

63761-5

12/6/2007

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

DEC 6 2007

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

Subject: Sterilex Ultra Powder
EPA Registration No. 63761-5
Amendment Date: January 16, 2006
EPA Receipt Date: January 17, 2006

Dear Ms. Weiner,

The following amendment submitted in connection with registration under FIFRA, as amended, is acceptable with the conditions listed below.

- Addition of disinfection directions for hard non-porous surfaces

Conditions

Revise the label as follows:

1. Since a protocol and data were not sent to support a biofilm claim on hard nonporous surfaces, you must revise the 3rd bullet on page 1 to read "Kills biofilm bacteria in dental unit water lines."
2. Revise the nomenclature for *Salmonella choleraesuis* (ATCC 10708) to reflect the new designation of "*Salmonella enterica*."
3. The submitted efficacy data was not conducted with soil. Any claims for "One-step cleaning and disinfecting" is unacceptable and must be deleted from the label. Therefore, you must revise the "Precognizing Instructions (Optional Step)" heading by deleting "Optional Step." Also, you must delete the statement, "Although Sterilex Ultra Powder provides one-step cleaning and disinfection, precleaning may be desired on some surfaces in certain cases."

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Data Summary

Data Requirement	Means of Support	Status
AOAC Use Dilution Method-S. aureus, S. enterica, P. aeruginosa	Submitted study, MRID 455876-06	Acceptable, 50g/liter water on precleaned hard nonporous surfaces for 10 minutes in 400 ppm hard water

General Comments

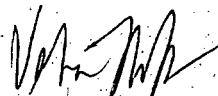
A stamped copy of the label accepted with conditions is enclosed. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

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

Sincerely,



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

Enclosures: Stamped Label
 Efficacy Data Evaluation

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Sterilex Ultra Powder

Think Pink Once A Week®

- Removes* biofilm from dental unit water lines
- Prevents and suppresses formation of biofilm in dental unit water lines
- Kills biofilm bacteria
- Maintains dental unit water line effluent water <500 cfu/ml

* Laboratory studies have shown >90% removal

Active Ingredients:

N-Alkyl(C₁₄95%, C₁₂3%, C₁₆2%)
 dimethylbenzylammonium chloride..... 10.00%
 Sodium Carbonate Peroxyhydrate.....29.75%
 Other Ingredients.....60.25%
 TOTAL..... 100.00%

KEEP OUT OF THE REACH OF CHILDREN

DANGER

(See back panel for additional precautionary and first aid statements)

**STERILEX CORPORATION
Owings Mills, MD 21117**

Phone: 1-800-511-1659 Fax: 410-581-8864

www.sterilex.com

EPA Reg. No. 63761-5 EPA Est. No. 21737-MN-01

Net Contents: _____

ACCEPTED
with COMMENTS
in EPA Letter Dated:

DEC 6 2007

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

63761-5

4029

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

TREATMENT OF DENTAL UNIT WATER LINES

Important Notice:

Before using Sterilex Ultra please read the following information.

- 1. This product is to be used in conjunction with regular testing of dental unit water.
- 2. The manufacturer of the dental unit should be consulted before use of this product about compatibility of Sterilex Ultra with the dental unit.

- 1. Initial Start-Up Treatment: Treat the Dental Unit Water Lines (DUWL) for three consecutive nights.
- 2. Routine Treatment: Treat DUWL one night/week (Monday-Thursday recommended) after Initial Start-up treatment.

How To Apply Sterilex Ultra Powder:

- 1. At the end of the workday, add eight (8) ounces of **HOT** water to a Sterilex measuring cup or other empty container.
- 2. Add one packet of Sterilex Ultra to the hot water. Use stirrer to mix or swirl to dissolve. Be sure all powder is dissolved. Pour pink liquid into an empty external dental unit water bottle. Do not use PET Bottles (See note for bottle requirements). Use within 24 hours after powder has been dissolved in water.
- 3. Run Sterilex Ultra mixture through the system until the pink mixture appears at the end of the A/W Syringe and Handpiece Line. Always remove the Handpiece.
- 4. Allow the mixture to sit in the unit overnight (Place the ends of waterlines into a sink or cuspidor in case any pink mixture drips overnight).
- 5. At the beginning of the next workday, discard any remaining mixture in external water bottle. Rinse the external water bottle with hot water.
- 6. Fill the external water bottle with hot water. Flush each line (A/W Syringe, Handpiece) until the bottle is empty.

Note: Do Not Use Thin Walled Polyethylene Terephthalate (PETE) Bottles. We Recommend Either A High Density Polyethylene Bottle With A Minimum Thickness Of 0.08 Inches Or A High/Low Density Polyethylene Blend With A Minimum Thickness Of 0.14 Inches.

DISINFECTON of HARD NON-POROUS SURFACES

[REDACTED] - Cleaner

Staphylocidal – Pseudomonacidal – Salmonellacidal

Sterilex Ultra Powder is a hospital-use disinfectant at 50 grams per liter, Bactericidal according to the current AOAC Use-Dilution Test Method modified in the presence of 400 ppm hard water **[REDACTED]** against:

- (Bacteria:)
- Pseudomonas aeruginosa (Pseudomonas)(ATCC# 15442)*
- Staphylococcus aureus (Staph)(ATCC# 6538)*
- Salmonella choleraesuis (Salmonella)(ATCC# 10708)*

Sterilex Ultra Powder is for use on washable hard, nonporous surfaces in: hospitals, medical and dental offices, nursing homes, health care facilities, ultrasonic baths (ultrasonic cleaning units), federally inspected food processing facilities, federally inspected meat and poultry plants, wineries, breweries, beverage manufacturing facilities, dairy farms, swine farms, poultry and turkey farms, farm premises,

5089

hatcheries, refrigerated trucks, kennels, pet animal quarters, zoos, pet shops, animal laboratories, veterinary facilities, animal care facilities, transportation terminals, hotels and motels, factories, business and office buildings, barber shops, salons, boats, ships, campers, trailers, mobile homes, homes, kitchens, bathrooms, household areas, cars, buses, trains, taxis, airplanes, restaurants, bars, cafeterias, institutional kitchens, food preparation and storage areas, convenience stores, food storage areas, public rest rooms, institutions, schools and colleges, athletic facilities, locker rooms, dressing rooms, shower and bath areas, and exercise equipment.

Sterilex Ultra Powder is for use on the following washable hard, nonporous surfaces:

Medical machines (x-ray, MRIs, CAT scanners), noncritical medical devices and equipment surfaces (that do not penetrate the body or contact the human bloodstream or mucous membranes);

Steam sterilizer water reservoirs, steam sterilizer water reservoir tubing;

Water reservoir tanks, water reservoir pipes, tanks, and piping systems used in food processing;

Floors, walls, countertops, stovetops, sinks, appliances, refrigerators, plastic and other nonporous cutting boards and chopping blocks; coolers, ice chests; non residential refrigerator bins for meat, fruit, vegetable and egg; food processing equipment (k-pac equipment, injectors, slicers, knives, steel mesh gloves, deboners, saws, grinders, cutters, racks, dairy equipment, interlocking belts, outside surfaces of kitchen equipment; beer fermentation and holding tanks, brewery pasteurizers, wine fermentation tanks, beverage dispensing equipment, beverage transfer lines, bottling or premix dispensing equipment);

Drinking water coolers, ice making machines, transfer line tubing, water lines, watering systems, farm animal nipple drinkers;

Cabinets, highchairs, garbage cans, garbage storage areas, refrigerated storage and display equipment, tables, picnic tables, outdoor furniture, chairs, desks, telephones, doorknobs, shower stalls, tubs and glazed tiles, whirlpool bathtubs, bathtubs, sinks, urinals, exterior toilet bowl surfaces, other bathroom fixtures;

Kennel runs, cages, waterers and feeders, automatic feeders, hauling equipment, dressing plants, loading equipment, farrowing barns and related areas (nursery blocks, creep areas), chutes, feed racks, mangers, troughs, fountains and waterers, forks, shovels, scrapers, barns, pens, stalls, facilities and fixtures occupied or traversed by animals, hatchery areas (egg receiving and holding, setter room, tray dumping, chick holding, processing and loading), trays, buggies, racks, egg flats, poultry buildings, ceilings, sidewalls and floors, drinkers and other poultry house related equipment;

Coils and drain pans of air conditioning and refrigeration equipment and heat pumps, conductive flooring;

Nonporous salon/barber tools and instruments (combs, brushes, scissors, blades, pedicure and manicure instruments, pedicure and manicure tubs);

Hard nonporous surfaces, listed on this label, that are made of metal, stainless steel, glazed porcelain, glazed ceramic, sealed stone, hard fiberglass, plastic (such as polystyrene, polypropylene), glazed porcelain tiling, enameled surfaces, finished/sealed and painted woodwork, finished floors, Formica®, vinyl and plastic upholstery.

DISINFECTION IN HOSPITALS, MEDICAL OFFICES, DENTAL OFFICES, DENTAL OPERATORIES, NURSING HOMES AND OTHER HUMAN HEALTH CARE FACILITIES:

NOTE:

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or

leaf 9

normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

APPLICATION INSTRUCTIONS:

- 1) Add 50 g of **Sterilex Ultra Powder** to 1 liter tap water in an appropriate plastic container and stir. Be sure all powder is dissolved.
- 2) Thoroughly wet surfaces with use-solution by pouring, wiping, brushing, scrubbing, spraying with a coarse trigger sprayer, sponging, using a clean in place (CIP) system, pumping it through the system, drawing it through the system or mopping.
- 3) Allow surfaces to remain wet for at least 10 minutes
- 4) Rinse all surfaces thoroughly with a potable water rinse.

PRECLEANING INSTRUCTIONS

~~Sterilex Ultra Powder provides one step cleaning and disinfection, pre-cleaning may be desired.~~

- 1) Prepare a precleaning solution by adding 1 – 25 g of **Sterilex Ultra Powder** to 1 liter hot tap water in an appropriate plastic container, depending on the level of gross filth to be precleaned.
- 2) Clean surfaces with precleaning solution by pouring, wiping, brushing, scrubbing, spraying with a coarse trigger sprayer, sponging, immersing, using a clean in place (CIP) system, pumping it through the system, drawing it through the system or mopping.
- 3) Rinse all surfaces thoroughly with a potable water rinse.

INSTRUMENT PRE-SOAK:

For use as an instrument pre-soak, prepare a solution by adding 50 g of **Sterilex Ultra Powder** to 1 liter tap water in an appropriate plastic container and stir. Immerse instruments completely and allow to soak for 10 minutes. Rinse all surfaces thoroughly with a potable water rinse. Instruments must undergo high-level disinfection or sterilization following pre-soak treatment.

DISINFECTION IN ULTRASONIC BATHS:

NOTE:

Use **Sterilex Ultra Powder** to disinfect hard nonporous non-critical objects compatible with Ultrasonic Cleaning Units.

APPLICATION INSTRUCTIONS:

- 1) Pre-clean heavily soiled objects following the PRECLEANING INSTRUCTIONS below.
- 2) Add 50 g of **Sterilex Ultra Powder** to 1 liter tap water in an appropriate plastic container and stir.
- 3) Pour fresh use-solution directly into bath chamber.
- 4) Place objects into unit and operate for a minimum of 10 minutes, according to the manufacturer's directions.
- 5) Remove objects and wash with sterile water (sterile water for injection) and allow to air dry.
- 6) Prepare fresh solution for each use.

PRECLEANING INSTRUCTIONS

~~Sterilex Ultra Powder provides one step cleaning and disinfection, pre-cleaning may be desired.~~

- 1) Prepare a precleaning solution by adding 1 – 25 g of **Sterilex Ultra Powder** to 1 liter hot tap water in an appropriate plastic container, depending on the level of gross filth to be precleaned.
- 2) Clean surfaces with precleaning solution by pouring, wiping, brushing, scrubbing, spraying with a coarse trigger sprayer, sponging, immersing, pumping it through the system, or drawing it through the system.
- 3) Before disinfecting rinse all surfaces thoroughly with a potable water rinse.

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DISINFECTION OF FOOD PROCESSING EQUIPMENT AND HARD SURFACES IN FOOD PROCESSING FACILITIES, BREWERIES, WINERIES AND OTHER BEVERAGE MANUFACTURING FACILITIES, RESTAURANTS, BARS, CAFETERIAS, INSTITUTIONAL KITCHENS, CONVENIENCE STORES FOOD PREPARATION AREAS, FOOD STORAGE AREAS AND FOOD SERVICE AREAS:

NOTE:

Before use in federally inspected meat and poultry food processing plants and dairies, food products and packaging materials must be removed from the room or carefully protected. Follow all applicable local health and sanitation codes for sanitizing food processing equipment post-disinfection.

APPLICATION INSTRUCTIONS FOR SURFACES:

- 1) Remove gross food particles and soil from all articles using a pre-flush, or pre-scrape and, if necessary, presoak.
- 2) Add 50 g of **Sterilex Ultra Powder** to 1 liter tap water in an appropriate plastic container and stir.
- 3) Thoroughly wet surfaces with use-solution by pouring, wiping, brushing, scrubbing, spraying with a coarse trigger sprayer, sponging, immersing, using a clean in place (CIP) system, pumping it through the system, drawing it through the system or mopping.
- 4) Allow surfaces to remain wet for at least 10 minutes
- 5) Rinse all surfaces thoroughly with a potable water rinse.

PRECLEANING INSTRUCTIONS ()::

~~Always clean and disinfect equipment before cleaning and disinfection. Precleaning may be required for some equipment.~~

- 1) Prepare a precleaning solution by adding 1-25 g of **Sterilex Ultra Powder** to 1 liter hot tap water in an appropriate plastic container, depending on the level of gross filth to be precleaned.
- 2) Clean surfaces with precleaning solution to by pouring, wiping, brushing, scrubbing, spraying with a coarse trigger sprayer, sponging, immersing, using a clean in place (CIP) system, pumping it through the system, drawing it through the system or mopping.
- 3) Before disinfecting rinse all surfaces thoroughly with a potable water rinse.

APPLICATION INSTRUCTIONS FOR TRANSFER LINES:

- 1) Add 50 g of **Sterilex Ultra Powder** to 1 liter tap water in an appropriate plastic container and stir.
- 2) Introduce use solution into transfer lines and tanks.
- 3) Soak or circulate use solution for at least 10 minutes.
- 4) Drain transfer lines.
- 5) Rinse all surfaces thoroughly with a potable water rinse.

DISINFECTION OF VETERINARY FACILITIES, ANIMAL CARE FACILITIES, ANIMAL LABORATORIES, ZOOS, PET SHOPS, KENNELS AND ANIMAL QUARTERS, FARM AND DAIRY FARM PREMISES, POULTRY AND SWINE PREMISES, FARM AND DAIRY FARM PREMISE EQUIPMENT, POULTRY AND SWINE PREMISE EQUIPMENT AND HATCHERIES.

- 1) Remove all animals and feed from premises, vehicles, and enclosures.
- 2) Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals.
- 3) Empty all troughs, racks, and other feeding and watering appliances.
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water or follow

PRECLEANING INSTRUCTIONS below.

- 5) Saturate all surfaces with a solution prepared by adding 50 g of **Sterilex Ultra Powder** to 1 liter tap water in an appropriate plastic container and stirring.
- 6) Thoroughly wet surfaces with use-solution by pouring, wiping, brushing, scrubbing, spraying with a coarse trigger sprayer, sponging, using a clean in place (CIP) system, pumping it through the system, drawing it through the system or mopping. The use-solution can be used to disinfect hatchers, setters, trays, racks, carts, sexing tables, delivery trucks and other hard surfaces in

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hatcheries. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.

- 7) Allow surfaces to remain wet for at least 10 minutes
- 8) Rinse all surfaces thoroughly with a potable water rinse.
- 9) Ventilate buildings, cars, boats, and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed, set, or dried.
- 10) Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

APPLICATION INSTRUCTIONS FOR TRANSFER LINES:

- 1) Add 50 g of **Sterilex Ultra Powder** to 1 liter tap water in an appropriate plastic container and stir.
- 2) Introduce use solution into transfer lines and tanks for watering systems and nipple drinkers.
- 3) Soak or circulate use solution for at least 10 minutes.
- 4) Drain transfer lines and tanks.
- 5) Rinse all surfaces thoroughly with a potable water rinse.

PRECLEANING INSTRUCTIONS (OPTIONAL STEP):

[REDACTED]

- 1) Prepare a precleaning solution by adding 1-25 g of **Sterilex Ultra Powder** to 1 liter hot tap water in an appropriate plastic container, depending on the level of gross filth to be precleaned.
- 2) Clean surfaces with precleaning solution to by pouring, wiping, brushing, scrubbing, spraying with a coarse trigger sprayer, sponging, immersing, using a clean in place (CIP) system, pumping it through the system, drawing it through the system or mopping.
- 3) Before disinfecting rinse all surfaces thoroughly with a potable water rinse.

DISINFECTION IN REFRIGERATED TRUCKS AND OTHER VEHICLES, INSTITUTIONS, INDUSTRIAL FACILITIES, SCHOOLS, ATHLETIC FACILITIES, REST ROOMS, HOTELS, MOTELS, OFFICE BUILDINGS AND OTHER PUBLIC AREAS, AND HOUSEHOLDS:

APPLICATION INSTRUCTIONS:

- 1) Add 50 g of **Sterilex Ultra Powder** to 1 liter tap water in an appropriate plastic container and stir.
- 2) Thoroughly wet surfaces with use-solution by pouring, wiping, brushing, scrubbing, spraying with a coarse trigger sprayer, sponging, using a clean in place (CIP) system, pumping it through the system, drawing it through the system or mopping. Clean all areas of vehicles, including mats, crates, cabs and wheels.
- 3) Allow surfaces to remain wet for at least 10 minutes.
- 4) Rinse all surfaces thoroughly with a potable water rinse.

PRECLEANING INSTRUCTIONS [REDACTED]

[REDACTED]

- 1) Prepare a precleaning solution by adding 1-25 g of **Sterilex Ultra Powder** to 1 liter hot tap water in an appropriate plastic container, depending on the level of gross filth to be precleaned.
- 2) Clean surfaces with precleaning solution to by pouring, wiping, brushing, scrubbing, spraying with a coarse trigger sprayer, sponging, immersing, using a clean in place (CIP) system, pumping it through the system, drawing it through the system or mopping.
- 3) Before disinfecting rinse all surfaces thoroughly with a potable water rinse.

DISINFECTION OF SALON (BARBER) INSTRUMENTS AND TOOLS:

APPLICATION INSTRUCTIONS:

- 1) Add 50 g of **Sterilex Ultra Powder** to 1 liter tap water in an appropriate plastic container and stir.
- 2) Completely immerse combs, brushes, rollers, manicure and other hard, nonporous salon instruments and tools for 10 minutes.
- 3) Allow surfaces to remain wet for at least 10 minutes.

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- 4) Rinse all thoroughly with potable water and dry before use.
- 5) Fresh solution should be prepared daily or more often if solution becomes diluted or soiled.

NOTE:

Plastics may remain immersed until ready to use. Stainless steel shears and instruments must be removed after 10 minutes, rinsed, dried and kept in a clean, non-contaminated receptacle. Prolonged soaking may cause damage to metal instruments.

PRECLEANING INSTRUCTIONS

~~Through the Ultra Powder provides one step cleaning and disinfecting for all surfaces. It is not intended for use on metal instruments.~~

- 1) Prepare a precleaning solution by adding 1-25 g of **Sterilix Ultra Powder** to 1 liter hot tap water in an appropriate plastic container, depending on the level of gross filth to be precleaned.
- 2) Clean surfaces with precleaning solution to by pouring, wiping, brushing, scrubbing, spraying with a coarse trigger sprayer, sponging or immersing.
- 3) Before disinfecting rinse all surfaces thoroughly with a potable water rinse.

PRECAUTIONARY STATEMENTS

Hazard To Humans And Domestic Animals.

DANGER. Corrosive. Causes irreversible eye damage and skin burns. Harmful if swallowed or absorbed through skin. Wear protective eyewear (goggles and/or face shield), protective clothing and waterproof gloves. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

WHEN POWDER IS DILUTED: Causes moderate eye irritation. Harmful if absorbed through skin or inhaled. Avoid breathing vapor. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse

FIRST AID

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. 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 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.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

STORAGE AND DISPOSAL

STORAGE: Keep out of children's reach. Store at room temperature out of direct sunlight, DO NOT store about 30°C (or 86°F).

DISPOSAL: Do not reuse empty pouch, discard in trash.

Made in USA