

 <p>U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Antimicrobials Division (7510C) 1200 Pennsylvania Avenue, N.W. Washington, D.C. 20460</p> <p>NOTICE OF PESTICIDE: <u> X </u> Registration <u> </u> Re-registration</p> <p>(under FIFRA, as amended)</p>	EPA Reg. Number: 63761-6	Date of Issuance: MAY 12 2005
	Term of Issuance: CONDITIONAL	
	Name of Pesticide Product: Sterilex Ultra Liquid B Solution 2	
Name and Address of Registrant (include ZIP code): Sterilex Corporation 11409 Cronhill Drive Owings Mills, MD 21117		
<p>Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.</p> <p>On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended.</p> <p>Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.</p> <p>This product is conditionally registered in accordance with FIFRA Section 3(c)(7)(A) provided that you:</p> <ol style="list-style-type: none"> 1. Submit and/or cite all data required for registration of your product under FIFRA Section 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA Section 4. 2. Make the following labeling changes: <ol style="list-style-type: none"> a. Revise the EPA Registration Number to read "EPA Reg. No. 63761-6". 3. The Agency has not developed a performance standard for dental unit waterlines. Once a method and performance standard has been established, you will be required to submit appropriate data to the Agency to maintain your product's registration. 		
Signature of Approving Official: Velma Noble, Product Manager, Team 31, Regulatory Management Branch I, Antimicrobials Division	<p><i>Tracy Lentz for</i></p> <p>Date: MAY 12 2005</p>	

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4. Submit three copies of a final printed label within 90 days.

This product can not be used alone. It must be used with "Sterilex Ultra Liquid B Solution 1" (EPA Reg. No. 63761-9). If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA Section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A copy of the label stamped "Accepted" is enclosed for your records.

If you have any questions regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,



for

Velma Noble
Product Manager 31
Regulatory Management Branch 1
Antimicrobial Division(7510C)

Enclosure: Acute Toxicology Data Evaluation
Stamped Accepted Label



Important Notice:

Before using Sterilex Ultra Liquid B Solution 2 please read the following information.

1. This product is to be used in conjunction with regular testing of dental unit water.
2. The manufacturer of the dental unit should be consulted before use of this product about compatibility of Sterilex Ultra Liquid B Solution 2 with the dental unit.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Always Use Sterilex Ultra Liquid B Solution 2 with Sterilex Ultra Liquid B Solution 1

1. Initial Start-Up Treatment: Treat the Dental Unit Water Lines (DUWL) for three consecutive nights starting on Monday.
2. Routine Treatment: Treat DUWL one night/week (Monday-Thursday recommended) after Initial Start-up treatment.
3. If two or more weekly treatments are skipped, repeat initial start-up treatment.

How To Apply Sterilex Ultra Liquid B Solutions 1 and 2:

1. Add one bottle (3 ounces) of Sterilex Ultra Liquid B Solution 1 and one bottle (3 ounces) of Sterilex Ultra Liquid B Solution 2 in a measuring cup or other empty container and stir. Pour appropriate amount of the combined mixture into an empty external dental unit water bottle. Do not use PET bottles (See note below). After Sterilex Ultra Liquid B Solution 1 and Sterilex Ultra Liquid B Solution 2 have been mixed together use within 24 hours.

2. Run Sterilex Ultra Liquid B mixture through the system until the pink mixture appears at the end of the Air/Water syringes and handpiece lines. Always remove the handpiece. It may be advisable to remove coupler depending on the type of coupler. Contact manufacturer for specific recommendations.

4. Allow the Sterilex Liquid Ultra mixture to sit in the unit overnight. Place the ends of water lines into a sink or cuspidor in case any pink mixture drips overnight).

5. At the beginning of the next workday, discard any remaining Sterilex Liquid Ultra mixture. Rinse the external water bottle with water.

6. Fill the external water bottle with water. Flush each line (Air/Water syringe, handpiece lines) until the bottle is empty.

Sterilex Ultra Liquid B Solution 2

**(This is a 2 part liquid product)
Always Use With
Sterilex Ultra Liquid B Solution 1**

- Removes* biofilm from dental unit water lines
- Prevents and suppresses formation of biofilm in dental unit water lines
- Kills biofilm bacteria
- Maintains dental unit water line effluent water <500 cfu/ml **

Note: Do Not Use Thin Walled Polyethylene Terephthalate (PET) Bottles. We Recommend Either A High Density Polyethylene Bottle With A Minimum Thickness Of 0.08 Inches Or A High/Low Density Polyethylene Blend With A Minimum Thickness Of 0.14 Inches.

* Laboratory studies have shown >90% removal
 ** Control of bacterial contamination in the DUWL is affected by the quality of incoming water. Sterile water is recommended by the Organization for Safety and Asepsis Procedures (OSAP).

Active Ingredients:

n-Alkyl(C ₁₂ 68%, C ₁₄ 32%) ethylbenzylammonium chloride	0.5%
n-Alkyl(C ₁₄ 60%, C ₁₆ 30%, C ₁₂ 5%, C ₁₈ 5%) dimethyl benzyl ammonium chloride	0.5%
Other Ingredients	99.0%
TOTAL	100.0%

KEEP OUT OF THE REACH OF CHILDREN

CAUTION

(See side panel for additional precautionary and first aid statements)

**STERILEX CORPORATION
11409 Cronhill Drive
Owings Mills, MD 21117**

Phone: 1-800-511-1659 Fax: 410-581-8864

NET WEIGHT _____ EPA REG. NO. 43761-A
 LOT NO. _____ EPA EST. NO. 73516-N 1

PRECAUTIONARY STATEMENTS

Hazards To Humans and Domestic Animals.
CAUTION. Causes eye irritation. Do not get in eyes, on skin or on clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, egg whites, gelatin, or if these are not available, drink large quantities of water. Avoid alcohol.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by improper storage or disposal.

STORAGE: Keep product in closed original container when not in use. Store in a cool, dry area away from potential sources of heat, open flames, sunlight or other chemicals. DO NOT store above 30°C (or 86°F).

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Containers less than or equal to 1 gallon: Securely wrap original container in several layers of newspaper and discard in trash. Containers greater than 1 gallon: Triple-rinse then dispose of in sanitary landfill or by other approved state or local procedures. Made in USA

RECEIVED
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