

63761-5

8/9/2013

1/17

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AUG 9 2013

Ms. Wendy A. McCombie
Agency for
Sterilex Corporation
111 Lake Front Drive
Hunt Valley, MD 21030

Subject: **Sterilex Ultra Power**
EPA Registration Number 63761-5
Notification Application Dated July 15, 2013
EPA Received Date July 15, 2013

Dear Ms. McCombie:

This will knowledge receipt of your notification, submitted under the provisions of FIFRA section 3c 9. Based on a review of the submitted material the following comment apply.

Proposed Amendment:

- Make minor changes to label

General Comments:

Based on a review of the material submitted, the following comment apply:

The notification is acceptable. A copy has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, please contact Drusilla Copeland at (703) 308-6224.

Sincerely,



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

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

2/14

 EPA United States Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other NOTIFICATION	OPP Identifier Number
--	--	-----------------------

Application for Pesticide - Section I

1. Company/Product Number 63761-5	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Sterilex Ultra Powder	PM# Team 31	
5. Name and Address of Applicant (Include ZIP Code) Sterilex Corporation 111 Lake Front Drive Hunt Valley, MD 21030 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

APPLICATION FOR NOTIFICATION: MINOR LABEL CHANGES

Notification of Minor Label Changes in Accordance With PR Notice 1998-10: See Cover Letter

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 95-2 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be the subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

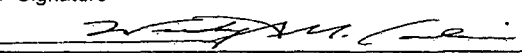
Signature: _____ Date: July 15, 2013

THIS SUBMISSION IS NOT SUBJECT TO PRIA FEES

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) <u>Fiber drums with plastic liner bags</u>	
*Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container <p style="text-align: center;">0.44oz. to 10 lbs</p>		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input checked="" type="checkbox"/> On labeling accompanying product	
6. Manner in Which Label is Affixed to Product		<input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input checked="" type="checkbox"/> Paper glued <input checked="" type="checkbox"/> Stenciled			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)			
Name Mark Wozniak (m.wozniak@sterilex.com)	Title Senior Scientist/ R&D Manager	Telephone No. (Include Area Code) (800) 511-1659 x 111	
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Agent for Sterilex Corporation	
4. Typed Name Wendy A. McCombie		5. Date <p style="text-align: center;">July 15, 2013</p>	



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 in dental unit water lines
- Maintains dental unit water line effluent water <500 cfu/ml

* Laboratory studies have shown >90% removal

Active Ingredients:

N-Alkyl(C ₁₄ 95%, C ₁₂ 3%, C ₁₆ 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] [side panel] [box] panel for [additional] [first aid] [and] precautionary statements

[Based off of] [Based on] [Including] [Includes] [Using] [patented] Perquat™ technology

Manufactured for
STERILEX CORPORATION
111 Lake Front Drive Hunt Valley, MD
Phone: 1-800-511-1659 Fax: 410-581-8864

Made in USA

EPA Reg. No. 63761-5
EPA Est. No. 21737-MN-01
EPA Est. No. 44636-CA-001
EPA Est. No. 67441-IL-001

[NET CONTENTS: _____] (*NOTE TO REVIEWER – this may be printed on container itself)
[LOT NUMBER: _____][BATCH NUMBER: _____] (*NOTE TO REVIEWER – this may be printed on container itself)

NOTIFICATION
Date Reviewed: 8/9/13
Reviewed By: PC

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 [0.44 ounces (12.5 grams)][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 (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.

DISINFECTATION OF HARD NON-POROUS SURFACES

One-Step Disinfectant – Cleaner

Sanitizer

Solid Floor Sanitizer

Staphylocidal – Pseudomonacidal – Salmonellacidal

Use within 24 hours after powder has been dissolved in water

Sterilex Ultra Powder is a hospital-use disinfectant at 0.42 lb per gallon (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 enterica (Salmonella) (ATCC# 10708)

6/14

SANITIZING OF INANIMATE SURFACES

Sterilex Ultra Powder eliminates 99.9% of the following bacteria in 5 minutes according to the Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces:

- Enterobacter aerogenese* (ATCC 13048)
- Staphylococcus aureus* (ATCC 6538)
- Escherichia coli* (ATCC 11229)
- Listeria monocytogenes* (ATCC 49594)

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, 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), appliances exterior, refrigerators exterior;

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.

GENERAL CLEANING AND DISINFECTION:

APPLICATION INSTRUCTIONS:

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. Mix 0.42 lbs Sterilex Ultra Powder per gallon of water [50 grams/liter]. Thoroughly wet surfaces by pouring, wiping, brushing, scrubbing, foaming, 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. Allow surfaces to remain wet for at least 10 minutes. Do not breathe spray. Rinse all surfaces thoroughly with a potable water rinse. Use within 24 hours after powder has been dissolved in water

PRECLEANING DIRECTIONS:

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 0.01 - 0.21 lb. of **Sterilex Ultra Powder** to 1 gal. tap water [1-25 g of **Sterilex Ultra Powder** to 1 liter 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, foaming, 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.

SANITIZING DIRECTIONS FOR NON-FOOD CONTACT SURFACES

Add a solution of 0.93 ounces Sterilex Ultra Powder per gallon of water [7 grams/liter] (or equivalent use dilution) to sanitize hard, non-porous surfaces. Apply sanitizer use solution to pre-cleaned, hard, non-porous surfaces with a cloth, mop, sponge, sprayer, foaming or by immersion. For sprayer applications, use a coarse pump or trigger sprayer. Spray 6-9 inches [15-22 cm] from surface and rub with brush sponge or cloth. Do not breathe spray. Treated surfaces must remain wet for 5 minutes, then wipe with sponge, mop or cloth or allow to air dry. Use within 24 hours after powder has been dissolved in water.

[For food processing or other facilities that have installed entryway sanitizing systems.]

ENTRYWAY SANITIZING SYSTEMS:

To prevent cross contamination of harmful organisms from area to area, set the entryway system to apply a solution of 0.93 ounces Sterilex Ultra Powder per gallon of water [7 grams/liter] (or equivalent use dilution). The entire doorway path must be covered with the [spray] [foam] [footbath]. Ensure a continuous wet blanket of sanitizer solution is delivered to the [floor] [bath]. Use within 24 hours after powder has been dissolved in water.

GLOVE DIP SANITIZING DIRECTIONS:

To prevent cross contamination into animal areas and the packaging and storage areas of food plants, dip pre-washed (plastic, latex or other synthetic rubber) non-porous gloved hands into a suitable clean container that contains enough freshly made sanitizing solution to cover the gloved area. Do not let sanitizing solution come into contact with the exposed skin. Make up the sanitizing solution by mixing 0.93 ounces Sterilex Ultra Powder per gallon of water [7 grams/liter] (or equivalent use dilution). Gloves must remain wet for 5 minutes. Change the sanitizing solution in the bath daily. **Do not let sanitizing solution come into contact with exposed skin.**

GLOVE SPRAY SANITIZER DIRECTIONS:

Gloves must be sanitized before wearing. To prevent cross contamination from area to area in animal areas and the packaging and storage areas of food plants, spray pre-washed (plastic, latex or other synthetic rubber) gloves with enough freshly made sanitizing solution to cover the gloves. Do not let

8/14

sanitizing solution come into contact with the exposed skin. Make up the sanitizing solution by adding 0.93 ounces Sterilex Ultra Powder per gallon of water [7 grams/liter] (or equivalent use dilution). Apply use solution prior to [usage] [wearing], using a coarse spray device, completely covering all glove surfaces. After applying solution, allow gloves to remain wet for at least 5 minutes. Let surface air dry thoroughly before wearing gloves. NO POTABLE WATER RINSE IS ALLOWED. [Change the solution] [A Fresh solution must be prepared] [Prepare a fresh solution] at least daily or [more often if use solution] [when solution appears] becomes visibly [dirty] [soiled] [diluted].

SANITIZATION OF HARD, NON-POROUS (INANIMATE) (ENVIRONMENTAL) SURFACES ON [(PERSONAL PROTECTIVE EQUIPMENT) (PPE)]:

[Add] [Mix] 0.93 ounces Sterilex Ultra Powder per gallon of water [7 grams/liter] (or equivalent use dilution). Gently mix for uniform solution. Apply solution to hard, non-porous [inanimate] [environmental] surfaces of the [Personal Protective Equipment] [PPE] with a brush, cloth, mop, sponge, auto scrubber, mechanical spray device, foam or by immersion. Thoroughly wet all surfaces to be sanitized. Treated surfaces must remain wet for five (5) minutes. Remove excess solution from equipment prior to storage. Change cloth, sponge or towels frequently to avoid redeposition of soil. [Change the solution] [A Fresh solution must be prepared] [Prepare a fresh solution] at least daily or [more often if use solution] [when solution appears] becomes visibly [dirty] [soiled] [diluted].

SHOE FOAM DIRECTIONS:

Apply a foam layer that is approximately 0.5 to 2 inches [1.2 cm to 5 cm] thick at all entrances using a foam generating machine or aerator and a solution containing 0.93 ounces Sterilex Ultra Powder per gallon of water [7 grams/liter] (or equivalent use dilution). Scrape waterproof shoes and boots. Walk through foamed. Boots must remain wet for at least 5 minutes prior to entering area. Foamed entranceways must be washed and the foam replaced at least daily or when it foam/area appears dirty. Foam should be applied to entrances of buildings, hatcheries, production and packaging rooms to prevent cross contamination from area to area in the packaging and storage areas of food plants. Use within 24 hours after powder has been dissolved in water

APPLICATION INSTRUCTIONS FOR USE AS A FLOOR SANITIZER:

After cleaning and sanitizing equipment, [apply] [sprinkle] [spread] Sterilex Ultra Powder evenly to the floor and drain surface, at a rate of 3.7 oz. [105 grams] per 100 square feet of floor surface containing 1.3 fl. oz. – 5.1 fl. oz. [38 ml – 150 ml] of processing water per square foot. Product may be re-applied as needed during the production process. Sterilex Ultra Powder does not become active until it comes in contact with moisture on the floor.

Sterilex Ultra Powder has been evaluated at a concentration that supports a dilution of 0.93 ounces/gallon [7 grams/liter] in the presence of 5% soil contamination and in waters up to 500ppm hardness (29.2 gpg calculated as CaCO3). Treated surfaces must remain wet for 5 minutes.

Sterilex Ultra Powder was evaluated using the Non-Food Contact Surface Sanitizer Test and was proven to be effective against the following organisms:

- | | |
|--|--|
| <i>Staphylococcus aureus</i> (ATCC 6538) | <i>Enterobacter aerogenes</i> (ATCC 13048) |
| <i>Escherichia coli</i> (ATCC 11229) | <i>Listeria monocytogenes</i> (ATCC 49594) |

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.

9/14

APPLICATION INSTRUCTIONS:

- 1) Add 0.42 lb. of **Sterilex Ultra Powder** to 1 gal. tap water [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, foaming, 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.
- Use product within 24 hours after powder has been dissolved in water.

INSTRUMENT PRE-SOAK:

For use as an instrument pre-soak, prepare a solution by adding 0.42 lb. of **Sterilex Ultra Powder** to 1 gal. tap water [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. Use product within 24 hours after powder has been dissolved in water.

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 on this label.
 - 2) Add 0.42 lb. of **Sterilex Ultra Powder** to 1 gal. tap water [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.
- Use product within 24 hours after powder has been dissolved in water.

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 0.42 lb. of **Sterilex Ultra Powder** to 1 gal. tap water [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, foaming, 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.
- Use product within 24 hours after powder has been dissolved in water.

APPLICATION INSTRUCTIONS FOR TRANSFER LINES:

- 1) Add 0.42 lb. of **Sterilex Ultra Powder** to 1 gal. tap water [50 g of **Sterilex Ultra Powder** to 1 liter tap

10/14

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.

Use product within 24 hours after powder has been dissolved in water.

PREPARATION OF NON-FOOD CONTACT SANITIZER USE SOLUTION:

For heavily soiled areas, a preliminary cleaning is required. [Add] [Mix] 0.93 ounces Sterilex Ultra Powder per gallon of water [7 grams/liter] (or equivalent use dilution). Apply sanitizer use solution to hard, nonporous [inanimate] [environmental] non-food contact surfaces with a brush, cloth, mop, sponge, auto scrubber, sprayer, coarse pump, foam or by immersion so as to thoroughly wet surface to be sanitized. For sprayer applications, spray 6-8 inches from surface. Do not breathe spray. Rub with brush, cloth, or sponge. Treated surfaces must remain wet for 5 minutes. [Rinse] [Wipe up excess liquid] [Allow to air dry]. Use product within 24 hours after powder has been dissolved in water.

[For food processing or other facilities that have installed entryway sanitizing systems.]

ENTRYWAY SANITIZING SYSTEMS:

To prevent cross contamination of harmful organisms from area to area, set the entryway system to apply a solution of 0.93 ounces Sterilex Ultra Powder per gallon of water (7 grams/liter) (or equivalent use dilution). The entire doorway path must be covered with the [spray] [foam] [footbath]. Ensure a continuous wet blanket of sanitizer solution is delivered to the [floor] [bath]. Use within 24 hours after powder has been dissolved in water.

GLOVE DIP SANITIZING DIRECTIONS:

To prevent cross contamination into animal areas and the packaging and storage areas of food plants, dip pre-washed (plastic, latex or other synthetic rubber) non-porous gloved hands into a suitable clean container that contains enough freshly made sanitizing solution to cover the gloved area. Do not let sanitizing solution come into contact with the exposed skin. Make up the sanitizing solution by mixing 0.93 ounces Sterilex Ultra Powder per gallon of water [7 grams/liter] (or equivalent use dilution). Gloves must remain wet for 5 minutes. Change the sanitizing solution in the bath daily. **Do not let sanitizing solution come into contact with exposed skin.**

GLOVE SPRAY SANITIZER DIRECTIONS:

Gloves must be sanitized before wearing. To prevent cross contamination from area to area in animals areas and the packaging and storage areas of food plants, spray pre-washed (plastic, latex or other synthetic rubber) gloves with enough freshly made sanitizing solution to cover the gloves. Do not let sanitizing solution come into contact with the exposed skin. Make up the sanitizing solution by adding 0.93 ounces Sterilex Ultra Powder per gallon of water [7 grams/liter] (or equivalent use dilution). Apply use solution prior to [usage] [wearing] using a coarse spray device, completely covering all glove surfaces. After applying solution, allow gloves to remain wet for at least five minutes. Let surface air dry thoroughly before wearing gloves. **NO POTABLE WATER RINSE IS ALLOWED.** [Change the solution] [A Fresh solution must be prepared] [Prepare a fresh solution] at least daily or [more often if use solution] [when solution appears] becomes visibly [dirty] [soiled] [diluted].

SANITIZATION OF HARD, NON-POROUS [INANIMATE] [ENVIRONMENTAL] SURFACES ON [PERSONAL PROTECTIVE EQUIPMENT] [PPE]:

(Add) (Mix) 0.93 ounces Sterilex Ultra Powder per gallon of water [7 grams/liter] (or equivalent use dilution). Gently mix for uniform solution. Apply solution to hard, non-porous [inanimate] [environmental] surfaces of the (Personal Protective Equipment) (PPE) with a brush, cloth, mop, sponge, auto scrubber, mechanical spray device, foam or by immersion. Thoroughly wet all surfaces to be sanitized. Treated surfaces must remain wet for five (5) minutes. Remove excess solution from equipment prior to storage. Change cloth, sponge or towels frequently to avoid redeposition of soil. [Change the solution] [A Fresh solution must be prepared] [Prepare a fresh solution] at least daily or [more often if use solution] [when solution appears] becomes visibly [dirty] [soiled] [diluted].

11/19

SHOE FOAM DIRECTIONS:

Apply a foam layer that is approximately 0.5 to 2 inches [1.2 cm to 5 cm] thick at all entrances using a foam generating machine or aerator and a solution containing 0.93 ounces Sterilex Ultra Powder per gallon of water [7 grams/liter] (or equivalent use dilution). Scrape waterproof shoes and boots. Walk through foamed. Boots must remain wet for at least 5 minutes prior to entering area. Foamed entranceways must be washed and the foam replaced at least daily or when it foam/area appears dirty. Foam should be applied to entrances of buildings, hatcheries, production and packaging rooms to prevent cross contamination from area to area in the packaging and storage areas of food plants. Use within 24 hours after powder has been dissolved in water.

APPLICATION INSTRUCTIONS FOR USE AS A FLOOR SANITIZER:

After cleaning and sanitizing equipment, [apply] [sprinkle] [spread] Sterilex Ultra Powder evenly to the floor and drain surface, at a rate of 3.7 oz. (105 grams) per 100 square feet of floor surface containing 1.3 fl. oz. – 5.1 fl. oz. (38 ml – 150 ml) of processing water per square foot. Product may be re-applied as needed during the production process. Sterilex Ultra Powder does not become active until it comes in contact with moisture on the floor.

Sterilex Ultra Powder has been evaluated at a concentration that supports a dilution of 0.93 ounces/gallon [7 grams/liter] in the presence of 5% soil contamination and in waters up to 500ppm hardness (29.2 gpg calculated as CaCO3). Treated surfaces must remain wet for 5 minutes.

Sterilex Ultra Powder was evaluated using the Non-Food Contact Surface Sanitizer Test and was proven to be effective against the following organisms:

Staphylococcus aureus (ATCC 6538)
Escherichia coli (ATCC 11229)

Enterobacter aerogenes (ATCC 13048)
Listeria monocytogenes (ATCC 49594)

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 on this label.
 - 5) Saturate all surfaces with a solution prepared by adding 0.42 lb. of **Sterilex Ultra Powder** to 1 gal. tap water [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, foaming, 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 hatcher, 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 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.
- Use product within 24 hours after powder has been dissolved in water.

APPLICATION INSTRUCTIONS FOR TRANSFER LINES:

- 1) Add 0.42 lb. of **Sterilex Ultra Powder** to 1 gal. tap water [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.
- Use product within 24 hours after powder has been dissolved in water.

PREPARATION OF NON-FOOD CONTACT SANITIZER USE SOLUTION:

For heavily soiled areas, a preliminary cleaning is required. [Add] [Mix] 0.93 ounces Sterilex Ultra Powder per gallon of water [7 grams/liter] (or equivalent use dilution). Apply sanitizer use solution to hard, nonporous [inanimate] [environmental] non-food contact surfaces with a brush, cloth, mop, sponge, auto scrubber, sprayer, coarse pump, foam or by immersion so as to thoroughly wet surface to be sanitized. For sprayer applications, spray 6-8 inches from surface. Do not breathe spray. Rub with brush, cloth, or sponge. Treated surfaces must remain wet for 5 minutes. [Rinse] [Wipe up excess liquid] [Allow to air dry]. Use product within 24 hours after powder has been dissolved in water.

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 0.42 lb. of **Sterilex Ultra Powder** to 1 gal. tap water [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, foaming, 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.
- Use product within 24 hours after powder has been dissolved in water.

DISINFECTION OF SALON (BARBER) INSTRUMENTS AND TOOLS:

APPLICATION INSTRUCTIONS:

- 1) Add 0.42 lb. of **Sterilex Ultra Powder** to 1 gal. tap water [50 g of **Sterilex Ultra Powder** to 1 liter tap water] in an appropriate plastic container and stir.
 - 2) Completely immerse combs, brushes, plastic 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 must be prepared daily or more often if solution becomes diluted or soiled.
- Use product within 24 hours after powder has been dissolved in water.

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 OF WHIRLPOOL BATH, SPA AND JACUZZI TUB SURFACES:

Close the Whirlpool bath, Spa or Jacuzzi to bathers. Turn off/close all chemical treatment lines, sensors, chlorine (bromine) feeders and pH chemical adjusters. The amount of water to be treated equals the capacity in gallons of the Whirlpool bath, spa or Jacuzzi tub. Add 0.01 – 0.21 lbs. of **Sterilex Ultra Powder** in 1 gallon of water [1-25 g of **Sterilex Ultra Powder** to 1 liter water] to be treated. Briefly start the pump to circulate the solution. Turn off the pump. Wash down the sides, seat of the chair and any and all related equipment with a clean swab, sponge or brush. Drain solution from the unit and rinse cleaned surfaces and equipment with fresh water. Use product within 24 hours after powder has been dissolved in water.

13/14

DISINFECTION OF WHIRLPOOL BATH, SPA AND JACUZZI TUB SURFACES:

NOTE: During treatment bathers must not enter the whirlpool, spa and Jacuzzi tubs.

1. Turn off/close all chemical treatment lines, sensors, chlorine (bromine) feeders and pH chemical adjusters.
 2. The amount of water to be treated equals the capacity in gallons of the Whirlpool bath, spa or Jacuzzi tub. Add 0.42 lbs of product per gallon of water [50 g of **Sterilex Ultra Powder** to 1 liter water] to be treated.
 3. Begin circulation of the product to assure even distribution of the product through the piping systems. Circulate the product for at least 10 minutes after the product has been evenly distributed through the piping system.
 4. Drain the entire system. Flush (rinse) the entire system by refilling the entire system with clean fresh water.
 5. Rinse all cleaned surfaces with fresh water.
- Use product within 24 hours after powder has been dissolved in water.

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 and before eating, drinking, chewing gum, using tobacco or using the toilet. 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 and before eating, drinking, chewing gum, using tobacco or using the toilet. 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: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

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

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

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL:

[(NOTE TO REVIEWER: The following language is for the nonrefillable 0.44-ounce (12.5-gram) packet only)] Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. Completely empty packet into application equipment by shaking and tapping sides and bottom to loosen clinging particles. If not emptied in this manner, the packet may be considered an acute

14/14

hazardous waste and must be disposed in accordance with local, state and federal regulations. When completely empty discard packet in trash.]

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

[(NOTE TO REVIEWER: The following language is for nonrefillable rigid plastic containers having a capacity of 10 pounds or less)

Nonrefillable container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Fill the container ¼ full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Dispose of rinsate as pesticide waste. Do not reuse or refill this container. Offer for recycling, if available or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. If rinsate cannot be used, follow pesticide disposal instructions. If not triple rinsed these containers are acute hazardous wastes and must be disposed in accordance with local, state and federal regulations.]

[(NOTE TO REVIEWER: The following language is optional for nonrefillable rigid plastic containers having a capacity of 10 pounds or less when "or pressure rinse" appears in the Container Disposal statement)

Nonrefillable container. Triple rinse or pressure rinse container (or equivalent) promptly after emptying. Pressure rinse as follows: Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip. Dispose of rinsate as pesticide waste. Do not reuse or refill this container. Offer for recycling, if available or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. If rinsate cannot be used, follow pesticide disposal instructions. If not triple rinsed these containers are acute hazardous wastes and must be disposed in accordance with local, state and federal regulations.]