

63761-2

1068

SEP 13 2011

Wendy A. McCombie  
Lewis & Harrison  
122 C Street, N.W., Suite 740  
Washington DC, 20001

SUBJECT: Ultra-Kleen CW-502  
EPA Registration Number: 63761-2  
Application Date: August 16, 2011  
Receipt Date: August 19, 2011

Dear Ms. McCombie:

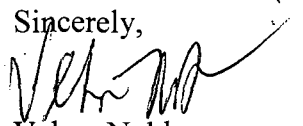
This letter acknowledges receipt of the notification identified above submitted under provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended and PR Notice 98-10.

- To make minor label changes to the product label in accordance with PR Notices 1998-10 and 2007-4.

Based on a review of the submitted information, this notification is acceptable. Your proposed changes will be made part of the record for this file.

**General Comments**

Should you have any questions concerning this letter, please contact Emilia Oiguenblik at (703) 347-0199 or Velma Noble at (703) 308-6233.

Sincerely,  


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

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

2 of 8

Please read instructions on reverse before completing form.

Form Approved B No. 2070-0060



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 <b>63761-2</b>	2. EPA Product Manager <b>Velma Noble</b>	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) <b>Ultra-Kleen CW-502</b>	PM# <b>31</b>	
5. Name and Address of Applicant (Include ZIP Code) <b>Sterilex Corporation 111 Lake Front Drive Hunt Valley, MD 21030</b> <input type="checkbox"/> Check if this is a new address		6. <b>Expedited Review.</b> 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 _____

**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.)

**APPLICATION FOR NOTIFICATION: MINOR LABEL CHANGES**

**Notification of Minor Label Changes in Accordance With PR Notices 1998-10 and 2007-4: See Cover Letter**

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: \_\_\_\_\_ Date: August 16, 2011

**THIS SUBMISSION IS NOT SUBJECT TO PRIA FEES**

**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.
3. Location of Net Contents Information <input type="checkbox"/> Label -OR- <input type="checkbox"/> Container		4. Size(s) Retail Container		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 <b>Mark Wozniak (m.wozniak@sterilex.com)</b>	Title <b>Senior Scientist/R&amp;D Manager</b>	Telephone No. (include Area Code) <b>(410) 581-8860</b>
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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 	3. Title <b>Agent for Sterilex Corporation</b>
4. Typed Name <b>Wendy A. McCombie</b>	5. Date <b>August 16, 2011</b>

# 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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direct 202.393.3903 ext. 11  
wmccombie@lewisharrison.com

August 16, 2011

**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 31**

**SUBJECT: Sterilex Corporation  
Ultra-Kleen CW-502 (EPA Reg. No. 63761-2)  
Response to July 29, 2011 Agency Letter  
Notification of Minor Label Changes per PR Notices 1998-10 and 2007-4  
This Submission is NOT Subject to PRIA fees**

Dear Ms. Noble:

On behalf Sterilex Corporation, I am submitting a Notification application to make minor changes to the product label for **Ultra-Kleen CW-502 (EPA Reg. No. 63761-2)**. All of the requested changes have been highlighted on the label and comply with the provisions of PR Notice 1998-10 Part II, Sections C, D and M, as well as with the provisions of PR Notice 2007-4. No other changes have been made to the labeling for this product.

A similar notification has recently been submitted to EPA for Sterilex Ultra Powder (EPA Reg. No. 63761-5), which is the same formulation as **Ultra-Kleen CW-502**. It had been pointed out by New York State for Sterilex Ultra Powder that the product is a solid formulation, so the storage and disposal language should reflect that. Also, the container types are 5 pound rigid containers or 10 pound, 25 pound and 50 pound fiber drums with plastic liners. Therefore, Sterilex is updating the "Storage and Disposal" language in accordance with the requirements and provisions of PR Notice 2007-4, PR Notice 83-3, 40 CFR 156.144 and 40 CFR 156.140(a)(1-3) for the container and product types.

Please note that in accordance with the July 29, 2011 letter from EPA, the "perquat technology" patent statement has been removed from the label.

Please note that Sterilex would like to retain the option to omit "or pressure rinse" and associated directions for pressure rinsing from the labels for the smaller size range of containers. Therefore, the phrase "or pressure rinse" has been placed in brackets. The pressure rinse directions have also been placed in brackets for each range of container sizes following the triple rinse instructions associated with the appropriate range. A "Note To Reviewer" to this effect has been indicated on the Master label for informational purposes.



# ULTRA-KLEEN™ CW502



NOTIFICATION  
Date Reviewed: 9/13/11  
Reviewed By: [Signature]

*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 <sub>14</sub> 95%, C <sub>12</sub> 3%, C <sub>16</sub> 2%) dimethylbenzylammonium chloride: .....	10.0%
Inert Ingredients: .....	90.0%
TOTAL: .....	100.0%

## KEEP OUT OF REACH OF CHILDREN DANGER

See Side (Back) Panel For Additional Precautionary Statements and First Aid

### 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 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 are 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 are 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 are 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 are 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 are 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 of water onto 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 are 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 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 is added 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  $\geq 90^{\circ}$  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 and before eating, drinking, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

**ENVIRONMENTAL HAZARDS.** This product is toxic to fish and aquatic invertebrates. 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 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.

**PESTICIDE 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:** 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.

**[(NOTE TO REVIEWER: The following language is for nonrefillable rigid plastic containers having a capacity of 5 pounds or less)** Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Fill the container ¼ full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Dispose of rinsate as pesticide waste.]

**[(NOTE TO REVIEWER: The following language is optional for nonrefillable rigid plastic containers having a capacity of 5 pounds or less when "or pressure rinse" appears in the Container Disposal statement)** Triple rinse or pressure rinse container (or equivalent) promptly after emptying. Pressure rinse as follows: 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. Dispose of rinsate as pesticide waste.]

**[(NOTE TO REVIEWER: The following language is for nonrefillable fiber drum with plastic liner bag containers having a capacity greater than 5 pounds)** Completely empty bag into application equipment by shaking and tapping sides and bottom to loosen clinging particles. If not emptied in this manner, the bag may be considered an acute hazardous waste and must be disposed in accordance with local, state and federal regulations. When completely empty, offer for recycling if available or dispose of bag in a sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.]

EPA Registration No. 63761-2

Reorder Number CW502

Net Weight {Note to reviewer: Net Weight and Lot Number may be printed on Container Itself}

Lot Number

Call 1-800-511-1659 for Technical Information

Made For:

Sterilex Corporation

111 Lake Front Drive

Hunt Valley, MD 21030

EPA Establishment Numbers: 21737-MN-01

44636-CA-001

4875-NJ-001

062788-AL-01

