

63761-3

3/19/2009

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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MAR 19 2009

Mr. Mark Wozniak
Sterilex
11409 Cronhill Drive, Suite L
Owings Mills, MD 21117

Subject: Sterilex Ultra Kleen Solution I
EPA Registration No.: 63761-3
Notification Date: February 10, 2009
EPA Receipt Date: February 17, 2009

Dear Mr. Wozniak,

This letter acknowledges receipt of your notification submitted under the provisions of FIFRA section 3(c)9, as amended, and PR Notice 98-10.

- Clarify "Drain" directions application methods

General Comments

Based on a review of the submitted materials, your notification to clarify "Drain" directions application methods 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 or Velma Noble at (703) 308-6233.

Sincerely,

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

CONCURRENCES

YMBOL							
URNAME							
DATE							

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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 63761-3	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) 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: EPA Reg. No. _____ Product Name _____

Check if this is a new address

Section - II

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

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

Notification to add clarification to use directions. Please reference cover letter for details.

Notification of MINOR LABELCHANGES in Accordance With PR Notice 98-10 Section II-M

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: *Wendy A. McCombie*

Date: 10 FEB 2009

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 <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)		
*Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
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	
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
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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 <i>Wendy A. McCombie</i>	3. Title Agent for Sterilex Corporation
4. Typed Name Wendy A. McCombie	5. Date February 10, 2009

LEWIS &
HARRISON

Consultants in Government Affairs

122 C Street, N.W., Suite 740
Washington, D.C. 20001

telephone 202.393.3903
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wmccombie@lewisharrison.com

February 10, 2009

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 ~~30~~ 31

SUBJECT: *Sterilex Corporation
Ultra Kleen Solution 1 (EPA Reg. No. 63761-3)
Application For Notification of Minor Label Changes
Per the Provisions of PR Notice 98-10 Section II-M
This Submission is NOT Subject to PRIA fees*

Dear Ms. Noble:

On behalf Sterilex Corporation, I am submitting an Application for Notification for **Ultra Kleen Solution 1 (EPA Reg. No. 63761-3)** pursuant to the provisions of PR Notice 98-10, Section II, Part M. The changes to the label are highlighted on the enclosed product label. The label revisions include the following, and do not affect the dilution ratio or the minimum or maximum use dilutions:

- 1) Clarification within the use directions section for "Drains" to indicate the product can also be applied by foaming, wiping, brushing, clean in place ("CIP"), pumping and mopping. The current directions for use only include application by pouring.
- 2) Addition of explanatory language within the use directions section for "Drains" to use the product in a foaming device.

The label is otherwise identical to that approved by the Agency on January 9, 2006.

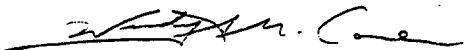
Please find enclosed the following documents in support of this Notification:

- 1) Application for Pesticide Notification, which includes a signed statement certifying compliance with PR Notice 98-10; and,
- 2) Three (3) copies of the proposed product label, with changes highlighted in yellow.

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Thank you in advance for your assistance with this submission.

Sincerely,



Wendy A. McCombie
Agent for,
Sterilex Corporation

Enclosures

cc: Mark Wozniak, Sterilex Corporation

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Ultra-Kleen™ Solution 1

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

- Recirculating Cooling Water Systems
- Brewery Pasteurizing Systems
- Pulp and Paper Mills producing pulp and paper that will not come in contact with food products
- 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	<u>94.00%</u>
TOTAL	100.00%

Controls Mold and Mildew

KEEP OUT OF REACH OF CHILDREN

DANGER

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS AND FIRST AID

Manufactured by
 Sterilex Corporation
 11409 Cronhill Drive Suite L
 Owings Mills, MD 21117
 phone 1-800-511-1659, fax 410-581-8864

NOTIFICATION
 Date Reviewed: _____
 Reviewed By: _____

EPA Reg. No. 63761-3

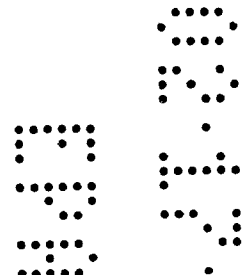
- EPA Est. No. 4875-NJ-001
- EPA Est. No. 44636-CA-001
- EPA Est. No. 21737-MN-01
- EPA Est. No. 062788-AL-01
- EPA Est. No. 60156-IL-001
- EPA Est. No. 085684-AL-001

Net Content:

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. CORROSIVE. Causes irreversible eye damage and skin burns. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin, or on clothing. Wear goggles and/or face shield, protective clothing and rubber gloves. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.



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ENVIRONMENTAL HAZARDS. The product is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, ocean or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously consulting the local sewage treatment plant authority. For guidance contact your local State Water Board or Regional Office of the EPA.

PHYSICAL AND CHEMICAL HAZARDS. When exposed to fire Ultra-Kleen Solution 1 may release oxygen and oxides of carbon and/or nitrogen.

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 the eyes. 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. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

NOTE: Seller warrants that this product complies with the specifications expressed in this label. Seller makes no other warranties; and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for the intended purpose. Seller's liability for default, breach or failure under this label shall be limited to the amount of the purchase price. Seller shall have no liability for consequential damages.

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 area away from potential sources of heat, open flames, sunlight or other chemicals. Product should be stored below 90°F.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture 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: Completely empty and triple-rinse container into application equipment. Dispose of empty container in a sanitary landfill, or incinerate. Burn only if allowed by state and local authorities.

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, DAIRY SWEET WATER SYSTEMS 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.

PULP AND PAPER MILLS. For use only in the production of pulp and paper that will not come in contact with food. Effectively removes and controls biofilm and other organic contaminants in pulp and paper mill fresh and seawater influent, water systems, wastewater treatment systems, nonpotable water systems, and other process water.

Routine Dose, when microbial control is evident: Subsequent slug additions of 8 to 50 oz. Ultra-Kleen Solution 1 per 1000 gallons of water (and if cleaning is desired or if 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 as needed. The frequency of addition depends on the quality of the makeup water and rate of inflow of airborne or other contaminants.

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 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 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 Other Organic Contaminants. Use as 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. This product can be poured, foamed, wiped, brushed, applied using a clean in place CIP system, pumping it through the system or mopping. Apply from 6 fl. oz to 15 fl. oz Ultra-Kleen Solution 1 per gallon of water to drain. Repeat until control is evident. Optionally, pour from 1 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. If cleaning is desired, add simultaneously Ultra-Kleen Solution 2 at the same volume as Ultra-Kleen Solution 1 (1 – 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.~~

For foam cleaning, add 6-15 oz. Sterilex Ultra-Kleen Solution 1 and an equal amount of Sterilex Ultra-Kleen Solution 2 per gallon of water to a foaming device and foam the mixture into the drain.

Subsequent Dose: When microbial control is evident, subsequent additions of 1-6 fl. oz Ultra-Kleen Solution 1 per gallon of water should be employed every 7 days or as needed. This product can be poured, foamed, wiped, brushed, applied using a clean in place CIP system, pumping it through the system or mopping. If cleaning is desired, add simultaneously Ultra-Kleen Solution 2 at the same volume as Ultra-Kleen Solution 1 (1 – 6 fl. oz) per gallon of water. ~~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.~~ Optionally, subsequent additions of 1 – 6 fl. oz Ultra-Kleen Solution 1 into one-inch diameter or smaller drains up to 6 fl. oz Ultra-Kleen Solution 1 into three-inch diameter drains, should be employed every 7 days or as needed. If cleaning is desired, add simultaneously Ultra-Kleen Solution 2 at the same volume as Ultra-Kleen Solution 1 (1 – 6 fl. oz). For foam cleaning, add 1 – 6 oz. Sterilex Ultra-Kleen Solution 1 and an equal amount of Sterilex Ultra-Kleen Solution 2 per gallon of water to a foaming device and foam the mixture into the drain.

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.

FOR PRE-CLEANING OF WHIRLPOOL BATHTUBS circulate a solution of 0.5 fl. oz. of Ultra-Kleen Solution 1 and 0.5 fl. oz. of Ultra-Kleen Solution 2 per 1 gal. tap water through tub and associated piping and filters at a temperature ≥ 90° F.

When mixtures of Ultra-Kleen Solution 1 and Ultra-Kleen Solution 2 are prepared in a batch process, always use the mixtures the same day they are prepared.

This product is water-based.

