

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

JAN - 9 2008

Judy Cornman
Regulatory Specialist
Sterilex Corporation
11409 Cronhill Drive Ste. L
Owings Mills, Md 21117

Subject: Sterilex Ultra-Kleen™ Solution 1
EPA Reg. No. 63761-3
Application Dated: December 13, 2007
Receipt Date: December 13, 2007

Dear Ms. Cornman,

The following notification submitted in connection with registration under the provisions of PR Notice 98-10, Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c) 9 is acceptable.

Proposed Notification

- Add EPA Establishment Numbers.

Comments

Based on a review of the material submitted, the following comments apply:
This application for notification to add EPA Establishment Numbers is acceptable.
A copy has been placed in our records for future reference.

Should you have any questions or comments concerning this letter, please contact Velma Noble at (703) 308-6233.

Sincerely,

Velma Noble
Product Manager (31)
Regulatory Management Branch1
Antimicrobial Division (7510P)

CONCURRENCES

SYMBOL	7510P						
JRNAME							
DATE	1/9/08						

284



EPA

United States
Environmental Protection Agency
 Washington, DC 20460

- Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 63761-3	2. EPA Product Manager Velma Noble	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Sterilex Ultra-Kleen Solution 1	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:
<p><u>NOTE: PLEASE SEND ALL CORRESPONDENCE TO "CONTACT POINT" LISTED BELOW</u></p> <input type="checkbox"/> Check if this is a new address		

Section - II

- Amendment - Explain below. Final printed labels in response to Agency letter dated _____
- Resubmission in response to Agency letter dated _____ "Me Too" Application
- Notification - Explain below. Other - Explain below

Explanation: Use additional page(s) if necessary. (For section I and Section II.)
 We are submitting a Notification regarding one of our registered products, **Sterilex Ultra-Kleen Solution 1 (63761-3)**. The purpose of the notification is to inform the agency of the addition of Multiple EPA Establishment Numbers to that product's label.

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	If "Yes" Unit Packaging wgt. No. per container		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)
*Certification must be submitted					
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"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____					

Section - IV

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

Name Judy Cornman	Title Regulatory Specialist	Telephone No. (Include Area Code) 410.581.8860
-----------------------------	---------------------------------------	--

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.

2. Signature	3. Title Regulatory Specialist	6. Date Application Received
4. Typed Name Judy Cornman	5. Date December 13, 2007	



STERILEX®

3 8 4

12/13/2007

Document Processing Desk
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

ATTENTION: Velma Noble
Product Manager, Team 31

SUBJECT: *Sterilex Corporation*
Sterilex Ultra-Kleen Solution 1
EPA Registration Number 63761-3
Notification to add Multiple EPA Establishment Numbers

Dear Ms. Noble:

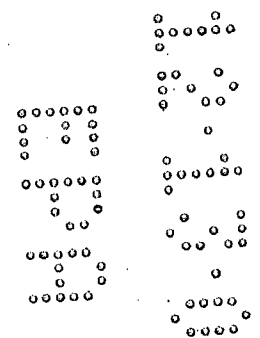
We are submitting a notification for **Sterilex Ultra-Kleen Solution 1**; the sole purpose of this notification is to inform the agency of the addition of Multiple Environmental Protection Agency (EPA) Establishment Numbers to the above referenced product label. At each facility the appropriate establishment number will be clearly identified with a check mark. Please find enclosed,

1. An EPA Application for Pesticide (8570-1)
2. A copy of the revised label for **Sterilex Ultra-Kleen Solution 1(63761-3)**

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

Sincerely,

Judy Cornman
Regulatory Specialist
Sterilex Corporation





Penetrates and Removes Biofilm and Other Organic Contaminants. Use as a Bactericide, Slimicide, Mildewstat, and Algicide in:

- Recirculating Cooling Water Systems
- Brewery Pasteurizing Systems
- Air Washers
- Dye Machines
- Water-Jet Looms
- Tanks, Piping and Industrial Equipment used to store and convey Industrial Process Water or Aqueous Mixtures not related to food processing
- Deionized Water Supply Systems not used in food processing or for human drinking water or dental lines
- Drains and Filter Traps
- Chair Side Evacuator Traps and Pump Filter Traps

May be used with **Ultra-Kleen Solution 2** to adjust pH, to inhibit corrosion and to enhance cleaning. Please consult directions for use for specific recommendations.

Active Ingredients:

n-Alkyl(C ₁₄ 60%, C ₁₆ 30%, C ₁₂ 5%, C ₁₈ 5%)	
dimethylbenzylammonium chloride.....	3.00%
n- Alkyl(C ₁₂ 68%, C ₁₄ 32%)	
dimethylethylbenzylammonium chloride.....	3.00%
Inert Ingredients.....	90.00%
TOTAL	100.00%

Controls Mold and Mildew

KEEP OUT OF REACH OF CHILDREN

DANGER

See Side Panel for Additional Precautionary Statements and First Aid

EPA Reg. No. 63761-2
 Reorder Number: 203E
 Net Weight _____
 Lot No _____ 11/07 AZW/JC

Ultra-Kleen™ Solution 1

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

RECIRCULATING COOLING WATER SYSTEMS, INCLUDING COOLING TOWERS, EVAPORATIVE CONDENSERS AND BREWERY PASTEURIZERS. Effectively removes and controls biofilm and other organic contaminants in commercial and industrial cooling towers; influent water systems such as flow-through filters; and heat exchange water systems.

DOSAGE RATES. Initial Dose for badly fouled systems: Add 1 to 4 gal. Ultra-Kleen Solution 1 per 1000 gallons of water in the system. If cleaning is desired or if the pH of the system is below 8, add simultaneously Ultra-Kleen Solution 2 at the rate of 1 to 3 times the volume of Ultra-Kleen Solution 1. Repeat until control is evident.

Routine Dose, when microbial control is evident: Subsequent slug additions of 28 to 64 fl. oz. Ultra-Kleen Solution 1 per 1000 gallons of water (and if cleaning is desired or the pH of the system is below 8, Ultra-Kleen Solution 2 at the rate of 1 to 3 times the volume of Ultra-Kleen Solution 1) should be employed every 2 to 5 days or as needed. The frequency of addition depends on the relative amount of bleedoff, the quality of the makeup water and rate of inflow of airborne or other contaminants. Slug additions should be made in the sump of water cooling towers.

AIR WASHERS. For use only in industrial air washing systems that maintain effective mist eliminating components. Effectively removes and controls biofilm and other organic contaminants in Industrial Water Scrubbing Systems.

DOSAGE RATES. Initial Dose for badly fouled systems: Add 3 to 16 gal. of Ultra-Kleen Solution 1 per 1000 gallons of water in the system. If cleaning is desired or if the pH of the system is below 8, add simultaneously Ultra-Kleen Solution 2 at the rate of 1 to 3 times the volume of Ultra-Kleen Solution 1. If necessary, apply a solution containing 0.4 to 2 fl. oz. Ultra-Kleen Solution 1 (and if cleaning is desired or the pH of the system is below 8, Ultra-Kleen Solution 2 at the rate of 1 to 3 times the volume of Ultra-Kleen Solution 1) per gallon of water onto interior surfaces of the system that are not continuously submerged. Repeat until control is evident.

Routine Dose, when microbial control is evident: Subsequent slug additions of 28 to 128 fl. oz. Ultra-Kleen Solution 1 per 1000 gallons of water and if cleaning is desired or the pH of the system is below 8, Ultra-Kleen Solution 2 at the rate of 1 to 3 times the volume of Ultra-Kleen Solution 1 should be employed every 1 to 5 days or as needed. The frequency of addition depends on the relative amount of bleedoff, the quality of the makeup water and rate of inflow of airborne or other contaminants. Slug additions should be made in the sump of Industrial Water Scrubbing Systems.

DYE MACHINES. Effectively removes and controls biofilm and other organic contaminants in Textile Dyeing Machines.

DOSAGE RATES. Add 16 to 40 gal. of Ultra-Kleen Solution 1 per 1000 gallons of water in a dye storage tank. If cleaning is desired or the pH of the mixture is below 8, add simultaneously Ultra-Kleen Solution 2 at the rate of 1 to 3 times the volume of Ultra-Kleen Solution 1. Circulate the mixture from the dye storage tank through the dye machine and all associated piping and other dye storage tanks. If necessary, apply a solution containing 2 to 5 fl. oz. Ultra-Kleen Solution 1 (and if cleaning is desired or the pH of the mixture is below 8, Ultra-Kleen Solution 2 at the rate of 1 to 3 times the volume of Ultra-Kleen Solution 1) per gallon of water onto surfaces of the system that are not continuously submerged.

WATER-JET LOOMS. Effectively removes and controls biofilm and other organic contaminants in Water-Jet Looms.

DOSAGE RATES. Initial Dose for badly fouled systems: Prepare a mixture of 2 to 5 fl. oz. of Ultra-Kleen Solution 1 per gallon of water. If cleaning is desired or if the pH of the mixture is below 8, add Ultra-Kleen Solution 2 at the rate of 1 to 3 times the volume of Ultra-Kleen Solution 1. Pump the mixture through the Water-Jet Loom and all associated piping. If necessary, apply a solution containing 2 to 5 fl. oz. of Ultra-Kleen Solution 1 (and if cleaning is desired or the pH of the mixture is below 8, Ultra-Kleen Solution 2 at the rate of 1 to 3 times the volume of Ultra-Kleen Solution 1) per gallon of water onto surfaces of the system that are not continuously submerged.

Ultra-Kleen Solution 1) per gallon of water onto surfaces of the system that are not continuously submerged.

Subsequent Dose, when microbial control is evident: Subsequent slug additions of 5 to 25 fl. oz. Ultra-Kleen Solution 1 (and if cleaning is desired or the pH of the mixture is below 8, Ultra-Kleen Solution 2 at the rate of 1 to 3 times the volume of Ultra-Kleen Solution 1) per 1000 gallons of daily water use should be employed every 1 to 5 days or as needed. The frequency of addition depends on the quality of the makeup water and rate of inflow of airborne or other contaminants.

TANKS, PIPING AND INDUSTRIAL EQUIPMENT USED TO STORE AND CONVEY INDUSTRIAL PROCESS WATER OR AQUEOUS MIXTURES. Do Not Use in equipment that will contact food. Effectively removes and controls biofilm and other organic contaminants in Tanks, Piping and Industrial Equipment used to store and convey Industrial Process Water or Aqueous Mixtures.

DOSAGE RATES. Fill equipment as completely as possible with a solution of 8 to 80 gal. of Ultra-Kleen Solution 1 (and if cleaning is desired or the pH of the mixture is below 8, Ultra-Kleen Solution 2 at the rate of 1 to 3 times the volume of Ultra-Kleen Solution 1) per 1000 gallons of system capacity. Circulate for at least 4 hours and then drain system. Rinse system with 6 volumes of water. If necessary, apply a solution containing 1 to 10 fl. oz. Ultra-Kleen Solution 1 (and if cleaning is desired or the pH of the mixture is below 8, Ultra-Kleen Solution 2 at the rate of 1 to 3 times the volume of Ultra-Kleen Solution 1) per gallon onto surfaces of the equipment that are not submerged.

DEIONIZED WATER SUPPLY SYSTEMS NOT USED IN FOOD PROCESSING, FOR HUMAN DRINKING WATER OR DENTAL LINES. Effectively removes and controls biofilm and other organic contaminants in Tanks, Filters and Piping used to store and convey Deionized Water.

DOSAGE RATES. Add 3 to 16 gal. of Ultra-Kleen Solution 1 and if cleaning is desired or the pH of the mixture is below 8, Ultra-Kleen Solution 2 at the rate of 1 to 3 times the volume of Ultra-Kleen Solution 1 per 1000 gallons of system capacity. Circulate for at least 4 hours and then drain system. Rinse system with 6 volumes of water. If necessary, apply a solution containing 0.4 to 2 fl. oz. Ultra-Kleen Solution 1 (and if cleaning is desired or the pH of the system is below 8, Ultra-Kleen Solution 2 at the rate of 1 to 3 times the volume of Ultra-Kleen Solution 1) per gallon onto surfaces of the equipment that are not submerged.

Penetrates and Removes Biofilm and Other Organic Contaminants. Use as a Bactericide, Slimicide, Mildewstat, and Algicide in:

DRAINS. Effectively removes and controls plugging and odors caused by accumulation of biofilm and other organic contaminants in drains. Prevents stoppage and odors.

DOSAGE RATES. Initial Dose for badly fouled systems. Pour from 10 fl. oz. Ultra-Kleen Solution 1 around or into one-inch diameter or smaller drains up to 90 fl. oz. Ultra-Kleen Solution 1 around or into three-inch diameter drains. Add simultaneously Ultra-Kleen Solution 2 at the same volume as Ultra-Kleen Solution 1 (10-90 fl. oz.). If the drain is not in use at the time, follow with one gallon of hot water for every 10 fl. oz. of Ultra-Kleen Solution 1 added. Allow to stand for 30 minutes. Repeat until control is evident.

Subsequent Dose: When microbial control is evident, subsequent additions of 1.5-2 fl. oz. Ultra-Kleen Solution 1 into one-inch diameter or smaller drains up to 15 fl. oz. Ultra-Kleen Solution 1 into three-inch diameter drains, should be employed every 7 days or as needed. Add simultaneously Ultra-Kleen Solution 2 at the same volume as Ultra-Kleen Solution 1 (1.5-15fl. oz.). If the drain is not in use at the time, follow with one gallon of hot water for every 1.5 fl. oz. of Ultra-Kleen Solution 1 added.

CHAIR SIDE EVACUATOR TRAPS AND PUMP FILTER TRAPS. Effectively removes and controls plugging and odors caused by accumulation of biofilm in chair side evacuator traps and pump filter traps. Prevents stoppage and odor.

DOSAGE RATES. Initial Dose for badly fouled systems. Mix 10 fl. oz. of Ultra-Kleen Solution 1 and 10 fl. oz. of Ultra-Kleen Solution 2 into one gallon of hot water at the end of the working day. Draw all of the solution into the trap and allow to stand overnight. Repeat until control is evident.

Subsequent Dose: When microbial control is evident, subsequent slug additions of 1.5-2 fl. oz. Ultra-Kleen Solution 1 and 1.5-2 fl. oz. of Ultra-Kleen Solution 2 mixed into one gallon of hot water should be employed every 7 days or as needed.

Call 1-800-511-1659 for Technical Information
 Sterilex Corporation
 Owings Mills, MD 21117
www.sterilex.com

EPA Est. No.