

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUL 1 2005

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

Subject: Sterilex Ultra Liquid B Solution 2
EPA Registration No. 63761-6
Notification Date: June 9, 2005
EPA Receipt Date: June 14, 2005

Dear Dr. Weiner,

This letter acknowledges receipt of the following notification under FIFRA section 3(c)9 and PR Notice 91-2.

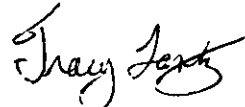
- Addition of Non-Pesticidal Claim

General Comments

Based on a review of the submitted materials, your notification to add the claims, "Think Pink Once a Week" and "Ready to Use-Do Not Add Water," is acceptable and apart of the records on file.

Should 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 I
Antimicrobials Division (7510C)

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060

 EPA	United States Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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Application for Pesticide - Section I

1. Company/Product Number 63761-6	2. EPA Product Manager Velma Noble	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Sterilex Ultra Liquid B Solution 2	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) Sterilex Corporation 11409 Cronhill Drive, Suite L Owings Mills, MD 21117		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to:
<input type="checkbox"/> Check if this is a new address		

Section - II

<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application <input type="checkbox"/> Other - Explain below
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Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of minor packaging and related label changes per PR Notice 98-10 consisting of (1) the addition of "Think Pink Once A Week" to a label and (2) "Ready to Use - Do Not Add Water" to the label.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Package wgt No. per container	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 5, 30 and 55 gallons	
5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product		Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)

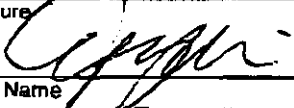
Name April Zambelli-Weiner	Title Senior Research Scientist, Sterilex Corporation	Telephone No. (Include Area Code) 410-581-8860
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Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received

(Stamped)

2. Signature 	3. Title Senior Research Scientist, Sterilex Corporation	
4. Typed Name April Zambelli-Weiner	5. Date July 1, 2005	



STERILEX®

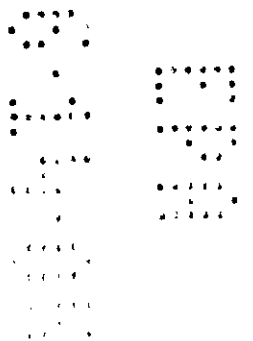
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09 June 2005

Document Processing Desk [NOTIFICATION]
Office of Pesticide Programs (7504C)
US Environmental Protection Agency
Room 266A, Crystal Mall 2
1801 Bell Street South
Arlington, VA 22202

ATTENTION: **Velma Noble**
Product Manager, Team 31

SUBJECT: **Sterilex Corporation**
Sterilex Ultra Liquid B Solution 2
EPA Registration Number 63761-6
Notification of minor label changes



Dear Ms. Noble:

We are submitting a notification for Sterilex Ultra Liquid B Solution 2. The sole purpose of this notification is to inform the agency of the following minor label changes to the above referenced product:

1. "Think Pink Once A Week" has been added to the label
2. "Ready to Use – Do Not Add Water" has been added to the label

Please find enclosed a copy of the revised label with the above changes highlighted in yellow.

If you have any questions, please contact me at 410-581-8860 or by email at april@sterilex.com.

Sincerely,

April Zambelli-Weiner, Ph.D.
Senior Research Scientist
Sterilex Corporation

NOTIFICATION
Date Reviewed: 8/13/02
Reviewed By: [Signature]

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

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-Alky(C ₁₁ 68%, C ₁₄ 32%) ethylbenzylammonium chloride	0.5%
n-Alky(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

www.sterilex.com

NET WEIGHT _____ EPA REG. NO. 761-6
LC _____ EPA EST. NO. 73516-ML

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 rinseate 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

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