

blue etch

38% PHOSPHORIC ACID

Dental Etching Gel • For Acid Etching Dentin, Enamel and Glass Ionomer Cement



BLUE ETCH is a thixotropic, phosphoric acid etch gel which stays in place and will not run onto exposed tissue. Syringe dispensing through pre-bent small gauge applicator tips offers precise placement of gel even in relatively inaccessible areas. BLUE ETCH washes off easily with water.

DIRECTIONS FOR USE

1. Prepare tooth and cleanse the enamel surface to be etched with a slurry of pumice or non-oil containing prophyl paste. Rinse and dry thoroughly.
2. Securely attach 25-gauge luer lock applicator tip to syringe. **Start flow on pad; not in patient's mouth. Do not push on plunger with thumb.** For safe, controlled dispensing, rest plunger in palm of hand and pull back on syringe barrel with thumb, index and middle fingers. Do not force plunger down into barrel.
3. Recommended etching time for enamel is 15-20 seconds and for dentin is 15 seconds. To the extent possible, apply BLUE ETCH first to enamel and then to dentin. Leave on dentin for 15 seconds. Cap syringe immediately after use.
4. Rinse off BLUE ETCH with copious amounts of water. Do not disturb this surface.
5. Leave surface wet, or dry surface with clean, uncontaminated air, depending on the instructions for use for the bonding system you are using.

NOTE: Etched enamel should appear chalky white. If not, reapply etch gel to enamel for 20 seconds and rinse with copious amounts of water.

WARNING:

If BLUE ETCH contacts skin or soft tissue, rinse off immediately with copious amounts of water.

NOTE: Apply disposable barrier sleeves/wraps over multiple-use dental dispensers before use with each patient. For additional information, refer to: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/ucm404472.htm>

Français

Gel de mordantage à 38 % d'acide phosphorique
Pour mordancer la dentine, l'émail, les ciments verre ionomères
BLUE ETCH est un gel thixotrope d'acide phosphorique qui reste où il est appliqué et ne coule pas sur les tissus exposés.
Les seringues avec applicateurs courbés permettent une application précise aussi dans les espaces moins accessibles. BLUE ETCH se rince facilement avec de l'eau.

MODE D'EMPLOI

1. Préparer la dent à mordancer et nettoyer l'émail avec une pâte prophylactique sans huile ou une pâte contenant de la ponce. Rincer abondamment et sécher.
2. Fixer solidement l'embout applicateur 25-gauge luer-lock sur la seringue. **Démarrez l'écoulement sur un pad de mélange, et non dans la bouche du patient. Ne pas pousser sur le piston avec le pouce.** Pour une application sûre et contrôlée poser le piston dans la paume de la main et tirer la seringue avec le pousse, l'index et le médium. Ne pas pousser le piston dans la seringue.
3. Le temps de mordantage recommandé pour l'émail est de 15-20 secondes et pour la dentine est de 15 secondes. Dans la mesure du possible, appliquer BLUE ETCH d'abord sur l'émail puis sur la dentine. Laisser agir sur la dentine 15 secondes.
4. Rincer BLUE ETCH abondamment à l'eau. Ne pas contaminer la surface mordancée.
5. Laisser la surface légèrement humide ou la sécher avec de l'air propre, suivant les instructions du produit de collage utilisé.
6. Reboucher la seringue immédiatement après usage.

NOTE: l'émail mordancé doit paraître blanc crayeux. Si ce n'est pas le cas, recommencer l'application de BLUE ETCH pendant 20 secondes et rincer abondamment.

PRECAUTION D'EMPLOI : si BLUE ETCH entre en contact avec les mains ou la muqueuse, rincer immédiatement abondamment à l'eau.

NOTE: seringues multidoses doivent être soit enfermées dans une nouvelle barrière protectrice pour chaque patient ou nettoyées et désinfectées entre les patients, le cas échéant.

Deutsch

Ätzel 38% Phosphorsäure
Zur Ätzung von Dentin, Zahnschmelz und Glasionomerzement
BLUE ETCH ist ein thixotropes Phosphorsäure Gel, das an Ort und Stelle bleibt und nicht an exponiertes Gewebe fließt.

Die Spritze mit vorgebogenen Applikationskanülen bietet eine präzise Applikation des Gels auch an relativ unzugänglichen Stellen. BLUE ETCH lässt sich leicht mit Wasser abspülen.

GEBRAUCHSANWEISUNG

1. Zahn vorbereiten und Schmelzoberfläche mit einer feinen Bimssteinpaste reinigen. Verwenden Sie keine ölhaltigen Polierpasten. Anschließend gut spülen und trocknen.
2. Befestigen Sie den Luer-lock-Verschluss 25-gauge gut auf der Spritze. **Material auf ein Pad ausdrücken; keine Anwendung im Mund des Patienten vornehmen. Den Kolben nicht mit dem Daumen drücken.** Um den Fluss des Materials besser zu kontrollieren, sollte der Kolben in der Handfläche liegen. Die Spritze mit Daumen, Zeige- und Mittelfinger vorsichtig gegen die Handfläche ziehen, um den Fluss auszulösen. Den Kolben nicht mit dem Daumen in die Spritze forcieren.
3. Empfohlene Ätzzeit für Zahnschmelz ist 15-20 Sekunden und für Dentin 15 Sekunden. Wenn möglich, zuerst auf Zahnschmelz und dann auf das Dentin auftragen. Auf dem Dentin 15 Sekunden einwirken lassen.
4. Spülen Sie BLUE ETCH mit reichlich Wasser weg. Bitte beachten Sie, dass diese Stelle von jeder Kontamination frei bleibt.
5. Lassen Sie die Oberfläche feucht oder trocknen Sie mit sauberer, nicht kontaminierter Luft, je nach Gebrauchsanweisung für das Bondingsystem, das Sie verwenden.
6. Spritze sofort nach Gebrauch verschliessen.

ACHTUNG: Wenn die geätzte Oberfläche nicht kalkig weiß erscheint, Ätzel nochmals auf den Zahnschmelz für 20 Sekunden auftragen. Mit reichlich Wasser spülen.

WARNUNG: Wenn BLUE ETCH mit Haut oder Weichgewebe in Berührung kommt, spülen Sie sofort mit reichlich Wasser.

ACHTUNG: Mehrfachdosis-Spritzen sollten entweder in einer frischen Schutzhülle für jeden Patienten verpackt oder nach jedem Patienten angemessen gereinigt und desinfiziert werden.

Italiano

BLUE ETCH è un gel tissotropico di acido fosforico che aderisce e non cola sui tessuti esposti. Dispensato da una siringa con aghi pre-piegati di piccolo calibro, può essere applicato anche in aree relativamente inaccessibili. BLUE ETCH si lava via facilmente con acqua.

ISTRUZIONI D'USO

1. Preparare il dente da mordenzare e pulire la superficie dello smalto con pasta pomice oppure con una pasta "prophy" non oleosa. Sciacquare e asciugare bene.
2. Rimuovere il tappo e applicare saldamente il puntale alla siringa; iniziare a far colare il gel su un tampone e non direttamente nella bocca del paziente. Per una applicazione sicura e controllata, è preferibile non agire con la pressione diretta del pollice sullo stantuffo ma bensì appoggiare lo stesso sul palmo della mano e tirare la siringa tenendola tra il pollice, l'indice e il medio.
3. Si raccomanda un tempo di mordenzatura di 15-20 secondi per lo smalto, e di 15 secondi per la dentina. Per quanto possibile, applicare Blue Etch prima sullo smalto e poi sulla dentina. Tappare la siringa subito dopo l'uso.
4. Sciacquare BLUE ETCH con abbondante acqua, senza contaminare la superficie.
5. A seconda delle istruzioni del sistema adesivo utilizzato, mantenere la superficie umida oppure essicarla con aria pulita, non contaminata.

ATTENZIONE: Normalmente, lo smalto mordenzato ha un aspetto bianco gessoso; in caso contrario riapplicare BLUE ETCH sullo smalto per 20 secondi, poi sciacquare con abbondante acqua.

AVVERTIMENTO: Nel caso di un contatto di BLUE ETCH con pelle o tessuto molli, sciacquare immediatamente con abbondante acqua.

NOTA: Le siringhe multi-dose devono essere confezionate in una nuova guaina monouso per ogni paziente o pulite e disinfettate dopo ogni uso, se appropriato.



Shelf life is indicated on outer package.



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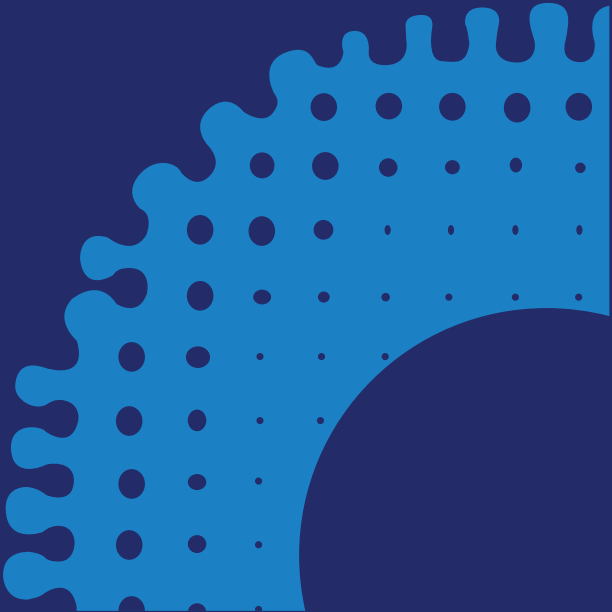
FOR USE BY DENTAL PROFESSIONALS ONLY

Rev. 05/2018

blue etch

la maison
dentaire sa

FL-9496 Balzers



blue etch

DENTAL ETCHING GEL

For acid etching of enamel
and glass ionomer cement

- 38% H₃PO₄
- Thixotropic

8 NEEDLES

Contents:
4 x 1.2 ml etching gel
8 dispenser needles
instructions for use

FOR PROFESSIONAL USE BY DENTISTS



La Maison Dentaire SA
Alte Churerstrasse 36, FL-9496 Balzers - LIECHTENSTEIN

Safety Data Sheet

Trade Name: Blue Etch 38% Phosphoric Acid Etching Gel

1.0	Commercial Product Name and Supplier		
1.1	Commercial product name / designation	Blue Etch 38% Phosphoric Acid Etching Gel	
1.2	Application / Use	Dental etching gel for use by dental professional only.	
1.2.2	SIC	851 Human health activity	
1.2.3	Use Category	55	
1.3	Manufacturer/Importer	LA MAISON DENTAIRE SA	
1.3.1	Manufacturer	Alte Churerstrasse 36 FL-9496 BALZERS LIECHTENSTEIN	
1.3.2	Distributor	MEDIREL SA CH-6982 Agno Switzerland Tel. +41 91 604 54 34 Email: info@medirel.ch	
1.4	Emergency Telephone Number	Tel. + 41 91 604 54 34	

2.0	Hazards Identification			
2.1	Classification			
2.1.1	Classification according to Regulation (EC) No. 1272/2008 [CLP] BLUE ETCH, 38% Phosphoric Acid Etching Gel	Hazard Class Skin corrosion Eye irritation	Hazard Category 1B 2	Hazard Statement H314 H319
2.1.2	Classification according to Directive 67/548/EEC (See SECTION 16 for full text of risk phrases)	Corrosive (C); R 34; R 36 / 37/ 38		
2.2	GHS Label Elements Hazard Pictograms			



Signal Word: **DANGER**
Restricted to use by dental professional only.
Hazard Statements
H314: Causes severe skin burns and eye damage.
H319: Causes serious eye irritation.

Precautionary Statements
P264: Wash hands thoroughly after handling.
P280: Wear protective gloves, clothing and eye/face protection.
P301 + P330 + P331: If swallowed, rinse mouth. Do NOT induce vomiting.
P303 + P361 + P353: If on skin (or hair), remove all contaminated clothing. Rinse skin with water.
P363: Wash contaminated clothing before reuse.
P310: Immediately call a Poison Center or doctor/physician.
P305 + P351 + P338: If in eyes, rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing until pH of tears is 7.

3.0	Composition				
3.1	Chemical characterization of the preparation		Phosphoric acid in a gel matrix.		
3.2	Hazardous ingredients				
	CAS Number	Name of the Ingredient	Concentration	Classification per 67/548/EEC	Classification per Regulation (EC) No.1278/2008 (CLP).
	7664-38-2	Phosphoric Acid	38%	Corrosive (C) R34; R36/ 37/38	Skin corrosion; 1B Eye irritant, 2

4.0	First Aid Measures	
4.1	General Information	May cause burns or irritation to eyes, skin or mucous membranes. Acute effects may be delayed. Show this safety data sheet to medical personnel. Get medical attention in case of uncertainty.
4.2	Eye Contact	Remove contact lenses. Keep eyelids apart and flush with running water for 15+ minutes or until pH of tears is 7. Get medical attention.
4.3	Skin Contact	Immediately flush skin with running water for 15 minutes. Get medical attention for persistent irritation or burns.
4.4	Ingestion	Rinse mouth with water. Do not induce vomiting. Give water to dilute. Get immediate medical attention. Never give anything by mouth to an unconscious person.
4.5	Inhalation	Move to fresh air. If necessary, administer oxygen and/or artificial respiration and seek medical attention.
4.6	Precautions for first responders	Ventilate the area. Wear safety glasses, gloves and lab coat.
4.7	Information for physicians	
	Symptoms	Irritation, pain or redness in eyes, mucous membranes or skin. Acute effects may be delayed so continued monitoring of the patient is indicated.
	Hazards	May cause burns or irritation to eyes, skin or mucous membranes. Acute effects may be delayed.
	Treatment	Same as above under First Aid.

5.0	Fire Fighting Measures	
5.1	Suitable extinguishing media	Not a fire hazard. Use water spray to keep fire-exposed containers cool. Extinguish fire with agent suitable for surrounding fire.
5.2	Extinguishing media to avoid	None
5.3	Special exposure hazards in a fire	Phosphoric acid can react with metals to liberate hydrogen, a flammable gas. Combustion by-products include oxides of phosphorus.
5.4	Special protective equipment for fire-fighters	A self-contained breathing apparatus should be worn by firefighting personnel.

6.0	Accidental Release Measures	
6.1	Personal precautions.	Wear chemical splash goggles and gloves.
6.2	Environmental precautions	Avoid releasing large quantities into the environment as phosphoric acid may affect pH of water or soil.
6.3	Method for clean up	For small quantities (as in this product): Wear safety glasses, lab coat and gloves. Absorb or wipe up spill with dry paper towels. Place all material in covered chemical waste container for disposal. Flush spill area with water.

7.0	Handling and Storage	
7.1	Handling	For use by dental professionals only. Wear safety glasses and gloves; wash hands after use. Avoid unnecessary exposure. Follow good hygiene practices. Do not smoke, eat or drink while using. Protect soft tissue from etchant during intraoral procedures.
7.2	Storage	Remove applicator tip after use. Keep tightly capped in original container. Store at cool room temperature. Avoid extremes of temperature (>27° C/80° F, <5° C/40° F), alkalies, sulfites, sulfides and most metals.
7.3	Specific uses	Dental etchant

8.0	Exposure Controls / Personal Protection	
8.1	Exposure limit values	TWA: 1 mg/m³ TLV: 3 mg/m³
8.2	Exposure controls	No special equipment required under normal conditions of use of this product in the quantity provided.
8.2.1	Occupational exposure controls	No special equipment required under normal conditions of use of this product in the quantity provided.
8.2.1.1	Respiratory protection	Non required. Good general ventilation is sufficient to control airborne vapors.
8.2.1.2	Hand protection	No special requirements. The usual surgical gloves worn by dental staff will limit contact with this material.
8.2.1.3	Eye protection	No special requirements other than the usual safety glasses worn by dental staff.
8.2.1.4	Skin protection	No special requirements. Good personal hygiene and safety practices and wearing a lab coat should protect dental staff. Protect from unnecessary exposure to etchant.
8.2.1.5	Other controls	Emergency eye wash fountain should be available. Protect soft tissue from etchant during intraoral procedures. Wash hands after use.
8.2.2	Environmental exposure controls	Avoid releasing large quantities of phosphoric acid into the environment as phosphoric acid may affect pH of water or soil.

9.0	Physical and Chemical Properties	
9.1	Appearance / Color	
9.1.1	Color / Physical state	Medium blue, thixotropic gel.
9.1.2	Odor	Mild, characteristic
9.2	Important health, safety and environmental information	
9.2.1	pH	pH 1
9.2.2	Boiling point	135°C
9.2.3	Flash point	Not combustible
9.2.4	Flammability (solid, gas)	Not combustible
9.2.5	Explosive properties	Not applicable
9.2.6	Oxidizing properties	Not determined
9.2.7	Vapor pressure	2.933 mbar / Id: C
9.2.8	Specific gravity	1.380
9.2.9	Solubility in water	Complete
9.2.10	Partition coefficient	Not determined
9.2.11	Viscosity	Not determined
9.2.12	Vapor density	Not determined
9.2.13	Evaporation rate	Not determined

10.0	Stability and reactivity	
10.1	Conditions to avoid	Not applicable
10.2	Materials to avoid	Avoid contact with materials such as sulfides and sulfites that could release toxic gases. Avoid strong alkalies because high heat of reaction can generate steam. Avoid most metals because phosphoric acid can react to liberate hydrogen, a flammable gas.
10.3	Hazardous decomposition products	Avoid contact with materials such as sulfides and sulfites that could release toxic gases. Avoid strong alkalies because high heat of reaction can generate steam. Avoid most metals because phosphoric acid can react to liberate hydrogen, a flammable gas.
10.4	Further information	Stable under normal conditions of use and storage.

11.0	Toxicological information	
11.1	Acute toxicity	Not toxic
11.2	Irritation and corrosiveness	Corrosive. May cause burns or irritation to eyes, skin, mouth, throat or gastrointestinal tract. Not expected to be an inhalation hazard unless product is misted or heated at high temperatures.
11.3	Sensitization	Not applicable.
11.4	Sub-acute, sub-chronic and prolonged toxicity	None known.
11.5	Carcinogenicity, Mutagenicity, Reproductive Toxicity	Not considered a carcinogen, mutagen, teratogen or reproductive toxin.
11.6	Empirical data	Not available
11.7	Clinical Experience	Using phosphoric acid etchants to prepare teeth for bonding procedures is a well-established (more than 20 years), industry-accepted, dental procedure. Etching enamel with phosphoric acid is safe and effective treatment in the hands of a dental professional.

12.0	Ecological Information	
12.1	Ecotoxicity	No specific information available. Use according to good working practices. Avoid release into the environment as it may cause pH variation.

13.0	Disposal Considerations	
13.1	Regulations	Follow all local and national government regulations in disposing material or contaminated packaging.

14.0	Transport Information	
14.1	UN Number	1805
14.2	Technical name	Phosphoric acid
14.3	Packing group	Packing Group III
14.4	IATA class	Class 8, Corrosive

15.0	Regulatory Information	
15.1	EU	Class IIa medical device under MDD 93/42/EEC.
15.2	US FDA	Class II medical device.
15.3	Health Canada	Class II medical device.

16.0	Other information	
16.1	List of relevant R phrases	R 34: Causes burns R 36 / 37 / 38: Irritating to eyes, respiratory system and skin.
16.2	Hazard Statements	H314: Causes severe skin burns and eye damage. H319: Causes serious eye irritation.
16.3	Precautionary Statements	P264: Wash hands thoroughly after handling. P280: Wear protective gloves, clothing and eye/face protection. P301 + P330 + P331: If swallowed, rinse mouth. Do NOT induce vomiting. P303 + P361 + P353: If on skin (or hair), remove all contaminated clothing. Rinse skin with water. P363: Wash contaminated clothing before reuse. P310: Immediately call a Poison Center or doctor/physician. P305 + P351 + P338: If in eyes, rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing until pH of tears is 7.
16.4	Restrictions on use	Dental etchants are to be sold to and used by dental professionals only.
16.5	Further information	The information presented herein is believed to be factual as it has been derived from the works of persons believed to be qualified experts. However, nothing contained in this information is to be taken as a warranty or representation for which La Maison Dentaire bears legal responsibility. The user should review any recommendations in the specific context of the intended use to determine whether they are appropriate.
16.6	Sources of key data	National Institute for Occupational Safety (NIOSH) Occupational Safety and Health Administration (OSHA) Eur-Lex European Union Law: Regulation (EC) No. 1272/2008 (CLP) and Regulation (EC) No. 1907/2006 (REACH). Guidance on the compilation of safety data sheets. Version 1.1; December 2011. European Chemicals Agency
16.7	Information which has been added, deleted or revised.	This Safety Data Sheet has been revised to meet the requirements of the GHS SDS format and Regulations (EC) No. 1272/2008 (CLP) and (EC) No. 1907/2006 (REACH). Specifically, Sections 2.1, 2.2, 3.2, 16.2, 16.3 have been modified.

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