

63761-3

7/19/2011

10/6

Wendy A. McCombie
Sterilex Corporation
111 Lake Front Drive
Hunt Valley, MD 21030

JUL 19 2011

SUBJECT: Ultra Kleen Solution 1
EPA Registration Number: 63761-3
Application Dated: April 11, 2011
Receipt Date: April 22, 2011


Dear Ms. McCombie:

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

- Ultra Kleen Solution 1 (EPA Registration Number: 63761-3) in response to the conditions of the January 23, 2011 acceptance letter and stamped accepted label.

General Comments

Your accepted stamped label is attached. Should you have any questions concerning this letter, please contact Emilia Oiguenblik at (703) 347-0109 or Velma Noble at (703) 308-6233.

Sincerely,

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

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

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

Optional Marketing Language

[(Based off of) (Based on) (Including) (Includes) (Using) patented PerQuat™ technology]

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

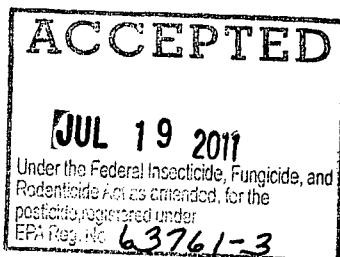
DANGER

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS AND FIRST AID

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

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
- EPA Est. No. 56485-PA-001
- EPA Est. No. 1270-GA-1
- EPA Est. No. 1270-TX-1
- EPA Est. No. 40849-GA-1



Net Content: {1 2.5, 5, 15, 30, 55, 275, 305} Gallons,

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.

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: 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.]

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. (1000-4000 ppm of this product) **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, optionally 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 5 oz. to 64 fl. oz. (40-499 ppm of this product) **Ultra-Kleen Solution 1** per 1000 gallons of water (and if cleaning is desired or the pH of the system is below 8, optionally add Ultra-Kleen Solution 2 at the rate of 1 to 3 times the volume of **Ultra-Kleen Solution 1**) are applied every 2 to 5 days or as needed. The frequency of addition depends on the relative amount of bleed-off, the quality of the makeup water and rate of inflow of airborne or other contaminants. Slug additions are made in the sump of water cooling towers.

Continuous Dosage: For continuous, or semi-continuous, low level dosage of **Ultra-Kleen Solution 1**, add 1 oz. to 20 oz. (8-156 ppm of this product) **Ultra-Kleen Solution 1** per 1000 gallons of water (and if cleaning is desired or the pH of the system is below 8, optionally add Ultra-Kleen Solution 2 at the rate of 1 to 3 times the volume of **Ultra-Kleen Solution 1**).

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. (3000-16000 ppm of this product) 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, optionally 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, optionally add 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. (62-390 ppm of this product) **Ultra-Kleen Solution 1** per 1000 gallons of water (and if cleaning is desired or if the pH of the system is below 8, optionally add Ultra-Kleen Solution 2 at the rate of 1 to 3 times the volume of **Ultra-Kleen Solution 1**) are applied 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.

Continuous Dosage: For continuous low level dosage of **Ultra-Kleen Solution 1**, add 1 oz. to 20 oz. **Ultra-Kleen Solution 1** per 1000 gallons of water (8-156 ppm of this product) (and if cleaning is desired or the pH of the system is below 8, optionally add Ultra-Kleen Solution 2 at the rate of 1 to 3 times the volume of **Ultra-Kleen Solution 1**).

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. (3000-16000 ppm of this product) 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, optionally 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, optionally add 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. (218-1000 ppm of this product) **Ultra-Kleen Solution 1** per 1000 gallons of water and if cleaning is desired or the pH of the system is below 8, optionally add Ultra-Kleen Solution 2 at the rate of 1 to 3 times the volume of **Ultra-Kleen Solution 1** are applied every 1 to 5 days or as needed. The frequency of addition depends on the relative amount of bleed-off, the quality of the makeup water and rate of inflow of airborne or other contaminants. Slug additions are 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. (16000-40000 ppm of this product) 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, optionally 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, optionally add 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, optionally 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, optionally add 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. (40-195 ppm of this product) **Ultra-Kleen Solution 1** per 1000 gallons of water in the system (and if cleaning is desired or the pH of the mixture is below 8, optionally add 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 are applied 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, SUMPS, AND OTHER HOLDING VESSELS, PIPING AND INDUSTRIAL EQUIPMENT USED TO STORE AND CONVEY INDUSTRIAL OR COMMERCIAL PROCESS WATER OR AQUEOUS MIXTURES~~TANKS,~~
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. Dose for badly fouled systems: Fill equipment as completely as possible with a solution of 8 to 80 gal. (8000-80000 ppm of this product) of **Ultra-Kleen Solution 1** per 1000 gallons of water in the system (and if cleaning is desired or the pH of the mixture is below 8, optionally add Ultra-Kleen Solution 2 at the rate of 1 to 3 times the volume of Ultra-Kleen Solution 1). 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, optionally add 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.

Subsequent Dose, when microbial control is evident: Subsequent slug additions of 5 to 25 fl. oz. (40-195 ppm of this product) **Ultra-Kleen Solution 1** per 1000 gallons of water in the system (and if cleaning is desired or the pH of the mixture is below 8, optionally add 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 are applied 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.

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. Dose for badly fouled systems : Add 3 to 16 gal. (3000-16000 ppm of this product) of **Ultra-Kleen Solution 1** per 1000 gallons of system capacity and if cleaning is desired or the pH of the mixture is below 8, optionally add Ultra-Kleen Solution 2 at the rate of 1 to 3 times the volume of **Ultra-Kleen Solution 1** . Circulate for at least four 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, optionally add 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.

Subsequent Dose, when microbial control is evident: Add subsequent slug additions of 5 oz. to 1 gal. (40-1000 ppm) **Ultra-Kleen Solution 1** (and if cleaning is desired or the pH of the system is below 8, optionally add 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 four 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, optionally add 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. 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). 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 is applied 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. 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, are applied 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 are applied 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.

This product is water-based.