



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

November 15, 2016

Georgia Anastasiou
Agent for Sterilex Corporation
Sterilex Corporation
c/o Lewis & Harrison
122 C St. NW, Suite 505
Washington DC, 20001

Subject: Notification per PRN 98-10 – minor label modifications
Product Name: Sterilex Ultra Step
EPA Registration Number: 63761-10
Application Date: October 26, 2016
Decision Number: 522941

Dear Ms. Anastasiou:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped "Notification" and will be placed in our records.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you have any questions, you may contact Tara Flint at flint.tara@epa.gov or Eric Miederhoff at Miederhoff.eric@epa.gov.

Sincerely,



Eric Miederhoff
Product Manager 31
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

NOTIFICATION

63761-10

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

11/15/2016



Sterilex® Ultra Step

[BASED OFF OF] [BASED ON] [INCLUDING] [INCLUDES] [USING] [PATENTED PERQUAT® TECHNOLOGY]

[NON-FOOD CONTACT SURFACE SANITIZER]

[Federally Inspected Food Processing Facilities], [Federally Inspected Meat And Poultry Plants], [Dairies], [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], [Food Service Facilities], [Kitchens], [Grocery Stores], [Deli Areas]

- [Floor Sanitizer]
- [For Use in Non-Food Contact Areas of Dairy, Food, Meat, and Beverage Processing Facilities]
- [Animal Premise Sanitizer]
- [Footpan Sanitizer]
- [Boot Sanitizer]
- [Floor sanitizing and deodorizing performance]

Active Ingredients:

N-Alkyl(C ₁₄ 95%,C ₁₂ 3%,C ₁₆ 2%) dimethyl benzyl ammonium chloride....	1.9%
Sodium Carbonate Peroxyhydrate.....	12.1%
Other Ingredients.....	86.0%
TOTAL	100.0%

KEEP OUT OF THE REACH OF CHILDREN

DANGER

See [back panel] [side panel] [box] for [additional] [first aid] [and] precautionary statement

Manufactured for STERILEX CORPORATION

111 Lake Front Drive Hunt Valley, MD

Phone: (443) 541-8800

Phone (Toll-Free): 1-800-511-1659

Fax: 410-581-8864

Made in USA

EPA Reg. No. 63761-10

EPA Est. No. _____

[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)

[NOT FOR SALE OR USE AFTER: _____] (*NOTE TO REVIEWER – this may be printed on container itself)
[Expiration Date][Exp. Date] [Expiry Date]

Sterilex Ultra Step is a moisture activated sanitizer specifically designed to improve environmental sanitation on surfaces where conditions favor microorganism growth and cause sanitation concern.

DIRECTIONS FOR USE

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

SANITIZING OF HARD, NON-POROUS, INANIMATE, NON-FOOD CONTACT SURFACES

Sterilex Ultra Step eliminates 99.9% of the following bacteria in 5 minutes on hard, non-porous, inanimate, non-food contact surfaces according to the Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces:

[*Enterobacter aerogenes* [(ATCC 13048)]]
[*Staphylococcus aureus* [(ATCC 6538)]]
[*Escherichia coli* [(ATCC 11229)]]
[*Listeria monocytogenes* [(ATCC 15313)]]
[*Salmonella enterica* (Salmonella) [(ATCC 10708)]]
[*Salmonella enterica enteritidis* [(ATCC 13076)]]

SANITIZING DIRECTIONS FOR NON-FOOD CONTACT SURFACES

Add a solution of [4.9 – 6.1 ounces per gallon of water] [37 - 46 grams per liter of water] (or equivalent use dilution) of Sterilex Ultra Step 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. 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 8 hours after powder has been dissolved in water.

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

ENTRYWAY SANITIZING [SYSTEMS] [FOOTBATHS]:

To prevent cross contamination on treated surfaces, apply a solution of [4.9 – 6.1 ounces Sterilex Ultra Step per gallon of water] [37 - 46 grams Sterilex Ultra Step per liter of water] (or equivalent use dilution) of Sterilex Ultra Step. The entire entryway path must be covered with the [spray] [foam] [footbath]. Use within 8 hours after powder has been dissolved in water.

ENTRYWAY [SHOE] [DOORWAY] 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 [4.9 – 6.1 ounces Sterilex Ultra Step per gallon of water] [37 - 46 grams Sterilex Ultra Step per liter of water] (or equivalent use dilution) of Sterilex Ultra Step. Scrape waterproof shoes and boots. Walk through foam. Boots must remain wet for at least 5 minutes prior to entering area. Foamed entrances 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 8 hours after powder has been dissolved in water

APPLICATION INSTRUCTIONS FOR USE AS A [FLOOR], [FLOOR MAT], [FOOT PAN] [FLOOR SURFACE] [BOOT] SANITIZER:

After cleaning and sanitizing equipment, [apply] [sprinkle] [spread] Sterilex Ultra Step evenly to the [floor] [foot pan] [floor mat] [containment device] [and] [drain] surface, at a rate of 3.7 – 7.4 oz. [105 – 210 grams] per 100 square feet of floor surface containing 0.25 fl. oz. – 0.97 fl. oz. [7.4 ml – 28 ml] of water per square foot. Product may be re-applied as needed during the production process. Sterilex Ultra Step does not become active until it comes in contact with moisture.

Sterilex Ultra Step 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)]]

[Salmonella enterica (Salmonella) [(ATCC# 10708)]]

[Enterobacter aerogenes [(ATCC 13048)]]

[Listeria monocytogenes [(ATCC 15313)]]

[Salmonella enterica enteritidis [(ATCC 13076)]]

APPLICATION INSTRUCTIONS FOR USE AS A SANITIZER IN A [FLOOR MAT], [FOOT PAN]:

After cleaning and sanitizing equipment, [apply] [sprinkle] [spread] Sterilex Ultra Step evenly to the [floor] [foot pan] [floor mat] [containment device] [and] [drain] surface, at a rate of 3.7 – 7.4 oz. [105 – 210 grams] per 100 square feet of floor surface containing 0.25 fl. oz. – 0.97 fl. oz. [7.4 ml – 28 ml] of water per square foot. Product may be re-applied as needed during the production process. Sterilex Ultra Step does not become active until it comes in contact with moisture.

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

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[Escherichia coli [(ATCC 11229)]]

[Salmonella enterica (Salmonella) [(ATCC# 10708)]]

[Enterobacter aerogenes [(ATCC 13048)]]

[Listeria monocytogenes [(ATCC 15313)]]

[Salmonella enterica enteritidis [(ATCC 13076)]]

PRECAUTIONARY STATEMENTS

Hazard To Humans And Domestic Animals.

DANGER. Corrosive. Causes irreversible eye damage and skin irritation. Harmful if swallowed or absorbed through skin. Do not get in eyes or on clothing. Avoid contact with skin. Wear protective eyewear (goggles, face shield, or safety glasses), coveralls worn over short-sleeved shirt and short pants, socks, chemical-resistant footwear and waterproof gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated 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.

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

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Keep out of children's reach. Store at room temperature out of direct sunlight, DO NOT store above 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 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 with plastic liner bag containers having a capacity of 10 pounds or less)

Nonrefillable container. Do not reuse or refill this container. 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 optional for nonrefillable rigid plastic containers having a capacity of 10 pounds or more 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.]

[Triple rinse as follows: Fill the container $\frac{1}{4}$ 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. If rinsate cannot be used, follow pesticide disposal instructions. 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 not triple rinsed these containers are acute hazardous wastes and must be disposed in accordance with local, state and federal regulations.]