

84545-11

02/04/2013

1/16



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Kevin Kutcel
c/o sBioMed, LLC
KRK Consulting LLC
5807 Churchill Way
Medina, OH 44256

FEB 4 2013

Subject: Steriplex SD (Part A)
EPA Registration Number 84545-11
Your Amendment Dated December 11th, 2012
EPA Received Date December 11th, 2012

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended, is acceptable.

A stamped copy of the labeling is enclosed for your records.

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

Sincerely,

Dennis H Edwards for

Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobial Division (7510P)

STERIPLEX® SD (Part A)

[Sanitizer and] *C. diff* Spore Disinfectant

STERIPLEX® SD is a two-part system and when Part A and Part B are combined, create an effective *C. diff* Sporicide, Tuberculocide, Bactericide, Virucide†, Fungicide, [and] One-Step Cleaner, Disinfectant & Deodorizer, [and Non-Food Contact Surface Sanitizer].

[FOR NON-FOOD CONTACT SURFACES]

IDEAL FOR WATER SENSITIVE EQUIPMENT & AREAS

For Hospital, Emergency, First Responder, Institutional and Industrial Use

Meets OSHA Bloodborne Pathogen Standards

Effective in the Presence of 5% Serum Contamination when used a One-Step Cleaner & Disinfectant

[An Effective Sanitizer for Use on Non-Food Contact Surfaces]

[For Farm, Dairy, School, Restaurant, [Non-Food Handling and Processing Areas], Bar and Institutional Kitchen Use]

[For Use in Federally Inspected Meat and Poultry Plants]

ACTIVE INGREDIENT:	Silver.....	00.015%
Inert Ingredients	99.985%
Total	100.000%

KEEP OUT OF REACH OF CHILDREN

CAUTION

Read [Entire] [Side] [Back] [Left] [Right] Panel[s] and Supplemental [Pamphlet] [Insert] for Complete Directions and Additional Precautionary Statements

E.P.A. Reg. No. 84545-11
E.P.A. Est. No. 84545-UT-001

sBioMED
sBioMed, LLC
1272 South 1380 West
Orem, Utah 84058
801-922-1111

ACCEPTED
with COMMENTS
in EPA Letter Dated:

FEB 4 2013

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

84545-11

Pre-Mixed Net Contents: 126.7 fl. oz.
Net Contents*: 1 GALLON
*Post[-Mixing][-Activation]

{Note to Reviewer: Language in brackets [] is optional or interchangeable. Language in curly brackets () is for administrative purposes only and will not appear on the printed label}

{The following is considered optional language that may be placed anywhere on label, pamphlet or container:}

- Kills [*Clostridium difficile**] [*C. diff**] [spores] [in 5 minutes] [on Pre-Cleaned, Hard, Non-Porous Surfaces] [without Bleach] [for Hospital Use]
- [Kills] [Is Effective Against] [More Than] [99.9999%] [*Clostridium difficile**] [*C. diff**] [spores] [in 5 [Minutes] [Min.]] [on Pre-Cleaned, Hard, Non-Porous Surfaces] [without Bleach] [for Hospital Use]
- [Passes] [Meets] [Satisfies] [EPA] Requirements for Killing [*Clostridium difficile**] [*C. diff**] [spores] [on Pre-Cleaned, Hard, Non-Porous Surfaces] [without Bleach] [for Hospital Use]
- Attacks and Kills [*Clostridium difficile**] [*C. diff**] [spores] [on Pre-Cleaned, Hard, Non-Porous Surfaces] [without Bleach] [for Hospital Use]
- Designed for Killing [*Clostridium difficile**] [*C. diff**] [spores] [on Pre-Cleaned, Hard, Non-Porous Surfaces] [without Bleach] [for Hospital Use]
- [Effective] [For Daily Use Against] [*Clostridium difficile**] [*C. diff**] [spores] [on Pre-Cleaned, Hard, Non-Porous Surfaces] [without Bleach] [for Hospital Use]
- Formulated to Kill [*Clostridium difficile**] [*C. diff**] [spores] [in 5 Minutes] [on Pre-Cleaned, Hard, Non-Porous Surfaces] [without Bleach] [for Hospital Use]
- Kills Bloodborne Pathogens and Microbes, Including [HIV] [MRSA] [Norovirus Virus[†]] [and] [the Spore Form of [*Clostridium difficile**] [*C. diff**] [spores] [in 5 Minutes] [on Pre-Cleaned, Hard, Non-Porous Surfaces] [without Bleach] [for First Responder Use] [for Hospital Use]
- Kills Norovirus Virus[†] [in 5 Minutes]
- Kills Pandemic 2009 H1N1 Influenza A Virus[†] [in 5 Minutes]
- Kills MRSA [in 5 Minutes]
- For [Hospital] [First Responder] Use
- Kills *C. diff** spores, bacteria, viruses[†] & fungi [in 5 Minutes] [on Hard, Non-Porous Surfaces] [without Bleach] [for Hospital Use] [for First Responder Use]
- Broad Spectrum [Disinfectant] [Antibacterial] [One-Step Cleaner and Disinfectant] [for Hospital Use] [for First Responder Use], proven to [kill] [destroy] [eliminate] [deodorize] *C. diff** spores, bacteria, viruses[†] & fungi [in 5 minutes] [on Hard, Non-Porous Surfaces] [without Bleach]
- Broad Spectrum [Disinfectant] [One-Step Cleaner and Disinfectant] [for Hospital Use]
- Meets OSHA Bloodborne Pathogen Standards [for First Responder Use] [for Hospital Use]
- One-Step Cleaner and Disinfectant [for Hospital Use]
- Hospital [Use] [One-Step Cleaner and] Disinfectant
- Contains No [Bleach] [or] [Sodium Hypochlorite]
- Clean, Fresh Smell [with No Bleach Fumes]
- Bleach Free
- Does Not Contain Bleach
- [Activated Solution] Acute Oral Toxicity [LD₅₀ >5,000 mg/kg] [Category IV] [Low]
- [Activated Solution] Acute Inhalation Toxicity [LC₅₀ >20 mg/L] [Category IV] [Low]
- [Activated Solution] Primary Skin Irritation Category IV [and] [Not a Skin Irritant or Sensitizer] [Non-Sensitizer [for Dermal Sensitization]]
- [Activated Solution is] [Non-Fuming], [[Non-] [Not] Corrosive to Skin or Eyes], [Not a Skin Irritant or Sensitizer] [and] [[Compatible with] [Non-Corrosive to] Hard, Non-Porous Environmental Surfaces]] [When Used as Directed]

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{The following is considered optional language that may be placed anywhere on label, pamphlet or container:}

- [Activated Solution is] Not a [Dermal] [Skin] Sensitizer
- [Activated Solution is] Negative for [Dermal] [Skin] Sensitization
- Prolonged or Frequent Repeated Skin Contact [with Activated Solution] Will Not Cause Allergic Reaction
- Cleans [and], Disinfects, [& Deodorizes] in One Step [without Bleach] [for Hospital Use]
- To Decontaminate [*Clostridium difficile**] [*C. diff**] [spores] [on Pre-Cleaned, Hard, Non-Porous Surfaces] [without Bleach] [for Hospital Use] [for First Responder Use]
- [Breaks Down and Kills] [Inactivates] [Helps Prevent the Spread of] [*Clostridium difficile**] [*C. diff**] [spores] [on Pre-Cleaned, Hard, Non-Porous Surfaces] [without Bleach] [for Hospital Use]
- To Fight [*Clostridium difficile**] [*C. diff**] [spores] [on Pre-Cleaned, Hard, Non-Porous Surfaces] [without Bleach] [for Hospital Use]
- [Destroys] [Deactivates] [[Helps] Eliminate] [Tough-to-Kill] [*Clostridium difficile**] [*C. diff**] [spores] [on Pre-Cleaned, Hard, Non-Porous [Hospital] Surfaces] [without Bleach]
- Aids in the Reduction of Cross Contamination between treated Hard, Non-Porous Surfaces
- Formulated for Bacteria Fighting
- Cleans, Deodorizes and Disinfects [without Bleach] [for Hospital Use]
- Deodorizes by Killing the Germs that Cause Odors
- Disinfects as it Cleans in One Operation [without Bleach]
- Disinfecting Formula [without Bleach] [for Hospital Use]
- Meets AOAC Use-Dilution Test Standards for Hospital Use [One Step Cleaner &] Disinfectants
- Broad Spectrum Hospital and Medical Environment Use [One-Step Cleaner and] Disinfectant [without Bleach]
- Disinfects and Deodorizes by Killing Bacteria and their Odors
- Easy and Convenient Disinfecting [without Bleach]
- Easy, One-Step Cleaning and Disinfecting [without Bleach] [for Hospital Use]
- Effectively Disinfects Hard, Non-Porous Environmental Surfaces [for Hospital Use]
- Eliminates Odors at their Source: Bacteria
- Suitable for Use on [Titanium-Coated] [Medical Grade] Stainless Steel
- Kills Odor-Causing Bacteria
- Eliminates Odors
- Kills Viruses[†], Germs, Mold & Mildew [without Bleach] [for Hospital Use]
- Kills 99.999% of Germs [in 30 seconds]
- Premeasured, Easy and Convenient [to Use] [for Hospital Use] [for First Responder Use]
- Multi-Purpose Disinfectant [for Hospital Use]
- Prevent Mold and Mildew Stains and Odors
- Use in Mold Remediation on Hard, Non-Porous Surfaces

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Under the Federal Insecticide,
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as in effect under EPA Reg. No. 84545-11

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(The following is considered optional language that may be placed anywhere on label, pamphlet or container:)

- Use to Disinfect Hard, Non-Porous Surfaces
- Use as a Sanitizer on Previously Cleaned Non-Food Contact Surfaces
- Will Not Leave Grit or Soap Scum
- Controls Cross-Contamination Between Treated Hard, Non-Porous Surfaces
- Formulated for Veterinary Practice / Animal Care / Animal Laboratory Disinfection
- Formulated for Effective [Dairy] [Farm] [Poultry] [Swine] Premise Sanitation
- [Bactericidal] [Tuberculocidal] [Virucidal] [Fungicidal] [Sporicidal Against [*Clostridium difficile**] [*C. diff**]] [Disinfectant] [Staphylocidal] [Pseudomonacidal] [*Salmonellacidal*] [[Non-Food Contact Surface] Sanitizer]
- Delivers Broad Spectrum Disinfectant Performance in a [Convenient] Post-Activated, Ready-to-Use Solution [without Bleach] [for Hospital Use]
- For use in All Federally Inspected Meat and Poultry Plants, Hospitals, Institutional and Industrial Facilities
- For Sanitizing Hard, Non-Porous Non-Food Contact Surfaces [in 30 seconds]
- Sanitizer for All Hard, Non-Porous Non-Food Contact Surfaces in Official Establishments Operating under the Federal Dairy, Meat, Poultry, Shell Egg Grading and Egg Products Inspection Programs
- [Kills] [Eliminates] [Destroys] [more than] [99.999%] *Bacteria* [*Staphylococcus aureus* [(Staph)], *Exherichia coli* [(E. coli)], *Pseudomonas aeruginosa* [(Pseudomonas)], *Salmonella typhimurium* [(Salmonella)], *Listeria monocytogenes* [(Listeria)], *Enterobacter sakazakii*, and *Vibrio cholerae*] [in 30 seconds] [on Hard, Non-Porous Surfaces]

[STERIPLEX SD] [Kills] [Destroys] [Eliminates] *C. diff spores, bacteria, viruses[†] & fungi [in 5 Minutes]:** *Aspergillus brasiliensis* [(Black Mold)], Avian Influenza Virus (H5N1) NIBRG-14[†], *Clostridium difficile** [(*C. diff*)] [spores], *Escherichia coli* O157:H7, Hepatitis B Virus[†] (HBV), Herpes Simplex Virus Type 1[†] (HSV-1), HIV-1[†] (AIDS Virus), Human Influenza A Virus[†], Influenza A (H1N1)[†] [2009 Pandemic] [Swine Influenza Virus], *Klebsiella pneumonia* (NDM-1), *Listeria monocytogenes*, Methicillin-Resistant *Staphylococcus aureus* (MRSA), *Acinetobacter baumannii*, Murine Norovirus[†], *Mycobacterium bovis* BCG (TB) [(at 20°±1C)], Norovirus[†] [Feline Calicivirus] [(FCV)], *Pseudomonas aeruginosa*, Respiratory Syncytial Virus[†] [(RSV)], *Salmonella enterica*, SARS-Associated Coronavirus[†], *Staphylococcus aureus*, *Trichophyton mentagrophytes* (Athlete's Foot), and Vancomycin-Resistant *Enterococcus faecium* (VRE)

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{The following is considered optional language that may be placed anywhere on label, pamphlet or container:}

{optional bullet list form}

[STERIPLEX SD] [Kills] [Destroys] [Eliminates] *C. diff** spores, bacteria, viruses[†] & fungi [in 5 Minutes]:

- *Aspergillus brasiliensis* [(Black Mold)]
- Avian Influenza A Virus[†]
- *Clostridium difficile** [(*C. diff*)] [spores]
- *Escherichia coli* O157:H7
- Hepatitis B Virus[†] (HBV)
- Herpes Simplex Virus Type 1[†] (HSV-1)
- HIV-1[†] (AIDS Virus)
- Human Influenza A Virus[†]
- Influenza A (H1N1)[†] [2009 Pandemic] [Swine Influenza Virus]
- *Klebsiella pneumonia* (NDM-1)
- *Listeria monocytogenes*
- Methicillin-Resistant *Staphylococcus aureus* (MRSA)
- *Acinetobacter baumannii*
- Murine Norovirus[†]
- *Mycobacterium bovis* BCG (TB) [(at 20°±1C)]
- Norovirus[†] [Feline Calicivirus] [(FCV)]
- *Pseudomonas aeruginosa*
- Respiratory Syncytial Virus[†] [(RSV)]
- *Salmonella enterica*
- SARS-Associated Coronavirus[†]
- *Staphylococcus aureus*
- *Trichophyton mentagrophytes* (Athlete's Foot)
- Vancomycin-Resistant *Enterococcus faecium* (VRE)

STERIPLEX SD is effective against the animal viruses of Avian Influenza Virus (H5N1), Feline Calicivirus and H1N1 Virus (2009 Pandemic strain) [(Swine Influenza Virus H1N1)].

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[STERIPLEX SD] [Kills] [Destroys] [Eliminates] [more than] [99.999%] bacteria in 30 seconds [reducing equipment down time] [reducing turnover times]: *Staphylococcus aureus* [(Staph)], *Escherichia coli* [(*E. coli*)], *Escherichia coli* O157:H7 [(*E. coli* O157:H7)], *Pseudomonas aeruginosa* [(*Pseudomonas*)], *Salmonella typhimurium* [(*Salmonella*)], *Listeria monocytogenes* [(*Listeria*)], *Enterobacter sakazakii* and *Vibrio cholerae* [(*V. cholerae*)]

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{optional bullet list form}

[STERIPLEX SD] [Kills] [Destroys] [Eliminates] [more than] [99.999%] *bacteria* in 30 seconds [reducing equipment down time] [reducing turnover times]:

- *Staphylococcus aureus* [(Staph)]
- *Escherichia coli* [(E. coli)]
- *Escherichia coli* O157:H7 [(E. coli O157:H7)]
- *Pseudomonas aeruginosa* [(Pseudomonas)]
- *Salmonella typhimurium* [(Salmonella)]
- *Listeria monocytogenes* [(Listeria)]
- *Enterobacter sakazakii*
- *Vibrio cholerae* [(V. cholerae)]

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STERIPLEX SD is for use in the disinfection of hard, non-porous surfaces in **Healthcare and other areas where control of cross contamination is required** and meets OSHA Bloodborne Pathogen Standards. **Applications. Hospital and Healthcare:** Hospitals, Medical Clinics, Dental Offices, Ophthalmology, Optometry, Blood Collection and Donation Centers, Hospital Central Service Areas, Nursing Homes, Hospices, Rehabilitation Centers, Orthopedics, Physical Therapy, Respiratory Therapy, Physician Offices, Radiology, Anesthesia, Laboratories, Cath Labs, Radiology, Pediatrics, Recovery Rooms and Surgery. **Critical Care Areas:** Emergency Rooms (ER), Intensive Care Units (ICU), Neonatal Intensive Care Units (NICU), Pediatric Intensive Care Units (PICU), Isolation Units, and Surgery. **Use Sites:** Autoclaves, baskets, bed pans, bed railings, blood glucose monitors, cabinets, cabinets, carts, chairs, counters, door knobs and handles, drawer pulls, exam tables, examination tables, gurneys, incubators, infant incubators and care cribs, IV poles, lighting fixtures, machines, mammography equipment and mammography compressor plates, pails, pans, patient monitoring equipment, physical therapy equipment, respiratory equipment, shower stalls, stethoscopes, stools, stretchers, tables, telephones, toilet exteriors and toilet seats, ultrasound transducers and probes, walkers, wheelchairs and other hard, non-porous, water sensitive equipment and surfaces listed on this label.

STERIPLEX SD is for use in the disinfection of hard, non-porous surfaces in **Ambulances, Police, Fire, Emergency and First Responder Vehicles and other areas where control of cross contamination is required** and meets OSHA Bloodborne Pathogen Standards. **Use Sites:** CBRNE PPE's, SCBA's, ventilation and airway equipment, monitoring and defibrillation equipment, resuscitators, immobilization devices, communication equipment, wheeled cots, folding stretchers, stair chairs, carry chairs, injury prevention equipment, IV poles, roof hooks, intravenous arm boards, cardiac equipment, nebulizers, cellular phones and other electronics, extrication equipment and other hard, non-porous, water sensitive equipment and surfaces listed on this label.

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STERIPLEX SD is for use in the disinfection of hard, non-porous surfaces in **Hotels, Motels, Cruise Ships, Restaurants, Trains, Airplanes, Subways, Buses, Offices, Beauty Salons, Barber Shops, Restrooms, Public Rest Stops, Prisons, Jails, Correctional Facilities, Military & Other Barracks** and other areas where there is the close proximity of people and/or where skin or clothing may come into direct contact with hard, non-porous surfaces contaminated with the community-acquired pathogens listed on this label. **Use Sites:** Seats, benches, stools, arm rests, table trays, railings, toilet surfaces, sinks, faucet fixtures, handles, counter tops, tubs, showers, glazed tiles, door knobs, scales, mirrors, window sills, cabinets, floors, walls and other hard, non-porous surfaces listed on this label.

STERIPLEX SD is for use in the disinfection of hard, non-porous surfaces in **School Premises, College and University Premises, Amateur and Professional Sports Facilities, Athletic Stadiums and Arenas, Field Houses, Gyms, Athletic Facilities, School Buses, Whirlpools, Spas, Lockers, Restrooms, Fitness Centers** and other areas where there is the close proximity of people and/or where skin or clothing may come into direct contact with hard, non-porous surfaces contaminated with the community-acquired pathogens listed on this label. **Use Sites:** Personal protective safety equipment, athletic helmets, wrestling headgear, boxing headgear, protective headgear, half mask respirators, full face breathing apparatus, gas masks, goggles, spectacles, face shields, hearing protectors, ear muffs, athletic mats, wrestling mats, gymnastic mats, exercise equipment, weight machines, aerobic equipment, training tables, seats, benches, stools, arm rests, table trays, railings, toilet surfaces, sinks, faucet fixtures, handles, counter tops, tubs, showers, glazed tiles, door knobs, scales, mirrors, floors, walls and other hard, non-porous surfaces listed on this label.

STERIPLEX SD is for use in the disinfection of hard, non-porous surfaces in **Nurseries and Daycare Centers**. **Use Sites:** Changing tables, cribs, bassinets, toys, toy boxes, riding toys, bath toys, play pens, activity centers, play sets, play table & chairs, strollers, baby car seats, reception desks, trash cans, diaper pails and other hard, non-porous surfaces listed on this label.

STERIPLEX SD is for use in the disinfection of hard, non-porous surfaces in **Veterinary Clinics, Animal Hospitals, Animal Shelters, Kennels and Animal Life Science Labs, Animal Laboratories, Tack Shops, Pet Shops, Zoos, Pet Animal Quarters, Stables, Farms and Pet Grooming and Breeding Establishments**. **Use Sites:** Operating tables, kennel runs, cages, sink tops, equipment, utensils, instruments, kennels, stables, stalls, catteries, furniture, walls, floors and animal transportation vehicles and will deodorize those areas that are generally hard to keep fresh smelling such as garbage storage areas, empty garbage bins and cans, and any other hard, non-porous areas which are prone to odors caused by microorganisms.

STERIPLEX SD is for use in the disinfection of hard, non-porous surfaces in **Livestock Premises, Poultry Premises, Poultry Hatcheries and Animal Housing Facilities**.

STERIPLEX SD is for use in the disinfection of hard, non-porous surfaces in **Laboratories, Pharmaceutical and Cosmetic Facilities and Equipment, Morgues, Mortuaries, Funeral Homes and Funeral Parlors**.

STERIPLEX SD is for use in the disinfection of hard, non-porous surfaces on **Coils and Drain Pans, Air Conditioning and Refrigeration Equipment and Heat Pumps**.

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Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, and the Federal
Pesticide Control Act of 1947,
Page 7 of 15
EPA No. 84545-41

{The following is considered optional language that may be placed anywhere on label, pamphlet or container:}

STERIPLEX SD is for Institutional/industrial sanitizing of hard, non-porous non-food contact surfaces in **Dairies, Wineries, Breweries and Beverage Plants**. **Use Sites:** The non-food contact surfaces of beer fermentation tanks, dairy equipment, vats, filters, evaporators, pasteurizers, holding tanks, beverage dispensing equipment, blenders, coolers, bottling or premix dispensing equipment and external spraying of filler and closer machines.

STERIPLEX SD is for Institutional/industrial sanitizing of hard, non-porous non-food contact surfaces in **Meat and Poultry Processing and Packaging Plants, Seafood and Produce Processing and Packing Plants, Food and Pet Food Processing and Packing Plants, Restaurants and Eating Establishments**. **Use Sites:** Non-Food processing equipment including the non-food contact surfaces of tanks, fillers, evaporators, aseptic equipment, conveyors and display equipment.

STERIPLEX SD is for use in the sanitation of hard, non-porous surfaces in **Poultry Premises and Poultry Hatcheries**. **Use Sites:** Egg receiving area, tray dumping area, egg holding area, chick holding area, setter room, hatchery room, trays, buggies, racks, egg flats, chick processing area, chick loading area, poultry buildings, ceilings, sidewalls and floors.

STERIPLEX SD is for use in the sanitation of hard, non-porous surfaces in **Swine Premises**. **Use Sites:** Farrowing barns and areas, dressing plants, blocks, loading equipment, creep area, hauling equipment, nursery and chutes.

STERIPLEX SD is for use in the sanitation of hard, non-porous surfaces in **Animal Farms**. **Use Sites:** Mangers, non-food contact surfaces of feed racks, troughs, automatic feeders, fountains and waterers, forks, shovels, scrapers, floors, walls, and all other hard, non-porous surfaces in barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals.

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DIRECTIONS FOR USE

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

MIXING DIRECTIONS FOR ACTIVATION

STERIPLEX SD (Part A) is formulated as one component of a two-part system and therefore must not be used alone as a sanitizer or disinfectant without activating. Activate STERIPLEX SD prior to use by pouring the contents of the STERIPLEX SD Activator (Part B) 1.3 fl. oz. net contents bottle into the STERIPLEX SD (Part A) 1-gallon container as instructed below:

1. Using appropriate personal protective equipment (PPE), remove the cap on the STERIPLEX SD (Part A) 1-gallon container to expose the opening;
2. Obtain the STERIPLEX SD Activator (Part B) 1.3 fl. oz. net contents bottle and remove the child protective cap. CAREFULLY pour the STERIPLEX SD Activator (Part B) into the 1-gallon Part A container and shake the 1.3 fl. oz. net contents small bottle to release entire contents;
3. Replace cap on the empty STERIPLEX SD Activator (Part B) container and discard as directed;
4. Replace cap on the 1-gallon STERIPLEX SD (Part A) container and thoroughly shake for approximately 15 seconds to mix the combined solution; STERIPLEX SD Activated Solution is now Ready-to-Use as directed.

STERIPLEX SD is effective and for use as directed on hard, non-porous surfaces: stainless steel including titanium-coated and medical grade stainless steel, chrome, plastic (vinyl, LD and HD polyethylene, and polypropylene), silicone rubber, metal, Formica, medical tubing, vinyl rubber, laminated surfaces, glass, acrylic plastic, Plexiglas®, sealed fiberglass, glazed ceramic, glazed enamel, glazed porcelain, Corian®, sealed granite, sealed limestone, sealed marble, sealed slate, sealed stone, sealed terra cotta, sealed terrazzo, and sealed finished woodwork.

STERIPLEX SD is effective and for use as directed on hard, non-porous, water sensitive equipment surfaces: instruments, sealed electronics, computer keyboards, cell phones, telephones, appliances, remote controls, light switch covers and other hard, non-porous water sensitive equipment and surfaces listed on this label.

GENERAL CLEANING & DEODORIZING DIRECTIONS

STERIPLEX SD is for use in general cleaning and deodorizing. Apply a generous amount of [STERIPLEX SD] [the activated STERIPLEX SD solution] to soiled area using a cloth, mop, sponge, brush or mechanical coarse spray device as needed. Wipe clean or allow to air dry.

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DISINFECTION DIRECTIONS

STERIPLEX SD is for use in disinfecting hard, non-porous surfaces [against] [to kill] the following healthcare and animal pathogens:

- **CLOSTRIDIUM DIFFICILE* ACTIVITY – STERIPLEX SD** [exhibits sporicidal efficacy against] [kills] *Clostridium difficile** (spore form) (ATCC 43598) in 5 minutes according to the Standard Quantitative Disk Carrier Test Method when used as directed.
- **BACTERICIDAL HEALTHCARE ACTIVITY – STERIPLEX SD** is an effective one-step cleaner and disinfectant and [exhibits disinfectant efficacy against] [kills] *Staphylococcus aureus* (ATCC 6538), *Pseudomonas aeruginosa* (ATCC 15442), *Salmonella enterica* (ATCC 10708), **Methicillin-Resistant *Staphylococcus aureus* (MRSA)** (ATCC 33591), *Acinetobacter baumannii* (ATCC BAA-1605), **NDM-1 *Klebsiella pneumonia*** (CI 10002), *Escherichia coli* **O157:H7** (ATCC 35150), *Listeria monocytogenes* (ATCC 7644), and **Vancomycin-Resistant *Enterococcus faecium* (VRE)** (ATCC 51299) in 5 minutes according to the AOAC Use Dilution Test method in the presence of 5% Organic Load when used as directed.
- **TUBERCULOCIDAL ACTIVITY – STERIPLEX SD** [exhibits disinfectant efficacy against] [kills] *Mycobacterium bovis* BCG in 5 minutes at 20°±1C in the presence of 5% Organic Load according to the AOAC Tuberculocidal Activity of Disinfectants when used as directed.
- **FUNGICIDAL ACTIVITY – STERIPLEX SD** [exhibits disinfectant efficacy against] [kills] *Aspergillus brasiliensis* [(Black Mold)] (ATCC 16404) and *Trichophyton mentagrophytes* (Athlete’s Foot) (ATCC 9533) in 5 minutes in the presence of 5% Organic Load according to the AOAC Use Dilution Fungicidal Test when used as directed.
- **VIRUCIDAL[†] ACTIVITY – STERIPLEX SD** meets OSHA Bloodborne Pathogen Standards and [exhibits virucidal[†] efficacy against] [kills] **Human Immunodeficiency Virus Type 1 (HIV-1)**, **Hepatitis B Virus (HBV)**, **Norovirus (Feline Calicivirus)** (ATCC VR-782), **Murine Norovirus**, **SARS-Associated Coronavirus**, **H1N1 Virus (2009 Pandemic strain)** [(Swine Influenza Virus H1N1)], **Human Influenza A Virus (H1N1)**, **Avian Influenza Virus (H5N1)** (NIBRG-14), **Respiratory Syncytial Virus** (ATCC VR-26) and **Herpes Simplex Virus Type 1** (ATCC VR-260) in 5 minutes in the presence of 5% Organic Load and **Poliovirus Type 1** (ATCC VR-1562) in seven minutes in the presence of 5% Organic Load according to the Virucidal Efficacy Test when used as directed.

TO CLEAN, DISINFECT, AND DEODORIZE IN ONE STEP: Apply [STERIPLEX SD] [the activated STERIPLEX SD solution] using a cloth, mop, sponge or mechanical coarse spray device or by total immersion until the surface is thoroughly wet. Treated surfaces must remain wet for 5 minutes. Do not rinse. Allow to air dry. Gross soil must be removed prior to disinfecting.

TO DISINFECT NON-CRITICAL/SEMI-CRITICAL MEDICAL DEVICES, ENDOSCOPES, ULTRASOUND TRANSDUCERS AND PROBES:^{††} Pre-clean gels and other soils from external surfaces to be disinfected with a clean paper towel, cloth or sponge, which may be dry or wetted with STERIPLEX SD. Apply [STERIPLEX SD] [the activated STERIPLEX SD solution] using a cloth, mop, sponge or mechanical coarse spray device until the surface is thoroughly wet. Treated surfaces must remain wet for 5 minutes. Do not rinse. Allow to air dry.

(Note to Reviewer: Language in brackets [] is optional or interchangeable. Language in curly brackets { } is optional for administrative purposes only and will not appear on the printed label)

ACCEPTED with COMMENTS in EPA Letter dated:

FEB 4 2011

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 84545-11

TO DISINFECT WATER SENSITIVE EQUIPMENT HARD, NON-POROUS SURFACES: Completely power off electrical equipment prior to treatment. Pre-clean soils from external surfaces to be disinfected with a clean paper towel, cloth or sponge, which may be dry or slightly wetted with STERIPLEX SD. Carefully apply [STERIPLEX SD] [the activated STERIPLEX SD solution] using a cloth or calibrated mechanical coarse spray device so that only enough solution is applied to keep the surface thoroughly wet for 5 minutes. Avoid over soaking and prevent pooled or puddled areas. Treated surfaces must remain wet for 5 minutes. Do not rinse. Allow to air dry. **Do not restore power to electronic equipment until thoroughly dry.**

TO DISINFECT USING ULTRASONIC BATHS: Pre-clean soiled, hard, non-porous, non-critical instruments and objects compatible with Ultrasonic cleaning units. Pour [STERIPLEX SD] [the activated STERIPLEX SD solution] directly into bath chamber. Place objects into unit and operate for 5 minutes, according to the Ultrasonic manufacturer's use directions. Remove objects and allow to air dry or rinse with sterile water (sterile water for injection) and allow to air dry. Use fresh [solution] [STERIPLEX SD] [mixed STERIPLEX SD solution] [activated STERIPLEX SD solution] for each bath cycle.

TO CLEAN, DISINFECT, AND DEODORIZE [BEAUTY] [HAIR] SALON, BARBER SHOP, SPA AND NAIL [MANICURE] SALON HARD, NON-POROUS INSTRUMENTS AND TOOLS: Remove heavy soil prior to disinfection. Completely immerse combs, brushes, plastic rollers, razors, scissors, blades, manicure and other salon instruments and tools in [STERIPLEX SD] [the activated STERIPLEX SD solution] for 5 minutes. Do not rinse. Remove and allow to air dry or dry with a clean cloth prior to use. Plastics, instruments and tools may remain immersed until ready to use. If removed from disinfecting solution for storage prior to use, stainless steel shears and instruments must be kept in a clean, non-contaminated receptacle.

TO CLEAN, DISINFECT, AND DEODORIZE TOILET BOWL AND URINALS: Remove heavy soil prior to disinfection. Empty toilet bowl or urinal and apply [STERIPLEX SD] [the activated STERIPLEX SD solution] to exposed surfaces including under the rim with a cloth, mop, sponge or mechanical coarse spray device until the surface is thoroughly wet. Brush or swab thoroughly. Treated surfaces must remain wet for 5 minutes. Do not rinse. Allow to air dry.

TO DISINFECT AND INACTIVATE AVIAN INFLUENZA AND OTHER ANIMAL VIRUSES LISTED ON THIS LABEL AT DAIRY, POULTRY, SWINE, TURKEY AND ANIMAL FARMS, HATCHERIES, VETERINARY PRACTICES, ANIMAL CARE, ANIMAL LABORATORIES, ZOOS, PET SHOPS, KENNELS, BREEDING AND GROOMING ESTABLISHMENTS, TACK SHOPS AND ANIMAL LIFE SCIENCE LABORATORIES: Remove all animals and feed from the premises, vehicles and enclosures. Remove all litter, droppings and manure from the floors, walls and surfaces of pens, stalls, barns, chutes and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks and other watering appliances. Thoroughly clean all surfaces with soap, detergent and/or STERIPLEX SD and rinse with water. For hard, non-porous surfaces, apply [STERIPLEX SD] [the activated STERIPLEX SD solution] using a cloth, mop, sponge or mechanical coarse spray device until the surface is thoroughly wet. Immerse all animal handling and restraining equipment as well as forks, shovels, and scrapers used to remove litter and manure. Treated surfaces must remain wet or be immersed for 5 minutes. Do not rinse. Allow to air dry.

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with COMMENTS
in EPA Letter Dated:

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Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
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and under EPA Reg. No. 84545-11

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***Special Instructions to Clean Prior to Disinfection against *Clostridium difficile* spores. Personal Protection:** Wear appropriate barrier protection such as gloves, gowns, masks, or eye covering. **Cleaning Procedure:** Fecal matter/waste and gross soil must be thoroughly cleaned from surfaces/objects before disinfection by application with STERIPLEX SD. Cleaning is to include vigorous wiping and/or scrubbing, until all visible soil is removed. Special attention is needed for high-touch surfaces. To minimize spreading of spores, surfaces in patient rooms are to be cleaned in an appropriate manner such as clockwise or counter-clockwise for horizontal surfaces, and top to bottom on vertical surfaces. **Infectious Materials Disposal:** Materials used in the cleaning process that may contain feces/wastes are to be disposed of immediately in accordance with local regulations for infectious materials disposal. **Disinfection Procedure:** Apply [STERIPLEX SD] [the activated STERIPLEX SD solution] using a cloth, mop, sponge or mechanical coarse spray device until the surface is thoroughly wet. Treated surfaces must remain wet for 5 minutes. Do not rinse. Allow to air dry.

†KILLS HIV-1 AND HBV ON PRE-CLEANED ENVIRONMENTAL SURFACES / OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in healthcare settings (e.g. hospitals, nursing homes) or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of **Human Immunodeficiency Virus Type 1 (HIV-1)** (associated with AIDS) and **Hepatitis B Virus (HBV)**.

Special Instructions for Cleaning and Decontamination Against HIV-1 (AIDS Virus) and HBV on Surfaces / Objects Soiled with Blood/Body Fluids. Personal Protection: Wear disposable latex gloves, protective gown, face mask and eye covering, as appropriate, when handling items soiled with blood or body fluids. **Cleaning Procedure:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this disinfectant. **Contact Time:** Leave surfaces wet for 5 minutes. **Disposal of Infectious Materials:** Blood and other body fluids should be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.

†† 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 normally 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.

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14/16

NON-FOOD CONTACT SURFACE SANITIZING DIRECTIONS

STERIPLEX SD is for use in sanitizing previously cleaned, non-food contact surfaces [against] [to kill] the following pathogens:

- **GERMICIDAL ACTIVITY – STERIPLEX SD** is an effective sanitizer and [exhibits sanitizing efficacy against] [kills] *Staphylococcus aureus* (ATCC 6538), *Escherichia coli* (ATCC 11299), *Escherichia coli* O157:H7 (ATCC 35150), *Pseudomonas aeruginosa* (ATCC 15442), *Salmonella typhimurium* (ATCC 13311), *Listeria monocytogenes* (ATCC 7644), *Enterobacter sakazakii* (*Cronobacter spp*) (ATCC 51329), and *Vibrio cholerae* (ATCC 14035) in 30 seconds according to the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants test method when used as directed.

TO SANITIZE NON-FOOD CONTACT SURFACES: Apply [STERIPLEX SD] [the activated STERIPLEX SD solution] to previously cleaned, non-food contact surfaces using a cloth, mop, sponge, brush or mechanical coarse spray device or by total immersion until the surface is thoroughly wet. Treated surfaces must remain wet for 30 seconds. Do not rinse. Allow to drain and air dry. Use fresh [solution] [STERIPLEX SD] [mixed STERIPLEX SD solution] [activated STERIPLEX SD solution] in all applications.

TO SANITIZE WATER SENSITIVE EQUIPMENT HARD, NON-POROUS SURFACES: Completely power off electrical equipment prior to treatment. Pre-clean soils from external surfaces to be sanitized with a clean paper towel, cloth or sponge, which may be dry or slightly wetted with STERIPLEX SD. Carefully apply [STERIPLEX SD] [the activated STERIPLEX SD solution] using a cloth or calibrated mechanical coarse spray device so that only enough solution is applied to keep the surface thoroughly wet for 30 seconds. Avoid over soaking and prevent pooled or puddled areas. Treated surfaces must remain wet for 30 seconds. Do not rinse. Allow to air dry. **Do not restore power to electronic equipment until surfaces are thoroughly dry.**

MOLD & MILDEW DIRECTIONS

TO CONTROL MOLD AND MILDEW: Pre-clean hard, non-porous surfaces. Apply [STERIPLEX SD] [the activated STERIPLEX SD solution] using a cloth, mop, sponge, brush or mechanical coarse spray device until the surface is thoroughly wet. Treated surfaces must remain wet for 5 minutes. Do not rinse. Allow to air dry. Repeat application in weekly intervals or when mold and mildew growth appears.

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STORAGE AND DISPOSAL

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

Pesticide Storage

Store in a dry, cool area and away from direct sunlight. Do not double stack pallets. Use first in, first out storage system.

Pesticide Disposal

To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

Container Handling and Disposal

Nonrefillable container. Do not reuse or refill this container.

Clean container promptly after emptying. Offer for recycling if available or reconditioning if appropriate.

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16/16

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with eyes, skin or clothing. Wear protective eyewear, long-sleeved shirt and long pants, socks, shoes, and rubber 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 FOR MIXED STERIPLEX SD SOLUTION	
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, and then continue rinsing. Call a poison control center or physician for treatment advice.
IF ON SKIN OR CLOTHING	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or physician for treatment advice.
Have the product container with you when calling a poison control center or going for treatment.	
FOR EMERGENCY MEDICAL INFORMATION CALL TOLL FREE: 1-800-222-1222	

PHYSICAL OR CHEMICAL HAZARDS

Combustible. Do not use or store near heat or open flame.

Minimal corrosion effects may occur with natural rubber and soft iron products. Stainless steels, plastics and polymers exhibit no corrosive effects. Never bring mixture in contact with other sanitizers, cleaners or organic substances. This product is not flammable or explosive.

LIMITED WARRANTY AND DISCLAIMER

NOTICE: sBioMed, LLC ("sBioMed") warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes referred to in the Directions For Use. To the extent consistent with applicable law, the buyer assumes all risks of use and handling which is a variance in any way with the directions herein. Except as warranted by this label, sBioMed or the seller makes no other express or implied warranty of fitness or merchantability. To the extent consistent with applicable law, in no case shall sBioMed or the seller be liable for consequential, special or indirect damages resulting from the use or handling of this product. sBioMed and the seller offer this product and the buyer and user accept it, subject to the foregoing Limited Warranty and Disclaimer which may be varied only by agreement in writing, signed by a duly authorized representative of sBioMed.

Lot Number:

Mix [Activation] Date:

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