

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

AUG 2 3 2007.
OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Ms. April Zambelli-Weiner Senior Scientist for, Sterilex Corporation 11409 Cronhill Drive Suite L Ownings Mills, MD 21117

RECEIVED AUG 2 7 2002

Subject: Sterilex Ultra Disinfectant Cleaner Solution 1

EPA Registration Number 63761-8

Your Amendment Dated March 17th, 2007 EPA Received Date March 30th, 2007

The amendment referred to above, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended, to add use sites, directions for use, and additional labeling claims, is acceptable.

The submitted efficacy data (MRID No. 471145-01) support the use of the product, Sterilex Ultra Disinfectant Cleaner Solution combined with Sterilex Ultra Cleaner Solution 2 and diluted in 10.0 ml of 400 ppm hard, water as a disinfectant with bactericidal activity against Staphylococcus aureus-Methicillin Resistant on hard, non-porous surfaces in the presence of a 5% organic soil load for a contact time of 10 minutes at 20 degrees Celsius.

The submitted efficacy data (MRID No. 471145-01) support the use of the product, Sterilex Ultra Cleaner Solution 1 combined with Sterilex Ultra Cleaner Solution 2, and diluted in 10.0 ml of 400 ppm hard water, as fungicide against Aspergillus niger, when used on hard, non-porous surfaces for a contact time of 10 minutes in the presence of 5% organic soil load at room temperature 20 degrees Celsius.

The proposed label claims that the product, Sterilex Ultra Disinfectant Cleaner Solution 1 (one part) combined with Sterilex Ultra Disinfectant Cleaner Solution 2 (one part) and diluted in 10 parts of water, removes biofilm from dental unit lines, are acceptable.

Please note that the species name of these organisms (Salmonella choleraesius) has been changed by ATCC. The new designation of this organism is Salmonella enterica. The change is effective immediately, and should be used for all subsequent references to this organism in the future.

A stamped copy of the labeling is enclosed. Submit three (3) copies of your final printed labeling 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.

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely,

Marshall Swindell Product Manager 33

Regulatory Management Branch I Antimicrobial Division(7510P)

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 – Virucidal – Fungistat/Mildewstat

Effective against mycotoxin-producing molds

Removes* Biofilm From Dental Unit Water Lines

"laboratory studies show >90% removal

Kills/inactivates:

E. Coli

Avian Influenza

Zygosaccharomyces bailii

Asperallius niger

ACCEPTED with COMMENTS in EPA Letter Doted:

AUG 2 3 2007

Under the Federal Insecticids Pungicide, and Rodenticide Act an amended, for the pesticide, registered under EPA Reg. No.

Active Ingredients:

n-Alkyl (C12 68%, C14 32%) dimethylethylbenzyl ammonium chloride

n-Alkyl (C14 60%, C16 30%, C12 5%, C18 5%) dimethylbenzyl ammonium chloride

Hydrogen peroxide

Inert Ingredients:

TOTAL:

100.00%

6.30%

87.70%

3.00% 3.00%

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 -

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

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.

EPA Reg. No. 63761-8 EPA Est. No. 4875-NJ-001

Net Contents (insert container size here)

Manufactured by Sterilex Corporation 11409 Cronhill Drive Suite L Owings Mills, MD 21117 phone 1-800-511-1659, fax 410-581-8864

With COMMENTS in EPA Letter Dated:

AUG 2 3 2007

Under the Federal Insecticide.

Pungicide and Reference Act as amended, for the pessicide.

registered under EPA Reg. No. 637-67-8

PRECAUTIONARY STATEMENTS 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 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 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.

DISINFECTION

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. (each, Solution 1 & Solution 2) per gallon of water (1:1:10), 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)
Staphylococcus aureus – Methicillin Resistant (ATCC#33591) (MRSA)
Salmonella choleraesuis (Salmonella)(ATCC# 10708)
Escherichia coli O157:H7 (ATCC# 35150)
Listeria monocytogenes (ATCC# 19111)

Sterilex Ultra Disinfectant Cleaner Solution 1 (63761-8)

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SPOILAGE ORGANISMS

Sterilex Ultra Disinfectant Cleaner Solution 1, when mixed with Sterilex Ultra Activator Solution kills Zygosaccharomyces bailii on hard, inanimate surfaces in one step at 4 fl. oz. (each, Solution 1 & Solution 2) per gallon of water (1:1:32), according to the current AOAC Use-Dilution Test Method modified in the presence of 400 ppm hard water plus 5% organic serum. Apply as directed under disinfection.

Sterilex Ultra Disinfectant Cleaner Solution 1, when mixed with Sterilex Ultra Activator Solution is effective against Avian Influenza A (H3N2: Avian Reassortant) on hard, inanimate surfaces in one step at 2 fl. oz. (each, Solution 1 & Solution 2) per gallon of water (1:1:64), with a 5 minute contact time in the presence of 400 ppm hard water and organic soil. Apply as directed under disinfection.

FUNGISTAT/MILDEWSTAT

Sterilex Ultra Disinfectant Cleaner Solution 1, when mixed with Sterilex Ultra Activator Solution controls the growth of mold and mildew organisms (Aspergillus niger, ATCC#16404) and the odors they cause on hard, nonporous surfaces in one step at 12.8 fl. oz. (each, Solution 1 & Solution 2) per gallon of water (1:1:10) according to the current AOAC Use-Dilution Test Method modified in the presence of 400 ppm hard water plus 5% organic serum. Apply as directed under disinfection.

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, 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, sports facilities, gym rooms, locker rooms, dressing rooms, shower and bath areas, exercise equipment, large; inflatable, non-porous plastic and rubber structures (animals, promotional items, moonwalk, slides, obstacle course play equipment, exercise equipment and wrestling mats.

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 suffer scanners penetrate the body or contact the human bloodstream or mucous membranes. AUG 2 3 2007.

Steam sterilizer water reservoirs, steam sterilizer water reservoir tubing:

Water reservoir tanks, water reservoir pipes, tanks, and piping systems used in food processing and to the posticide.

Pungicide, and Rodenticide Act as registered under EPA Reg. No.

Floors, walls, countertops, stovetops, sinks, appliances, refrigerators (exteriors), plastic and other nonporous cutting boards and chopping blocks; coolers, ice chests; non residential refrigerator bins (exteriors) 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 (exteriors), tables, picnic tables (non-wooden and finished/sealed or painted), outdoor furniture, chairs, desks, telephones,

Sterilex Ultra Disinfectant Cleaner Solution 1 (63761-8)

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Under the Federal insecticide

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 (bathtubs, tubs, shower stalls, and sinks), plastic (such as polystyrene, polypropylene), glazed porcelain tiling, enameled surfaces, finished/sealed and painted woodwork, finished floors, Formica®, vinyl and plastic upholstery.

Sterilex Ultra Disinfectant Cleaner Solution 1, when mixed with Sterilex Ultra Activator Solution, removes biofilm from dental unit water lines (laboratory studies show >90% removal).

Cross-contamination is a significant housekeeping concern. Sterilex Ultra Disinfectant Cleaner Solution 1, when mixed with Sterilex Ultra Activator Solution, has been formulated to reduce cross-contamination in households, hospitals, schools, industrial settings and institutions.

Sterilex Ultra Disinfectant Cleaner Solution 1, when mixed with Sterilex Ultra Activator Solution, is recommended for use in federally inspected meat and poultry plants and as a disinfectant in dressing plants.

Sterilex Ultra Disinfectant Cleaner Solution 1, when mixed with Sterilex Ultra Activator Solution, provides optimal non-acid cleaning performance.

Both effective and economical, Sterilex Ultra Disinfectant Cleaner Solution 1, when mixed with Sterilex Ultra Activator Solution, is a heavy-duty product that disinfects, cleans and deodorizes all in one labor-saving step.

Formulated for effective poultry premise sanitation

Formulated for effective swine premise sanitation

Formulated for effective farm premise use

Heavy duty bathroom cleaner, mildewstat, and deodorizer

With COMMENTS in EPA Letter Dated:

AUG 2 3 2007

Under the Rederal Insections
Finglicide, and Rodenticide Act as
amended, for the posticide,
registered under EPA Reg. No. 63

Quickly removes soap scum from shower tile, fiberglass, chrome and glass, toilet bowls, sinks, tubs and spas-

Sterilex Ultra Disinfectant Cleaner Solution 1, when mixed with Sterilex Ultra Activator Solution kills household germs in ten minutes; effective against harmful Pseudomonas aeruginosa (pseudomonas), Staphylococcus aureus (staph) and Streptococcus pyogenes (strep), while effectively controlling mold and mildew.

Sterilex Ultra Disinfectant Cleaner Solution 1, when mixed with Sterilex Ultra Activator Solution, cleans, disinfects and deodorizes surfaces by killing odor-causing microorganisms and preventing [inhibiting] [controlling] the growth of mold and mildew.

Sterilex Ultra Disinfectant Cleaner Solution 1, when mixed with Sterilex Ultra Activator Solution, inhibits the growth of mold and mildew, leaving bathrooms and kitchens clean and fresh smelling.

Sterilex Ultra Disinfectant Cleaner Solution 1 (63761-8)

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Sterilex Ultra Disinfectant Cleaner Solution 1, when mixed with Sterilex Ultra Activator Solution, eliminates odors caused by bacteria, mildew, and non-fresh foods.

Sterilex Ultra Disinfectant Cleaner Solution 1, when mixed with Sterilex Ultra Activator Solution, controls mold and mildew on large, inflatable, non-porous plastic and rubber structures (animals, promotional items, moonwalk, slides, obstacle course play equipment, exercise equipment and wrestling mats.

Sterilex Ultra Disinfectant Cleaner Solution 1, when mixed with Sterilex Ultra Activator Solution, cleans, disinfects and deodorizes surfaces in locker rooms, gym rooms and sports facilities by killing odor-causing microorganisms and preventing [inhibiting] [controlling] the growth of mold and mildew.

Removes* biofilm from dental unit water lines

"laboratory studies show >90% removal

Prevents and suppresses formation of biofilm in dental unit water lines

Kills biofilm bacteria

Maintains dental unit water line effluent water <500 cfu/ml

ACCEPTED
with COMMENTS
in EPA Letter Dated:

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

GENERAL CLEANING AND DISINFECTION (IN HOUSEHOLDS, ATHLETIC FACILITIES, REST ROOMS, VEHICLES, SCHOOLS/COLLEGES, PLAY AREAS, HOTELS/MOTELS, INSTITUTIONS):

APPLICATION INSTRUCTIONS:

1) Remove gross filth [soil] from all areas, articles and surfaces to be disinfected using a pre-clean, 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, 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 areas, articles and 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 (soil) 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.

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:

Sterilex Ultra Disinfectant Cleaner Solution 1 (63761-8)

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- 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) 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:

ACCEPTED WITH COMMENTS in EPA Letter Dated:

NOTE:

AUG 2 3 2007 Use Sterilex Ultra Disinfectant Cleaner Solution 1 to disinfect hard nonporous non-critical objects compatible with Ultrasonic Cleaning Units. Pangicide, and Rodenticide Act as amended, for the pesticide,

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:

Before use in federally inspected meat and poultry food processing plants and dairies, food products and packaging

Sterilex Ultra Disinfectant Cleaner Solution 1 (63761-8)

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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 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:

- with COMMENTS 1) Add 12.8 fl. oz. of Sterilex Ultra Disinfectant Cleaner Solution 1 and 12 12 12 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.

AUG 2 3 2007 Under the Federal insections Renaicide, and Rodenticide Act as amended, for the posteride. registered under EPA Fog No. 637-61-8

ACCEPTED

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

- 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. 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:

Sterilex Ultra Disinfectant Cleaner Solution 1 (63761-8)

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- 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):

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 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 POULTRY HOUSE PREMISES, POULTRY HOUSE EQUIPMENT AND HATCHERIES

- 1) Remove all poultry and feeds from premises, trucks, coops, and crates.
- 2) Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry.
- 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
- 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 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
- Allow surfaces to remain wet for at least 10 minutes.
- 8) Ventilate buildings, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set, or dried.
- 9) Thoroughly scrub treated feed racks, 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 ACCEPTED Solution to 1 gal. tap water in an appropriate plastic container and stir. with COMMERTING
- 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 Disinfectant Cleaner Solution 1 provides one-step cleaning and disinfection of the provides of the provides one-step cleaning and disinfection of the provides one-step cleaning and distinct and di 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 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.

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Sterilex Ultra Disinfectant Cleaner Solution 1 (63761-8)

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

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 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.

with COMMENTS

WATER AND SMOKE DAMAGE REMEDIATION AGAINST ODOR-CAUSING BACTERIA AND PENSING DOISOL: HOSPITAL, INSTITUTIONAL AND INDUSTRIAL AREAS:

AUG 2 3 2007 Under the Federal Insecticide Progicide, and Rodonnessis Act as amended, for the pesticide.

Revised March 17, 2007/ Pageragistered under EPA Rey. No.

Sterilex Ultra Disinfectant Cleaner Solution 1 (63761-8)

Sterilex Ultra Disinfectant Cleaner Solution 1, when mixed with Sterilex Ultra Activator Solution, is for use in water and smoke damage remediation to control odor causing bacteria and fungi on porous and semi-porous materials such as subflooring, drywall, lumber (trim and frame), tackless strip and paneling.

REMEDIATION PROCESS FOR SEWER BACKUP AND RIVER FLOODING:

- 1) Mix 12:8 fl. oz. (each, Solution 1 & Solution 2) per gallon of water, allowing for the dilution by absorbed water within the affected materials.
- 2) Remove gross filth, heavy soil and non-salvageable materials.
- 3) Saturate all affected materials directly with a sprayer using a coarse spray tip before and after cleaning and extraction.

REMEDIATION PROCESS FOR POROUS MATERIALS SUCH AS SUBFLOORING, DRYWALL, LUMBER (TRIM AND FRAME), TACKLESS STRIP AND PANELING:

- 1) If water damage is from a clean source, extract excess water from affected materials.
- 2) Mix 12.8 ft. oz. (each, Solution 1 & Solution 2) per gallon of water, allowing for the dilution by absorbed water within the affected materials.
- 3) Remove gross filth, heavy soil and non-salvageable materials.
- 4) Saturate all affected materials directly with a sprayer using a coarse spray tip.
- 5) Roll, brush or agitate use solution into affected materials and allow affected materials to remain saturated for ten minutes.
- 6) Follow with a thorough extraction of the affected materials to remove excess moisture.
- 7) Dry affected materials rapidly and thoroughly.

REMEDIATION PROCESS FOR SMOKE DAMAGE AGAINST ODOR CAUSING BACTERIA AND FUNGI IN HOSPITAL, INSTITUTIONAL AND INDUSTRIAL AREAS SUCH AS MOTELS, HOTELS, NURSING HOMES, AND SCHOOLS:

- 1) Follow applicable instructions outlined in the preceding sections for water damage remediation.
- 2) Saturate affected materials with the use solution with enough product to remain wet for 10 minutes.
- 3) Use proper ventilation during treatment of affected materials.

DISINFECTION OF DENTAL UNIT WATER LINES:

IMPORTANT:

Always use Sterilex Ultra Disinfectant Cleaner Solution 1 with Sterilex Ultra Activator Solution.

This product is to be used in conjunction with regular testing of dental unit water.

The manufacturer of the dental unit should be consulted before use of this product about compatibility of Sterilex Ultra Disinfectant Cleaner Solution 1 with the dental unit. ACCEPTED

INITIAL START-UP TREATMENT:

Treat the Dental Unit Water Lines (DUWL) for three consecutive nights starting on Monday.

ROUTINE TREATMENT: Treat DUWL one night/week (Monday-Thursday recommended) after Initial Start-up treatmentlugicide, and Recontacte Act as

Under the Federal Insecticide amended, for the pesticide. registered under EPA Reg. No.

WILL COMMENTS

in EPA Letter Dated:

AUG 2 3 2007

Note: If two or more weekly treatments are skipped, repeat initial start-up treatment.

HOW TO APPLY STERILEX ULTRA DISINFECTANT CLEANER SOLUTION 1 WITH STERILEX ULTRA **ACTIVATOR SOLUTION:**

1) Add 1 ounce of Sterilex Ultra Disinfectant Cleaner Solution 1 and one ounce of Sterilex Ultra Activator Solution and 10 ounces of water in a measuring cup or other empty container and stir. Pour appropriate amount of the combined mixture into an empty external dental unit water bottle. Do not use PET bottles. (See note below). After Sterilex Ultra Disinfectant Cleaner Solution 1 and Sterilex Ultra Activator Solution have been mixed together use within 24 hours.

2) Run Sterilex Ultra Solution through the system until the mixture appears at the end of the air/water syringes and handpiece lines. Always remove the handpiece. It may be advisable to remove coupler depending on the type of coupler. Contact manufacturer for specific recommendations.

Sterilex Ultra Disinfectant Cleaner Solution 1 (63761-8)

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3) Allow the Sterilex Ultra mixture to sit in the unit overnight (Place the ends of water lines into a sink or cuspidor in case any pink mixture drips overnight).

4) At the beginning of the next workday, discard any remaining Sterilex Ultra mixture. Rinse the external water bottle with water.

5) Fill the external water bottle with water. Flush each line (air/water syringe; handpiece lines) until the bottle is empty.

Note: Do Not Use Thin Walled Polyethylene Terephthalate (PET) 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.

WITH COMMENTS in EPN Letter Duted:

Under the Pederal Insecticide.

Rungicide, and Rodenticide Act as amended, for the posticide, registered under EPA Reg. No.