NOTICE OF PESTICIDE:
   X  Registration
   ___ Re-registration

(under FIFRA, as amended)

Name of Pesticide Product:
Sterilex Ultra Disinfectant Cleaner Solution 1

Name and Address of Registrant (include ZIP code):
Sterilex Corporation
11409 Cronhill Drive Suite L
Owings Mills, MD 21117

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA Section 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA Section 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA Section 4.

2. Make the following labeling change:
   a. Revise the EPA Registration Number to read, "EPA Reg. No. 63761-8".
   b. Submit three copies of a final Master Label by 6/1/05.

Signature of Approving Official:
Marshall Swindell, Product Manager, Team 33, Regulatory Management Branch I, Antimicrobials Division

Date: APR 12 2005
3. Submit the missing one year storage stability (830.6317) and corrosion characteristics (830.6320) studies by 12/31/05. These studies are to be conducted under GLP guidelines.

If these 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 constitutes acceptance of these conditions.

A stamped copy of the label stamped "Accepted" is enclosed for your records.

If you have any questions concerning this letter, please contact myself at 703-308-6341, or Tony Kish at (703) 308-9443.

Sincerely,

[Signature]

Marshall Swindell
Product Manager 33
Regulatory Management Branch 1
Antimicrobial Division(7510C)

Enclosure
Sterilex Ultra Disinfectant Cleaner Solution 1

This is part one of a two-part product. This product must be used with Sterilex Ultra Activator Solution. Please consult the directions for use for specific instructions.

One-Step Disinfectant - Cleaner

Staphylocidal – Pseudomonacidal – Salmonellacidal – Listericidal - Kills E. Coli

Active Ingredients:
- n-Alkyl (C12 68%, C14 32%) dimethylethylbenzyl ammonium chloride 3.00%
- n-Alkyl (C14 60%, C16 30%, C12 5%, C18 5%) dimethylethylbenzyl ammonium chloride 3.00%
- Hydrogen peroxide 6.30%

Inert Ingredients:

TOTAL: 100.00%

KEEP OUT OF REACH OF CHILDREN
DANGER
SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

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 eye.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes.

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.

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 the poison control center or doctor. Do not give anything by mouth to an unconscious person.

Call a Poison Control Center or doctor for treatment advice. Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: Corrosive. Causes irreversible eye damage and skin burns. May be fatal if inhaled. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Do not breathe vapor or spray mist. Wear goggles and/or face shield, protective clothing and rubber gloves when handling. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove contaminated clothing and wash clothing before reuse. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant 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 notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

PHYSICAL AND CHEMICAL HAZARDS

When exposed to fire, Sterilex Ultra Disinfectant Cleaner Solution 1 may release oxygen and oxides of carbon and/or nitrogen.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE 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 or mixture or rinseate 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 and triple rinse container into application equipment. Dispose of empty container in a sanitary landfill, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

DIRECTIONS FOR USE

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

Sterilex Ultra Disinfectant Cleaner Solution 1 is part one of a two-part product. This product must ALWAYS be used in conjunction with Sterilex Ultra Activator Solution.

Sterilex Ultra Disinfectant Cleaner Solution 1, when mixed with Sterilex Ultra Activator Solution, is a one-step, hospital-use disinfectant at 12.8 fl. oz. per gallon. Bactericidal according to the current AOAC 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)
  - Enterobactera coli 0157:H7 (ATCC# 35150)
  - Listeria monocytogenes (ATCC# 19111)

Sterilex Ultra Disinfectant Cleaner Solution 1, when mixed with Sterilex Ultra Activator Solution, 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, 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, restaurants, bars, cafeteria's, 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 Disinfectant Cleaner Solution 1**, when mixed with Sterilex Ultra Activator Solution, 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, sidewalks 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 tubes);

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 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 12.8 fl. oz. of **Sterilex Ultra Disinfectant Cleaner Solution 1** and 12.8 fl. oz. of Sterilex Ultra Activator Solution to 1 gal. tap water in an appropriate plastic container and stir. 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 Disinfectant Cleaner Solution 1 provides one-step cleaning and disinfection, precleaning may be desired for some surfaces in certain cases.

1) Prepare a precleaning solution by adding 3 - 6 fl. oz. of Sterilex Ultra Disinfectant Cleaner Solution 1 and an equivalent amount of Sterilex Ultra Activator Solution to 1 gal. 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 12.8 fl. oz. of Sterilex Ultra Disinfectant Cleaner Solution 1 and 12.8 fl. oz. of Sterilex Ultra Activator Solution to 1 gal. 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 Disinfectant Cleaner Solution 1 to disinfect hard nonporous non-critical objects compatibly with Ultrasonic Cleaning Units.

APPLICATION INSTRUCTIONS:
1) Pre-clean heavily soiled objects following the PRECLEANING INSTRUCTIONS below.
2) Add 12.8 fl. oz. of Sterilex Ultra Disinfectant Cleaner Solution 1 and 12.8 fl. oz. of Sterilex Ultra Activator Solution to 1 gal. 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) or allow to air dry.
6) Prepare fresh solution for each use.

PRECLEANING INSTRUCTIONS (OPTIONAL STEP):
Although Sterilex Ultra Disinfectant Cleaner Solution 1 provides one-step cleaning and disinfection, precleaning may be desired for some surfaces in certain cases.

1) Prepare a precleaning solution by adding 3 - 6 fl. oz. of Sterilex Ultra Disinfectant Cleaner Solution 1 and an equivalent amount of Sterilex Ultra Activator Solution to 1 gal. 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.

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 12.8 fl. oz. of Sterilex Ultra Disinfectant Cleaner Solution 1 and 12.8 fl. oz. of Sterilex Ultra Activator Solution to 1 gal. 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 Disinfectant Cleaner Solution 1 provides one-step cleaning and disinfection, precleaning may be desired for some surfaces in certain cases.
1) Prepare a precleaning solution by adding 3 - 6 fl. oz. of Sterilex Ultra Disinfectant Cleaner Solution 1 and an equivalent amount of Sterilex Ultra Activator Solution to 1 gal. 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 12.8 fl. oz. of Sterilex Ultra Disinfectant Cleaner Solution 1 and 12.8 fl. oz. of Sterilex Ultra Activator Solution to 1 gal. 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 12.8 fl. oz. of Sterilex Ultra Disinfectant Cleaner Solution 1 and 12.8 fl. oz. of Sterilex Ultra Activator Solution to 1 gal. 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 hatcheries. Immerse all hatchers, 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 12.8 fl. oz. of Sterilex Ultra Disinfectant Cleaner Solution 1 and 12.8 fl. oz. of Sterilex Ultra Activator Solution to 1 gal. 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):
Sterilex Ultra Disinfectant Cleaner Solution 1

Revised 12 April 2005/ Page 5 of 6
Although Sterilex Ultra Disinfectant Cleaner Solution 1 provides one-step cleaning and disinfection, precleaning may be desired for some surfaces in certain cases.

1) Prepare a precleaning solution by adding 3 - 6 fl. oz. of Sterilex Ultra Disinfectant Cleaner Solution 1 and an equivalent amount of Sterilex Ultra Activator Solution to 1 gal. 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.

DISINFECTION OF 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 12.8 fl. oz. of Sterilex Ultra Disinfectant Cleaner Solution 1 and 12.8 fl. oz. of Sterilex Ultra Activator Solution to 1 gal. hot 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 Disinfectant Cleaner Solution 1 provides one-step cleaning and disinfection, precleaning may be desired for some surfaces in certain cases.

1) Prepare a precleaning solution by adding 3 - 6 fl. oz. of Sterilex Ultra Disinfectant Cleaner Solution 1 and an equivalent amount of Sterilex Ultra Activator Solution to 1 gal. 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.

DISINFECTION OF SALON (BARBER) INSTRUMENTS AND TOOLS:

APPLICATION INSTRUCTIONS:

1) Add 12.8 fl. oz. of Sterilex Ultra Disinfectant Cleaner Solution 1 and 12.8 fl. oz. of Sterilex Ultra Activator Solution to 1 gal. 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.

4) Rinse all surfaces 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 (OPTIONAL STEP):

Although Sterilex Ultra Disinfectant Cleaner Solution 1 provides one-step cleaning and disinfection, precleaning heavily soiled instruments and tools may be desired for some surfaces in certain cases.

1) Prepare a precleaning solution by adding 3 - 6 fl. oz. of Sterilex Ultra Disinfectant Cleaner Solution 1 and an equivalent amount of Sterilex Ultra Activator Solution to 1 gal. 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 or immersing.

3) Before disinfecting rinse all surfaces thoroughly with a potable water rinse.