



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510C)
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

EPA Reg. Number:
63761-9

Date of Issuance:
MAY 12 2005

NOTICE OF PESTICIDE:

- Registration
- Re-registration

(under FIFRA, as amended)

Term of Issuance:
CONDITIONAL

Name of Pesticide Product:
Sterilex Ultra Liquid B
Solution I

Name and Address of Registrant (include ZIP code):

Sterilex Corporation
11409 Cronhill Drive
Owings Mills, MD 21117

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.

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.

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.

This product is conditionally registered in accordance with FIFRA Section 3(c)(7)(A) provided that you:

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. Submit final printed labels (3 copies) within 90 days which make the following changes:
 - A. Revise the EPA Registration Number to read, "EPA Reg. No. 63761-9".

Signature of Approving Official:

Marshall Swindell,
Product Manager, Team 33,
Regulatory Management Branch I,
Antimicrobials Division

Date:

MAY 12 2005

B. Change the "Container Disposal" statement to the following:

"For containers one gallon or less, securely wrap original container in several layers of newspaper and discard in trash.

"For containers more than one gallon, triple-rinse, then dispose of in a sanitary landfill or by other approved state or local procedures".

C. Change the sub-title "Storage" to "Pesticide Storage".

3. Before 6/1/06, you must submit the required one year storage stability study (830-6317) and corrosion characteristics study (830.6320) conducted under GLP 5/1/06. Only a 30 day study was submitted.

4. Before 6/1/06, you must submit Part B (Series 63) physical-chemical characteristics to be conducted under GLP. These data were submitted but were not conducted under GLP.

This product can not be used alone. It must always be used with "Sterilex Ultra Liquid B Solution 2" (EPA Reg. No. 63761-6). 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.

Furthermore, the Agency has not developed a performance standard for dental unit water lines. Once a method and performance standard have been established, you will be required to submit appropriate data to EPA to maintain your product's registration.

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

If you have any questions concerning this letter, please contact myself at 703-308-6341, or Tony Kish at (703) 308-9443.

Sincerely,



Marshall Swindell
Product Manager 33
Regulatory Management Branch 1
Antimicrobial Division(7510C)

Enclosure

Importance: Before using Sterilex Ultra Liquid B Solution 1 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 1 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 1 with Sterilex Ultra Liquid B Solution 2

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.
3. 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).
4. At the beginning of the next workday, discard any remaining Sterilex Liquid Ultra mixture. Rinse the external water bottle with water.
5. 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 1

(This is a 2 part liquid product)

Always Use With

Sterilex Ultra Liquid B Solution 2

- 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 Ingredient:		
Hydrogen Peroxide.....	1.05%	
Other Ingredients.....	98.95%	
	TOTAL	100.00%

KEEP OUT OF THE REACH OF CHILDREN

DANGER

(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. 63761- Q
 LOT NO. _____ EPA EST. NO. 73516-MD-01
 Made in USA

PRECAUTIONARY STATEMENT

Hazards To Humans and Domestic Animals.

DANGER. Corrosive. Causes irreversible eye damage. Harmful if absorbed through skin. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses) and rubber gloves when handling. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

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.

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: Triple-rinse then dispose of in sanitary landfill or by other approved state or local procedures.

ACCEPTED
 with **COMMENTS**
 in EPA Letter Dated:

MAY 12 2005

Under the Federal Insecticide,
 Fungicide, and Rodenticide Act as
 amended, for the pesticide,
 registered under EPA Reg. No.

63761-9

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