

63761-6

08/31/2006

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AUG 31 2006

Dr. April Zambelli-Weiner
Sterilex Corporation
11409 Cronhill Drive, Suite L
Owings Mills, MD 21117

Subject: Sterilex Ultra Liquid B Solution 2
EPA Registration No. 63761-6
Notification Date: July 31, 2006
EPA Receipt Date: August 9, 2006

Dear Dr. Weiner,

The following amendment submitted in connection with registration under FIFRA, as amended, is acceptable with the following condition.

- Incorporated label changes from Agency letter dated 7/29/05
- Added Acute Oral Precautionary Statements

Condition

Revise the label as follows:

The Precautionary Statements must be reorganized to read as follows:

CAUTION. Causes moderate eye irritation and harmful if swallowed. Avoid contact with eyes, skin, or clothing. Do not get in eyes, skin, or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

General Comments

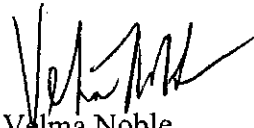
A stamped copy of the label accepted with conditions is enclosed. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Jacqueline McFarlane at (703) 308-6416.

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Sincerely,



Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510C)

Enclosure: Stamped Label

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

Important Notice:

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

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

1. Add one bottle (3 ounces) of Sterilex Liquid Ultra Solution 1 and one bottle (3 ounces) of Sterilex Liquid Ultra 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 Liquid Ultra Solution 1 and Sterilex Liquid Ultra Solution 2 have been mixed together use within 24 hours.
2. Run Sterilex Liquid Ultra 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
Solutions for Biofilm.

Sterilex Liquid Ultra Solution 2

(This is a 2 part liquid product)

Always Use With

Sterilex Liquid Ultra Solution 1

Ready to Use – Do Not Add Water

Think Pink Once A Week®

- 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

Active Ingredients:

n-Alkyl(C ₁₂ 68%, C ₁₄ 32%) dimethyl ethylbenzyl ammonium 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

(For containers less than or equal to 1 gallon: see package insert or hang tag prior to use for use instructions, first aid, and precautionary information.)

STERILEX CORPORATION

11409 Cronhill Drive

Owings Mills, MD 21117

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

www.sterilex.com

NET WEIGHT _____ EPA REG. NO. 63761-6
LOT NO. _____ EPA EST. NO. 73516-MD-01

PRECAUTIONARY STATEMENTS

Hazards To Humans and Domestic Animals.

CAUTION. Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. 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 06/06 AZW

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