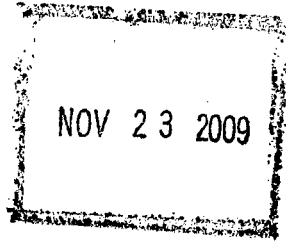


63761-2

11/23/2009

1044

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



Ms. Wendy McCombie
Agent for Sterilex
Lewis and Harrison
122 C Street, N.W., Suite 740
Washington, DC 20001

SUBJECT: Ultra-Kleen CW 502
EPA Registration Number: 63761-2
Application Date: August 25, 2009
Receipt Date: August 25, 2009

Dear Ms. McCombie:

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

- 1) Delete the word Sterilex from page one in the same line as the product name: Ultra-Kleen CW 502. The name of record is: Ultra-Kleen CW 502. You have not indicated that it is your intent to change the name of record at this time.
- 2) Revise the Precautionary Statements to be in agreement with the Label Review Manual as follows: "... Wash thoroughly with soap after handling *and before eating, drinking, using tobacco or using the toilet.* Remove contaminated..."
- 3) Add the following to the Environmental Hazards statement such that this section will reflect the environmental concerns associated with these active ingredients: "This pesticide is toxic to fish *and aquatic invertebrates.* Do not discharge..."

CONCURRENCES

SYMBOL	7510P						
SURNAME	J. Lopez						
DATE	11/19/09						

4) Should you wish to retain a reference to the company's website on your label, then please be aware that such a reference transforms the website into labeling under the Federal Insecticide Fungicide and Rodenticide Act sec 2 (p) (2) and then the website is subject to review by the Agency. If the website content is false or misleading, the product would be misbranded and its sale or distribution unlawful to sell or distribute under FIFRA section 12(a)(1)(E). In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Although EPA has not yet determined the extent to which it will routinely review company websites, if the Agency finds or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from claims approved through the registration process, the website may be referred to the EPA's Office of Enforcement and Compliance Assurance.

5) Revise the Storage and Disposal directions as follows. Change the Storage heading to read: "*Pesticide Storage*". In addition, please be aware that that the Storage and Disposal section is not in agreement with PR Notice 2007-4.

6) Your label is not in agreement with PR Notice 2000-5 which specifies that mandatory language be employed in the directions for use section of the label. As such, make the following revisions to your labeling:

a) Revise the Recirculating Cooling Water, subsequent dose section to read: "...Slug *additions are made* in the sump..."

b) Revise the Air Washers, subsequent dose section to read: "...per 1000 gallons of *water are employed every...*" and "...Slug *additions are made* in the sump..."

c) Revise the Pulp and Paper Mills, subsequent dose section to read: "...per 1000 gallons of *water are employed every...*"

d) Revise the Water Jet Looms, initial dose section to read: "...per gallon of water onto surfaces of the system that are not ..."
and subsequent dose section to read: "...per 1000 gallons of daily *water use are employed every...*"

e) Revise the Drains, subsequent dose section to read: "...*added every seven days and needed...*"

f) Revise the Chair Side Evacuator, subsequent dose section to read: "...one gallon of hot water *is added every 7 days...*"

General Comments

General Comments

A stamped copy of the accepted labeling is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling. Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,



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

7510P:T.Lantz:11/19/09:63761-2 a accepted label amend
Enclosure: Stamped accepted label

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

ULTRA-KLEEN™ CW502

Penetrates and Removes Biofilm and Other Organic Contaminants. For use as a Bactericide, Slimicide, Mildewstat 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 and Piping 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 in dental lines.
- Drains
- Chair Side Evacuator Traps and Pump Filter Traps

Controls Mold and Mildew

Active Ingredient:

n-Alkyl (C ₁₄ 95%, C ₁₂ 3%, C ₁₆ 2%) dimethylbenzylammonium chloride.....	10.0%
Inert Ingredients.....	90.0%
TOTAL.....	100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

See Side Panel For Additional Precautionary Statements and First Aid

DIRECTIONS FOR USE

In violation of Federal law to use this product in a manner inconsistent with 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 5 to 20 lbs. Ultra-Kleen CW-502 per 1000 gallons water contained in the system.

Subsequent Dose: When microbial control is evident, subsequent slug additions of 1 to 5 lbs. Ultra-Kleen CW-502 per 1000 gallons of water should be employed 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 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 16 to 80 lbs. of Ultra-Kleen CW-502 per 1000 gallons of water contained in the system. If necessary, apply a solution containing 0.016 to 0.08 lbs. Ultra-Kleen CW-502 per gallon of water onto interior surfaces of the system that are not continuously submerged. **Subsequent Dose:** When microbial control is evident, subsequent slug additions of 1 to 5 lbs. Ultra-Kleen CW-502 per 1000 gallons of water should be employed 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 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 contact 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 16 to 80 lbs. of Ultra-Kleen CW-502 per 1000 gallons of water contained in the system. If necessary, apply a solution containing 0.016 to 0.08 lbs. Ultra-Kleen CW-502 per gallon of water onto interior surfaces of the system that are not continuously submerged. **Subsequent Dose:** When microbial control is evident, subsequent slug additions of 0.3 to 2 lbs. Ultra-Kleen CW-502 per 1000 gallons of water 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. Clean badly fouled systems by adding 80 to 200 lbs. of Ultra-Kleen CW-502 per 1000 gallons of water contained in a dye storage tank. Circulate the solution from the dye storage tank through the dye machine and all associated piping and other dye storage tanks. If necessary, apply a solution containing 0.08 to 0.2 lbs. Ultra-Kleen CW-502 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 solution of 0.08 to 0.20 lbs. of Ultra-Kleen CW-502 per gallon of water and pump through the Water-Jet Loom and all associated piping. If necessary, apply a solution containing 0.08 to 0.2 lbs. Ultra-Kleen CW-502 per gallon surfaces of the system that are not continuously submerged. **Subsequent Dose:** When microbial control is evident, subsequent slug additions of 0.2 to 1.0 lbs. Ultra-Kleen CW-502 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 AND PIPING 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 and Piping used to store and convey Industrial Process Water or Aqueous Mixtures.

DOSAGE RATES. Fill equipment as completely as possible with a solution of 40 to 400 lbs. of Ultra-Kleen CW-502 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 0.04 to 0.2 lbs. Ultra-Kleen CW-502 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 IN DENTAL LINES.

Effectively removes and controls biofilm and other organic contaminants in Tanks, Filters and Piping used to store and convey Deionized Water. Do Not Use where deionized water will be used for food processing, for human drinking water or for medical/dental procedures. **DOSAGE RATES.** Add 16 to 80 lbs. of Ultra-Kleen CW-502 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 0.016 to 0.08 lbs. Ultra-Kleen CW-502 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 6 oz. Ultra-Kleen CW502 around or into one-inch diameter or smaller drains up to 54 oz. Ultra-Kleen CW-502 around or into three-inch diameter drains. If the drain is not in use at the time, follow with one gallon of hot water for every 6 oz. of Ultra-Kleen CW-502 added. Allow to stand for 30 minutes. Repeat until control is evident. **Subsequent Dose:** When microbial control is evident, subsequent additions of 1 oz. Ultra-Kleen CW-502 into one-inch diameter or smaller drains up to 9 oz. Ultra-Kleen CW-502 into three-inch diameter drains, followed by one gallon of hot water for every 1 oz. of Ultra-Kleen CW-502 added should be employed every 7 days or as needed.

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. Dissolve 6 oz. of Ultra-Kleen CW-502 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 oz. Ultra-Kleen CW-502 dissolved into one gallon of hot water should be employed every 7 days or as needed.

FOR PRE-CLEANING OF WHIRLPOOL BATHTUBS dissolve 0.5 oz. of Sterilex Ultra-Kleen CW-502 in 1 gal. tap water and circulate through tub and associated piping and filters at a temperature $\geq 90^\circ\text{F}$.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS
DANGER. Corrosive. Causes irreversible eye damage and skin burns. Harmful if swallowed or absorbed through skin. 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 CW-502 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 eye. 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 person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a 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 or 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 PESTICIDE 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, dry area away from potential sources of heat, open flames, sunlight or other chemicals. Product should be stored below 100°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 plastic liner bag into application equipment. Dispose of empty liner and drum in a sanitary landfill, or incinerate. Burn only if allowed by state and local authorities.



EPA Reg. No. 63761-2
 Reorder Number: CW502
 Net Weight
 Lot No. 03/25/2003 MEV/WAM

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

EPA Est. No.	<input type="checkbox"/>	4875-NJ-001
	<input type="checkbox"/>	44636-CA-001
	<input type="checkbox"/>	21737-MN-01
	<input type="checkbox"/>	062788-AL-01

ACCEPTED
 with COMMENTS
 in EPA Letter Dated:

NOV 23 2009

Under the Federal Insecticide,
 Fungicide, and Rodenticide Act as
 amended, for the pesticide,
 registered under EPA Reg. No. 63761-2

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