with pre-existing eye or skin disease may be at increased risk from exposure.
<u>Acute Toxicity Data:</u> Phosphoric Acid: Oral Rat LD50 - 1530 mg/kg; Inhalation Rat LC50 – >850 mg/m ³ /1 hour; Skin Rabbit LD50 – 2740 mg/kg Amorphous Precipitated Silica: Oral Rat LD50: >10,000 mg/kg; Inhalation Rat LC50: >0.139 mg/l/4 hrs (highest concentration – no deaths); Skin Rabbit LD50: >5,000 mg/kg
<u>Reproductive Toxicity Data:</u> Phosphoric Acid: In a one generational study with rats, the offspring of adult male and female rats dosed with phosphoric acid did not display any negative effects resulting from the treatment.
<u>Specific Target Organ Toxicity (STOT):</u> <u>Single Exposure:</u> No data available <u>Repeated Exposure:</u> No data available.

12. ECOLOGICAL INFORMATION

12.1 Toxicity: Phosphoric Acid: 96 hr LC50 Mosquitofish- 138 mg/L
12.2 Persistence and Degradability: No data available for mixture.
12.3 Bio-accumulative Potential: No data available. Product is not expected to bioaccumulate.
12.4 Mobility in Soil: No data available
12.5 Results of PBT and vPvB Assessment: Not applicable.
12.6 Other Adverse Effects: None

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:
<u>Regulations:</u> Dispose in accordance with all national and local regulations.
<u>Properties (Physical/Chemical) Affecting Disposal:</u> Empty containers retain product residues that can be hazardous. Follow all SDS precautions when handling empty containers.
<u>Waste Treatment Recommendations:</u> Dispose in accordance with national and local regulations.

14. TRANSPORT INFORMATION

	14.1 UN Number	14.2 UN Proper Shipping Name	14.3 Hazard Class(s)	14.4 Packing Group	14.5 Environmental Hazards
DOT	UN1805	Phosphoric Acid Solution	8	III	Not applicable
ADR/RID	UN1805	Phosphoric Acid Solution	8	III	Not applicable
IMDG	UN1805	Phosphoric Acid Solution	8	III	Not applicable
IATA/ICAO	UN1805	Phosphoric Acid Solution	8	III	Not applicable

14.6 Special Precautions for User: Not applicable.

14.7 Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code: Not applicable.

15. REGULATORY INFORMATION

15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture:

U.S. Federal Regulations

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): This product has a Reportable Quantity (RQ) of 12,500 lbs. based on the RQ for Phosphoric Acid of 5,000 lbs. Releases above the RQ must be reported to the National Response Center. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations.

Toxic Substances Control Act (TSCA): All of the components of this product are listed on the TSCA inventory.

Clean Water Act (CWA): This material is not regulated under the Clean Water Act.

Clean Air Act (CAA): This material is not regulated under the Clean Air Act.

Superfund Amendments and Reauthorization Act (SARA) Title III Information:

SARA Section 311/312 (40 CFR 370) Hazard Categories:

Immediate Hazard:	Yes	Pressure Hazard:	No
Delayed Hazard:	No	Reactivity Hazard:	No
Fire Hazard:	No		

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372):

Components	C.A.S. #	WT %
None		

State Regulations

California: This product contains the following substances known to the state of California to cause cancer and/or reproductive toxicity:

Components	C.A.S. #	WT %
None		

International Regulations

Canadian Workplace Hazardous Materials Information System (WHMIS): Medical devices are not subject to WHMIS.

Canadian Environmental Protection Act: This product is a medical device and not subject to chemical notification requirements.

This SDS has been prepared according to the criteria of the Controlled Products Regulation (CPR) and the SDS contains all of the information required by the CPR.

European Inventory of Existing Chemicals (EINECS): This product is a medical device and not subject to chemical notification requirements.

EU REACH: All components requiring registration have been pre-registered.

Australian Inventory of Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

China Inventory of Existing Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Japanese Existing and New Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Korean Existing Chemicals List: This product is a medical device and not subject to chemical notification requirements.

Philippine Inventory of Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

15.2 Chemical Safety Assessment: None required.

16. OTHER INFORMATION

HMIS Hazard Rating:

Health – 3 Flammability – 0 Physical Hazard – 0

Full text of Classification abbreviations used in Section 2 and 3:

C Corrosive

R34 Causes burns.

Skin Corr. Cat 1B Skin Corrosion Category 1B

H314 Causes severe skin burns and eye damage.

Supersedes: 24 June 2011

Date Revised: 25 August 2014

Revision Summary: Converted MSDS to Reach SDS. Updated all sections.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, IUCLID Dataset EU Chemical Bureau, ESIS, Country websites for occupational exposure limits.