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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AUG 23 2005

Sterilex Corporation
11409 Cronhill Drive, Suite L
Owings Mill, MD 21117

Subject: Sterilex Ultra Liquid B Solution I
EPA Registration No. 63761-9
Your Amendment Dated July 1, 2005

The amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

- Minor Confidential Statement of Formula Change
- Minor Label Change

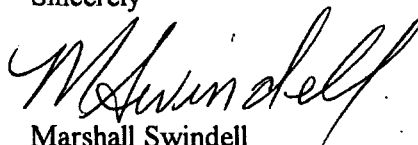
General Comments

The Alternate Confidential Statement of Formula dated June 30, 2005 is in consistent with the label declaration and is acceptable.

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

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely



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

Enclosure

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

Important Notice:

Before using Sterilex Liquid Ultra 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 Liquid Ultra 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 Liquid Ultra Solution 1 with Sterilex Liquid Ultra 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 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 Liquid Ultra Solution 1

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

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

KEEP OUT OF THE REACH OF CHILDREN

DANGER

(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. 63761-9

LOT NO. _____ EPA EST. NO. 73516-MD-01

Made in USA

PRECAUTIONARY STATEMENTS

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:

AUG 23 2005

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

63761-9

JFC



STERILEX LIQUID ULTRA

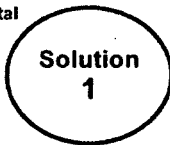
SOLUTION 1

This is a 2 part liquid product.

Always Use With Sterilex Liquid Ultra Solution 2.

Ready to use - do not add water

- 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



Think Pink Once A Week

* Laboratory studies have shown >90% removal

Sterilex Corporation Owings Mills, MD 21117 800-611-1659

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