

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JAN 10 2006

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

Subject: Ultra-Kleen Solution 1
EPA Registration No. 63761-3
Notification Date: December 7, 2005
EPA Receipt Date: December 12, 2005

Dear Dr. Weiner,

The following notification submitted in connection with the provisions under FIFRA section 3(c)9 and PR Notice 98-10 is acceptable.

- Add nonpublic health claims

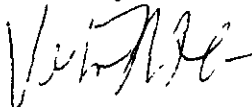
General Comments

Based on the submitted materials, the notification to add nonpublic health claims, mildewstat and controls mold and mildew, is acceptable and apart of the records on file.

Please Note: Delete the term, biofilm, from the label. Biofilm is a public health claim and this product is for nonpublic health use only.

Should you have any questions regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,



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

CONCURRENCES

SYMBOL	SURNAME	DATE						



2/4

STERILEX®

12/7/2005

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-Kleen Solution 1
 EPA Registration Number 63761-3
 Notification to add Non-Public Health Pest

Dear Ms. Noble:

We are submitting a notification for **Sterilex Ultra-Kleen Solution 1** per PR notice 98-10 and in accordance with DIS/TSS-16. The sole purpose of this notification is to inform the agency of the addition of a non-public health pest claim to the above referenced product label. As such, "Mildewstat" and "Controls Mold and Mildew" has been added to the product 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

Ultra-Kleen Solution 1

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

- Recirculating Cooling Water Systems
- Brewery Pasteurizing Systems
- Air Washers
- Pulp and Paper Mills producing pulp and paper that will not come in contact with food products
- 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.

Controls Mold and Mildew

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	94.00%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

See Side Panel For Additional Precautionary Statements and Statement of Practical Treatment

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 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 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 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.

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.

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

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 or as needed. The frequency of addition depends on the quality of the makeup water and rate of inflow of airborne or other contaminants.

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 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 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 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 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 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. 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 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 volumes of water. If necessary, apply a solution containing 1 to 10 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 sub-

DEIONIZED WATER SUPPLY SYSTEMS NOT USED IN FOOD PROCESSING FOR HUMAN DRINKING WATER OR DENTAL LINE. Effectively removes and controls biofilm and other organic contaminants in Tanks, Piping 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 gal. of system capacity. Circulate for at least 4 hours and then drain system with 6 volumes of water. If necessary, apply a solution containing 2 to 2 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.

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 1 to 10 oz. Ultra-Kleen Solution 1 around or into one-inch diameter or smaller diameter or 90 oz. Ultra-Kleen Solution 1 around or into three-inch diameter or smaller diameter. Add simultaneously Ultra-Kleen Solution 2 at the same volume as Ultra-Kleen Solution 1 (10-90 oz.). If the drain is not in use at the time, follow with one gallon of hot water for every 10 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 oz. Ultra-Kleen Solution 1 into one-inch diameter or smaller diameter or 15 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 (1.5-15oz.) if drain is not in use at the time, follow with one gallon of hot water for every 10 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 odors.

DOSAGE RATES. Initial Dose for badly fouled systems. Mix 10 oz. Ultra-Kleen Solution 1 and 10 oz. of Ultra-Kleen Solution 2 into one gallon of 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 oz. Ultra-Kleen Solution 1 and 1.5-2 oz. of Ultra-Kleen Solution 2 mixed into one gallon of hot water should be employed every 7 days or as needed.

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.



STERILEX
Solutions for Biofilms

HAZARDS

DANGER. Harmful if swallowed or on clothing. Wear rubber gloves and eye protection. Avoid contact with skin. Wash thoroughly if contact occurs. Do not discharge into waterways. Do not discharge into the environment. Do not discharge into the ocean. Do not discharge into the atmosphere. Do not discharge into the ground. Do not discharge into the sewer. Do not discharge into the storm drain. Do not discharge into the water supply. Do not discharge into the drinking water supply. Do not discharge into the food supply. Do not discharge into the animal feed supply. Do not discharge into the human waste supply. Do not discharge into the industrial waste supply. Do not discharge into the municipal waste supply. Do not discharge into the landfill. Do not discharge into the incinerator. Do not discharge into the ocean. Do not discharge into the atmosphere. Do not discharge into the ground. Do not discharge into the sewer. Do not discharge into the storm drain. Do not discharge into the water supply. Do not discharge into the drinking water supply. Do not discharge into the food supply. Do not discharge into the animal feed supply. Do not discharge into the human waste supply. Do not discharge into the industrial waste supply. Do not discharge into the municipal waste supply. Do not discharge into the landfill. Do not discharge into the incinerator.

Have the product tested by a doctor, or get a doctor's advice.

IF IN EYE, wash with water for 15 minutes. If irritation persists, consult a doctor for treatment.

IF ON SKIN, wash with water. If irritation persists, consult a doctor for treatment.

IF POWDERED, for treatment, induce vomiting. Do not give anything by mouth to someone who is unconscious or has seizures.

NOTE TO PHYSICIAN: For treatment of gastric lavage, use 1-2% solution. (After proper dilution.)

NOTE: See other warnings on this label. Do not use in food processing. Do not use in the pharmaceutical industry. Do not use in the food service industry. Do not use in the hospital. Do not use in the laboratory. Do not use in the research facility. Do not use in the school. Do not use in the office. Do not use in the home. Do not use in the public place. Do not use in the workplace. Do not use in the community. Do not use in the environment. Do not use in the water supply. Do not use in the drinking water supply. Do not use in the food supply. Do not use in the animal feed supply. Do not use in the human waste supply. Do not use in the industrial waste supply. Do not use in the municipal waste supply. Do not use in the landfill. Do not use in the incinerator.

STC

Do not store in a cool, dry place. Do not store in a container that is not properly labeled. Do not store in a container that is not properly sealed. Do not store in a container that is not properly marked. Do not store in a container that is not properly identified. Do not store in a container that is not properly described. Do not store in a container that is not properly explained. Do not store in a container that is not properly defined. Do not store in a container that is not properly demonstrated. Do not store in a container that is not properly illustrated. Do not store in a container that is not properly depicted. Do not store in a container that is not properly represented. Do not store in a container that is not properly portrayed. Do not store in a container that is not properly shown. Do not store in a container that is not properly displayed. Do not store in a container that is not properly exhibited. Do not store in a container that is not properly presented. Do not store in a container that is not properly offered. Do not store in a container that is not properly provided. Do not store in a container that is not properly supplied. Do not store in a container that is not properly delivered. Do not store in a container that is not properly distributed. Do not store in a container that is not properly disseminated. Do not store in a container that is not properly divulged. Do not store in a container that is not properly made known. Do not store in a container that is not properly brought to light. Do not store in a container that is not properly made manifest. Do not store in a container that is not properly made plain. Do not store in a container that is not properly made clear. Do not store in a container that is not properly made evident. Do not store in a container that is not properly made obvious. Do not store in a container that is not properly made apparent. Do not store in a container that is not properly made plain. Do not store in a container that is not properly made clear. Do not store in a container that is not properly made evident. Do not store in a container that is not properly made obvious. Do not store in a container that is not properly made apparent.

NET WEIGHT
LOT NO.