63761-3

1-7-2002 UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Mr. Bob MacDonald Scientific & Regulatory Consultants, Inc. P.O. Box 1014 Columbia City, IN 46725

JAN - 7 2002

Subject: Ultra-Kleen Solution 1 EPA Registration No. 63761-3 Amendment Date: October 9, 2001 EPA Receipt Date: October 11, 2001

Dear Mr. MacDonald:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with the conditions listed below.

• Adding non-public health use sites: drains, chair evacuator traps, and pump filter traps

# Conditions

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Revise the label as follows:

1. According to PR Notice 2001-1, the "Statements of Practical Treatment" must be revised to state :

# FIRST AID

If In Eyes: Hold eyes 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

CONCURRENCES									
SYMBOL	1500								
	mydalane								
DATE	1/1/02								

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

2. Under Storage/Disposal, Revise the "Disposal" heading to read "Pesticide Disposal."

# **General Comments**

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A stamped copy of the accepted labeling is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling. If you have any questions or comments concerning this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely ma Noble

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

# **Ultra-Kleen Solution 1**

Penetrates and Removes Biofilm and other Organic Contaminants. Use as a Bactericide, Slimicide 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, for human drinking water, or dental lines
- Drains and 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%) dimethyl benzyl ammonium chloride	3.00%
n-Alkyl (C <sub>12</sub> 68%, C <sub>14</sub> 32%) dimethyl ethyl benzyl ammonium chloride	3.00%
Inert Ingredients	. <u>94.00%</u>
TOTAL	100.00%

# KEEP OUT OF REACH OF CHILDREN DANGER

#### STATEMENT OF PRACTICAL TREATMENT

- IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention.
- IF ON SKIN: Wash with plenty of soap and water. Get medical attention.
- 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.

NOTE TO PHYSICIAN:

Probable mucosal damage may contraindicate the use of gastric lavage.

 NET WEIGHT\_\_\_\_\_
 EPA REG. NO. 63751.3

 LOT NO.\_\_\_\_\_
 ACCEPTED
 EPA EST. NO. 4875-NJ-001

 with COMMENTS
 in EPA Letter Dated:

JAN - 7 2002 Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the perdicide, registered under EPN Reg. No. 6 3 76/- 3

### STERILEX CORPORATION 1450 SOUTH ROLLING ROAD 4<sup>TH</sup> FLOOR BALTIMORE, MD 21227

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. Sellers shall have no liability for consequential damages.

#### 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.

ENVIRONMENTAL HAZARDS. This 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.

#### 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, EVAPORATE 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. <u>Initial Dose for badly fouled systems</u>. Add 1 to 4 gal. Ultra-Kleen Solution 1 per 1,000 gallons of water in the system. If cleaning is desired and pH of 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 are evident**: Subsequent slug additions of 28 to 64 oz. Ultra-Kleen Solution 1 per 1,000 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 arborne 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

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United the Fuckaral Insecticide, Function Lie, and Fordemicide Actigs amount of States per fielde, registered under EPA Reg. No. 6376/-3

# 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 biofilm and microbial control are 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 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 pH of the system is below 8, Ultra-Kleen Solution 2 at the rate of 1 to 3 times the volume 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 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 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 (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. **ACCEPTED** 

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with COMMENTS in EPA Letter Dated:

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Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pepticide, recontered under EPA Reg. No. 6 376/-3 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.

<u>Subsequent Dose, when microbial control is evident</u>: Subsequent slug additions of 5 to 25 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 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 RATE. 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 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 oz., Ultra-Kleen Solution (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 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. <u>Initial Dose for badly fouled systems.</u> Pour from 10 oz. Ultra-Kleen Solution 1 around or into one-inch diameter or smaller drains up to 90 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 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.

Solution 1 into one-inch diameter or smaller drains up to 15 oz Ultra-Kleen Solution 1 into three-inch ACCEPTED

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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 the drain is not in use at the time, follow with one gallon of hot water for every 1.5 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. <u>Initial Dose for badly fouled systems</u>. Mix 10 oz. of Ultra-Kleen Solution 1 and 10 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 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 mixture the same day it is prepared.

# 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  $90^{\circ}$  F.

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.

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Under the Ferleral Insecticide, Fungicide at 1 odeaticide Act as amended, for the pacticide, registered under EPA Reg. No. 6376/-3