

63761-6

10f8

APR - 9 2010

Wendy McCombie
Agent for Sterilex Corporation
Lewis and Harrison
122 C Street, N.W., Suite 740
Washington, D.C. 20001

SUBJECT: Ultra Kleen Solution 1
EPA Registration Number: 63761-3

Sterilex Liquid Ultra Solution 2
EPA Registration Number: 63761-6

Applications Dated: March 9, 2010
Receipt Dates: March 10, 2010

Dear Ms. McCombie:

This letter acknowledges receipt of the notification identified above submitted under the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended and PR Notice 98-10 and 2007-4.

- Revise Storage and Disposal Statements


Based on a review of the submitted information, this notification is acceptable. Your proposed label language is in agreement with the Agency Guidance for Container Disposal. This notification will be made part of the record for this file.

CONCURRENCES							
SYMBOL	7510P						
SURNAME	S. Jones						
DATE	4/9/10						

General Comments

Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,



for

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

7510P:T.Lantz:4/9/2010:63761-3 -6 acceptable notification

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

3098



EPA

United States
Environmental Protection Agency
Washington, DC 20460

- Registration
- Amendment
- Other NOTIFICATION

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 63761-6	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Sterilex Liquid Ultra Solution 2	PM# Team 31	
5. Name and Address of Applicant (Include ZIP Code) Sterilex Corporation 11409 Cronhill Drive Suite L Owings Mills, MD 21117 <u>PLEASE SEND ALL CORRESPONDENCE TO</u> <u>"CONTACT POINT" LISTED BELOW</u> <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

APPLICATION FOR NOTIFICATION: MINOR LABEL CHANGES

Notification of Minor Label Changes in Accordance With PR Notices 1998-10 and 2007-4: See Cover Letter

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 95-2 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be the subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Signature: _____ Date: March 9, 2010

THIS SUBMISSION IS NOT SUBJECT TO PRIA FEES

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
*Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container	<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. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product	
6. 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 Mark Wozniak (m.wozniak@sterilex.com)	Title Senior Scientist/ R&D Manager	Telephone No. (Include Area Code) 410-581-8860
2. Signature 		6. Date Application Received (Stamped)
3. Title Agent for Sterilex Corporation		
4. Typed Name Wendy A. McCombie		
5. Date March 9, 2010		

LEWIS & HARRISON

Consultants in Government Affairs

122 C Street, N.W., Suite 740
Washington, D.C. 20001
telephone 202.393.3903
fax 202.393.3906

direct 202.393.3903 ext. 11
wmccombie@lewisharrison.com

March 9, 2010

HAND DELIVERED

Document Processing Desk [NOTIFY]
Office of Pesticide Programs (7504P)
U. S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

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

**SUBJECT: Sterilex Corporation
Sterilex Liquid Ultra Solution 2 (EPA Reg. No. 63761-6)
Notification of Minor Label Changes per PR Notices 1998-10 and 2007-4
This Submission is NOT Subject to PRIA fees**

Dear Ms. Noble:

On behalf Sterilex Corporation, I am submitting a Notification application to make minor changes to the product label for **Sterilex Liquid Ultra Solution 2 (EPA Reg. No. 63761-6)**. The changes are as follows:

- 1) Update the "Storage and Disposal" language in accordance with the requirements and provisions of PR Notice 2007-4; and,
- 2) Add the appropriate container disposal language as indicated in the EPA letter dated January 28, 2010 regarding a similar Notification for EPA Reg. No. 63761-3 (*copy attached*).

No other changes have been made, so the label is otherwise identical to that accepted by EPA on February 27, 2007.

Please note that Sterilex would like to retain the option to omit "or pressure rinse" and associated directions for pressure rinsing from the labels for the smaller size range of containers. Therefore, the phrase "or pressure rinse" has been placed in brackets. The pressure rinse directions have also been placed in brackets for each range of container sizes following the triple rinse instructions associated with the appropriate range. A "Note To Reviewer" to this effect has been indicated on the Master label for informational purposes.


In addition to the aforementioned attachment, please find enclosed the following documents in support of this label Notification:

- 1) Application for Pesticide Notification; and;

- 2) Three (3) copies of the proposed product Master label, with changes highlighted and marked.

Thank you in advance for your assistance with this submission.

Sincerely,



Wendy A. McCombie
Agent for,
Sterilex Corporation

cc: Mark Wozniak, Sterilex Corporation

Handwritten marks resembling small 'u' or 'j' characters arranged in a grid-like pattern.

60f8



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.....	<u>99.0%</u>
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

Made in the USA

EPA REG. NO. 63761-6
EPA EST. NO. 73516-MD-01

NET CONTENTS _____
LOT NO. _____

Important Notice:

Before using Sterilex Liquid Ultra 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 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.

PRECAUTIONARY STATEMENTS

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

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 poison control center or doctor immediately for treatment advice. 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.

PESTICIDE 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: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. If rinsate cannot be used, follow pesticide disposal instructions. If not triple rinsed these containers are acute hazardous wastes and must be disposed in accordance with local, state and federal regulations. Triple rinse [or pressure rinse] container (or equivalent) promptly after emptying.

[(NOTE TO REVIEWER: The following language is for nonrefillable containers having a capacity of 5 gallons or less) Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.]

[(NOTE TO REVIEWER: The following language is optional for nonrefillable containers having a capacity of 5 gallons or less when "or pressure rinse" appears in the above Container Disposal statement)
Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip.]

[(NOTE TO REVIEWER: The following language is for nonrefillable containers having a capacity greater than 5 gallons) Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.]

[(NOTE TO REVIEWER: The following language is optional for nonrefillable containers having a capacity greater than 5 gallons when "or pressure rinse" appears in the above Container Disposal statement)
Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip.]