

63761-5

7/13/2006

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JUL 13 2006

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 labels as follows:

- 1) Revise the claim, "Sterilex Ultra Powder is a hospital use disinfectant ..... plus 5% organic serum: by deleting the phrase, "plus organic serum." The submitted study to support the disinfection claim was not conducted using an organic soil load. Also, you must delete the phrase (OPTIONAL STEP)" from the disinfecting directions.
- 2) The disinfection directions must be reorganized such that the "Pre-Cleaning" Instructions precede the "Disinfection" directions. Therefore, revise the heading "Application Instructions" to read "Disinfection Directions."
- 3) Under "Instrument Presoak," revise the first statement to read "For use on critical and/or semicritical medical instruments as a presoak,....."
- 4) The active ingredient, sodium percarbonate, is only approved for medical/institutional, ornamental, and aquatic area uses. The proposed label includes a number of uses that fall into the broad category of commercial and industrial which are not currently supported for this ingredient. You will need to contact your active ingredient supplier and notify them of your intent to broaden the approved use patterns and ask them to provide us with a letter authorizing your intent. We will need a generic data matrix from your active ingredient supplier addressing

generic data requirements that would support your proposed uses. At this time, delete all the

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

proposed industrial and commercial use sites and surfaces as well as applicable directions as follows:

Delete all of the text on pages 5 and 6. Delete the sections which are blacked out on pages 2 and 3 of the enclosed stamped label.

General Comments

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

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

Sincerely,

*Tracy Jantz*

for

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

Enclosure: Stamped Label

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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(C <sub>14</sub> 95%, C <sub>12</sub> 3%, C <sub>16</sub> 2%)	
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**

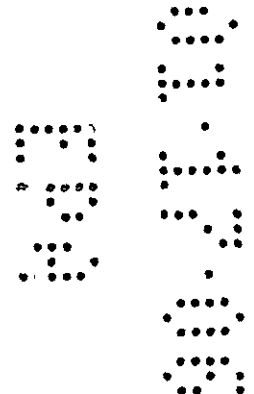
**www.sterilex.com**

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

**Net Contents:** \_\_\_\_\_

ACCEPTED  
with COMMENTS  
JUL 13 2006

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 63761-5



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**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.

**DISINFECTATION of HARD NON-POROUS SURFACES**

One-Step Disinfectant - 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 plus 5% organic serum 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), ~~inspected food processing facilities, federally inspected meat and poultry plants, swimming pools,~~

[REDACTED]

**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);

[REDACTED]

[REDACTED]

Floors, walls, countertops, [REDACTED] sinks, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] 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

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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 (OPTIONAL STEP):**

Although **Sterilex Ultra Powder** provides one-step cleaning and disinfection, precleaning may be desired for some surfaces in certain cases.

- 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 (OPTIONAL STEP):**

Although **Sterilex Ultra Powder** provides one-step cleaning and disinfection, precleaning may be desired for some surfaces in certain cases.

- 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.



atcheries. 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 live stock 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):**

Although **Sterilex Ultra Powder** provides one-step cleaning and disinfection, precleaning may be desired for some surfaces in certain cases.

- 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 (OPTIONAL STEP):**

Although **Sterilex Ultra Powder** provides one-step cleaning and disinfection, precleaning may be desired for some surfaces in certain cases.

- 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.



**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 facilities, 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 (OPTIONAL STEP)**

Although **Sterilex Ultra Powder** provides one step cleaning and disinfection, precleaning may be desired for some surfaces in certain cases.

- 1) Prepare a precleaning solution by adding 1-2% 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) 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, ZOO, 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, crates, 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