

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 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 / 1d: 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 Regulations	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.

Blue Etch™
Dental Etching Gel

Blue Etch™
Dental Etching Gel
38% H₃PO₄

FOR USE BY DENTAL PROFESSIONALS ONLY



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.

Instructions for filling 3 mL empty syringes

1. The bulk syringe should be used only for filling empty 3 mL syringes .
2. Remove caps from bulk syringe and from empty 3 mL syringe.
3. If necessary, depress plunger of bulk syringe so that the etch gel is at the luer tip.
4. Make sure the plunger on the 3 mL syringe is pushed all the way into the barrel.
5. Securely engage luer lock end of the 3 mL syringe into the luer adapter on the bulk syringe.
6. Carefully pull back on the plunger of the 3 mL syringe to fill the syringe.
7. Disengage the 3 mL syringe from the adapter. Place caps on the syringes.

DIRECTIONS FOR USE

1. Prepare tooth and cleanse the enamel surface to be etched with a slurry of pumice or non-oil containing prophy 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.
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.
6. Re-cap syringe immediately after use.

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 Mordançage à 38 % d'acide Phosphorique
Pour mordançer: La Dentine L'Email 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.
Instructions pour remplir les seringues vides de 3 mL
1. Utiliser la seringue de 25 mL seulement pour remplir les seringues vides de 3 mL.
2. Retirer les capuchons de la seringue de 25 mL et de la seringue vide de 3 mL.
3. Si nécessaire, appuyer sur le piston de la grande seringue afin que le gel de mordançage est à la pointe du luer.
4. Le piston de la petite seringue vide doit être poussé jusqu'au fond.
5. Fixer fermement la petite seringue sur la grande seringue (connexion Luer Lock).
6. Tirer avec attention le piston de la petite seringue pour la remplir.
7. Séparer les deux seringues et remettre le capuchon sur toutes les deux.
MODE D'EMPLOI
1. Préparer la dent à mordançer et nettoyer l'émail avec une pâte prophylactique sans

- huile ou une solution contenant de la ponce. Rincer abondamment et sécher
2. Dans la mesure du possible, appliquer BLUE ETCH d'abord sur l'émail puis sur la dentine. Laisser agir sur la dentine 15 secondes maximum. Il est recommandé d'attendre 20 secondes pour l'émail.
 3. Rincer BLUE ETCH abondamment à l'eau. Ne pas contaminer la surface mordancée par d'autres fluides comme la salive etc.
 4. Laisser la surface légèrement humide ou la sécher avec de l'air propre, suivant les instructions du produit de collage utilisé.
 5. Laisser la surface légèrement humide ou la sécher avec l'air propre, suivant des 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.
PRÉCAUTION 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

Aetzgel 38% Phosphorsäure
Zur Ätzung von 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.
Anleitung zum Befüllen der leeren 3 mL Spritzen
1. Benutzen Sie die 25 mL Spritze nur zum Befüllen der leeren 3 mL Spritzen.
2. Verschlusskappe von der grossen Spritze und der leeren 3 mL Spritze entfernen.
3. Falls erforderlich, drücken Sie den Kolben der grossen Spritze bis das Ätzgel an der Luer-Spitze ist.
4. Beachten Sie, dass der Spritzenkolben der 3 mL Spritze ganz nach unten geschoben ist.
5. Befestigen Sie den Luer Lock Verschluss der kleinen Spritze mit der 25 mL Nachfüllspritze.
6. Ziehen Sie vorsichtig den Kolben der kleinen Spritze, um diese zu befüllen.
7. Trennen Sie die beiden Spritzen und setzen Sie auf jede Spritze die Verschlusskappe.

GEBRAUCHSANWEISUNG

1. Schmelzoberfläche reinigen. Verwenden Sie keine ölhaltigen Polierpasten. Anschließend gut spülen und trocknen.
2. Schrauben Sie die Kanüle auf die BLUE ETCH Spritze
3. Applizieren Sie BLUE ETCH direkt auf die zu ätzende Zahnoberfläche. Lassen Sie BLUE ETCH 20 Sekunden einwirken.
4. Spülen Sie BLUE ETCH mit reichlich Wasser weg und trocknen Sie anschliessend.
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, wiederholen Sie Vorgang 3 und 4!
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

38% acido fosforico
Per la mordenzatura di dentina, smalto e cemento vetroionomero.
Blue Etch è un gel tissotropico d'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 per riempire le siringhe vuote da 3 mL
1. Utilizzare la siringa da 25 mL solo per riempire le siringhe vuote da 3 mL.
2. Togliere i coperchi della siringa da 25 mL e della siringa vuota da 3 mL.
3. Se necessario, spingere leggermente il pistone della siringa grande in modo che la massa del gel è sulla punta luer.
4. Il pistone della siringa piccola vuota deve essere spinto fino in fondo.
5. Fissare la siringa piccola su quella grande (connessione luer lock).
6. Aspirare con cautela tramite il pistone della siringa piccola per poterla riempire.
7. Separare le due siringhe e rimettere i coperchi sulle stesse.

APPLICAZIONE CONTROLLATA

1. Preparare il dente e pulire la superficie dello smalto da mordenzare con poco pomice oppure con una pasta "prophy". Sciacquare e asciugare bene.

2. Attaccare bene il bocchino d'applicazione alla siringa; iniziare a far colare il gel su un tampone - non nella bocca del paziente. Non premere il puntello col pollice. Per una applicazione sicura e controllata, far riposare il puntello nel palmo della mano e tirare la siringa con il pollice, indice e dito medio.
3. Si raccomanda un tempo di mordenzatura di 15-20 secondi per lo smalto, e di 15 secondi per la dentina. Idealmente applicare BLUE ETCH prima sullo smalto e dopo sulla dentina, dove rimane per 15 secondi.
4. Sciacquare BLUE ETCH con abbondante acqua, senza recare disturbi alla superficie.
5. Secondo le istruzioni per l'uso del sistema di adesivi che viene usato, tenere la superficie umida oppure essicare la superficie con aria pulita, non contaminata.
6. Chiudere la siringa subito dopo l'uso.

ATTENZIONE: Normalmente, lo smalto mordenzato ha un aspetto bianco creta; 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 morbido, sciacquare immediatamente con abbondante acqua.

ATTENZIONE: le siringhe multi-dose devono essere confezionate in un nuovo imballaggio protettivo per ogni paziente o pulite e disinfettate dopo ogni uso, se appropriato.

Rev. 05/2018

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.		