



U.S. ENVIRONMENTAL PROTECTION AGENCY  
 Office of Pesticide Programs  
 Antimicrobials Division (7510P)  
 1200 Pennsylvania Ave., N.W.  
 Washington, D.C. 20460

**EPA Reg. Number:**

84545-14

**Date of Issuance:**

8/28/18

**NOTICE OF PESTICIDE:**

Registration  
 Reregistration  
 (under FIFRA, as amended)

**Term of Issuance:**

Conditional

**Name of Pesticide Product:**

Axeniplex SD

**Name and Address of Registrant (include ZIP Code):**

sBioMed LLC  
 1272 South 1380 West  
 Orem, Utah 84058

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

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

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

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

**Signature of Approving Official:**

Zeno Bain, Product Manager 33  
 Regulatory Management Branch I  
 Antimicrobials Division (7510P)  
 Office of Pesticide Programs

**Date:**

8/28/18

2. You are required to comply with the data requirements described in the DCI identified below:
  - a. Silver - GDCI-072501-1129
  - b. Hydrogen Peroxide – GDCI-000595-1127
  - c. Peracetic Acid – GDCI-063201-1125

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Reevaluation Team Leader (Team 36): <http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division>

3. As per 40 CFR 156.10 (a)(6)(i), every new version of the final printed label must be submitted to the Agency for review and approval prior to the product being released for shipment bearing that label. Currently, the only final printed labels that may be used are:

Label Version #1.0; accepted August 28, 2018

4. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.
5. Make the following label changes before you release the product for shipment:
  - Revise the EPA Registration Number to read, “EPA Reg. No. 84545-14.”
6. You must submit this product for post market testing by the Office of Pesticide Programs Microbiology Laboratory after March 1, 2019 and no later than April 1, 2019. The following website has information on procedures for product sample submission:  
<https://www.epa.gov/pesticide-registration/antimicrobial-testing-program#submit>

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.

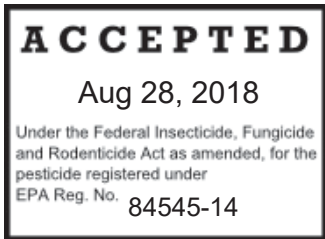
If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF Part A dated 03/07/2018
- Basic CSF Part B dated 03/07/2018

If you have any questions, you may contact Aline Heffernan at 703-347-8602 or via email at [heffernan.aline@epa.gov](mailto:heffernan.aline@epa.gov).

Enclosure: Stamped Master Label

cc. Adrienne Trivedi, EPA/OECA



# AXENIPLEX<sup>®</sup> SD (Part A & Part B)

Disinfectant Cleaner

AXENIPLEX SD is a two-part system and when Part A and Part B are combined, creates an effective Bactericide, One-Step Cleaner, Disinfectant & Deodorizer

*IDEAL FOR WATER SENSITIVE EQUIPMENT & AREAS*

For Pharmaceutical Manufacturing, Hospital, Emergency, First Responder, Institutional, Industrial and Home Use

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

First Aid and Precautionary Statements for AXENIPLEX SD Part A and AXENIPLEX SD Part B can be found in subsequent pages of this master label document.

## AXENIPLEX SD (Part A)

ACTIVE INGREDIENT: Silver.....	0.0155%
Inert Ingredients .....	99.9845%
Total .....	100.0000%

KEEP OUT OF REACH OF CHILDREN

Net Contents: 1 gallon

## AXENIPLEX SD (Part B)

ACTIVE INGREDIENTS:	
Hydrogen Peroxide .....	22.00%
Peroxyacetic acid .....	15.00%
Inert Ingredients .....	63.00%
Total .....	100.00%

KEEP OUT OF REACH OF CHILDREN

### DANGER

Read Panels and Supplemental Pamphlet for Complete Directions and Additional Precautionary Statements

## PRECAUTIONARY STATEMENTS FOR AXENIPLEX SD ACTIVATOR (PART B) ONLY

### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**DANGER. CORROSIVE.** Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through the skin. Harmful if swallowed. Do not breathe vapors or spray mist. Do not get in eyes, on skin or on clothing. Wear goggles and/or face shield and rubber gloves when handling. Do not enter an enclosed area without proper respiratory protection. 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 before reuse.

**PHYSICAL OR CHEMICAL HAZARDS FOR AXENIPLEX SD ACTIVATOR (PART B) ONLY**

**STRONG OXIDIZING AGENT.** Corrosive. Mix only with AXENIPLEX SD Part A solution. Product must be diluted in accordance with label directions prior to use. At temperatures exceeding 156°F, decomposition occurs, releasing oxygen. The oxygen released could initiate combustion.

**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.

EPA Reg. No. 84545-RU  
EPA Est. No. 84545-UT-001

sBioMed LLC  
1272 So. 1380 West  
Orem, Utah 84058  
801-922-1111

# AXENIPLEX<sup>®</sup> SD

## (Mixed Solution)

**Pharmaceutical Manufacturing Applications:** Mixed AXENIPLEX SD is for daily use in the cleaning and disinfection of hard, nonporous surfaces in pharmaceutical manufacturing, production, compounding and research facilities, including all ISO 5, ISO 6, ISO 7 and ISO 8 areas, clean rooms, floors, walls, ceilings, equipment, stainless steel, glass, hard nonporous plastics, aluminum, Formica, polycarbonates used for barrier systems, vinyl flooring, transfer carts, hoods, benchtops, drawers, cabinets and other hard nonporous surfaces and equipment listed on this label.

- Pre-cleaning not required
- One step cleaning and disinfecting
- Two in one cleaning and disinfecting
- Clean and disinfect in one step
- Broad Spectrum [Disinfectant] [Antibacterial] [One-Step Cleaner and Disinfectant] [for Hospital Use] [for Pharmaceutical Use], proven to [kill] [destroy] [eliminate] [deodorize] *bacteria* [in 5 minutes] [on Hard, Nonporous Surfaces] [without Bleach] For [Pharmaceutical] [Hospital] [First Responder] Use
- Broad Spectrum [Disinfectant] [One-Step Cleaner and Disinfectant] [for Pharmaceutical Use] [for Hospital Use]
- One-Step Cleaner and Disinfectant [for Pharmaceutical Use] [for Hospital Use]
- Cleans [and], Disinfects, [& Deodorizes] in One Step [without Bleach] [for Pharmaceutical Use] [for Hospital Use]
- Hospital [Use] Pharmaceutical [Use] [One-Step Cleaner and] Disinfectant
- Disinfects as it Cleans in One Operation [without Bleach]
- Meets AOAC Use-Dilution Test Standards for Hospital Use [One Step Cleaner &] Disinfectants
- Meets AOAC Use-Dilution Test Standards for Pharmaceutical Use [One Step Cleaner &] Disinfectants
- One-Step Cleaning and Disinfecting [without Bleach] [for Hospital Use] [for Pharmaceutical Use]
- Broad Spectrum Hospital and Medical Environment Use [One-Step Cleaner and] Disinfectant
- Kills bacteria [in 5 Minutes] [on Hard, Nonporous Surfaces] [without Bleach] [for Pharmaceutical Use] [for Pharmaceutical Manufacturing Use]
- [Disinfectant] [Antibacterial] [for Hospital Use] [for Pharmaceutical Use], proven to [kill] [destroy] [eliminate] [deodorize] *bacteria*, [in 5 minutes] [on Hard, Nonporous Surfaces] [without Bleach]
- [Disinfectant] [for Hospital Use] [for Pharmaceutical Use]
- Hospital [Use] Pharmaceutical [Use] Disinfectant
- Contains No [Bleach] [or] [Sodium Hypochlorite]
- Clean, Fresh Smell [with No Bleach Fumes]
- Bleach Free
- Does Not Contain Bleach
- Mixed Products [Low] Acute Oral Toxicity [Category IV]
- Mixed Products [Low] Acute Inhalation Toxicity [Category IV]
- Mixed Products Primary Skin Irritation Category IV [and] [Not a Skin Irritant or Sensitizer] [Non-Sensitizer [for Dermal Sensitization]
- Mixed Products Primary Eye Irritation Category IV [and] [Not an Eye Irritant or Sensitizer]
- Mixed Products [Odorless], [[Non-] [Not] Corrosive to Skin or Eyes], [Not a Skin Irritant or Sensitizer]
- [Compatible with] [Non-Corrosive to] Hard, Nonporous Environmental Surfaces [When Used as Directed]
- Mixed Products are Not a [Dermal] [Skin] Sensitizer
- Mixed Products are Negative for [Dermal] [Skin] Sensitization

- Prolonged or Frequent Repeated Skin Contact with Mixed products will Not Cause Allergic Reaction
- Cleans [and], Disinfects, [& Deodorizes] [without Bleach] [for Hospital Use] [for Pharmaceutical Use]
- Aids in the Reduction of Cross Contamination between treated Hard, Nonporous Surfaces
- Formulated for Bacteria Fighting
- Cleans, Deodorizes and Disinfects [without Bleach] [for Hospital Use]
- Deodorizes by Killing the Germs that Cause Odors
- Disinfects [without Bleach]
- Disinfecting Formula [without Bleach] [for Hospital Use] [for Pharmaceutical Use]
- Broad Spectrum Hospital and Medical Environment Use Disinfectant [without Bleach]
- Broad Spectrum Pharmaceutical Manufacturing Use Disinfectant [without Bleach]
- Disinfects and Deodorizes by Killing Bacteria and their Odors
- Convenient Disinfecting [without Bleach]
- Cleaning and Disinfecting [without Bleach] [for Hospital Use] [for Pharmaceutical Use]
- Effectively Disinfects Hard, Nonporous Environmental Surfaces [for Hospital Use] [for Pharmaceutical Use]
- Eliminates Bacterial Odors at their Source
- Suitable for Use on [Titanium-Coated] [Medical Grade] Stainless Steel
- Kills Odor-Causing Bacteria
- Eliminates Odors
- Premeasured, Easy and Convenient [to Use] [for Hospital Use] [for Pharmaceutical Use]
- Multi-Purpose Disinfectant [for Hospital Use] [for Pharmaceutical Use]
- For Daily Disinfection of Hard, Nonporous Surfaces
- Use to Disinfect Hard, Nonporous Surfaces
- Will Not Leave Grit or Soap Scum
- Controls Cross-Contamination between Treated Hard, Nonporous Surfaces
- Formulated for Veterinary Practice / Animal Care / Animal Laboratory Disinfection
- Formulated for Effective [Pharmaceutical Manufacturing] Disinfection [Bactericidal] [Disinfectant]
- Delivers Broad Spectrum Disinfectant Performance in a [Convenient] Post-Mixed, Ready- to-Use Solution [without Bleach] [for Hospital Use] [for Pharmaceutical Use]
- For use in Pharmaceutical Manufacturing, Hospitals, Institutional and Industrial Facilities
- [Kills] [Eliminates] [Destroys] [more than] [99.9%] *Bacteria* [*Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Salmonella enterica*, [in 5 minutes] [on Hard, Nonporous Surfaces]

**Mixed AXENIPLEX SD, Kills, Destroys, Eliminates, *bacteria*, in 5 Minutes,**

*Pseudomonas aeruginosa*, *Salmonella enterica*, *Staphylococcus aureus*.

**++Hospital and Healthcare Applications:** Mixed AXENIPLEX SD is for use in the disinfection of hard, nonporous surfaces in health care settings such as Hospitals and other areas where control of cross contamination of treated surfaces is required including: Medical Clinics, Dental Offices, Ophthalmology, Optometry, Blood Collection and Donation Centers, Hospital Central Service Areas, Nursing Homes, Hospices, Rehabilitation Orthopedics, Physical Therapy, Respiratory Physician Radiology, Anesthesia, Laboratories, Cath Labs, Pediatrics, Recovery Rooms 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 for Hard Nonporous Surfaces:** Autoclaves, baskets, bed pans, railings, blood glucose monitors, cabinets, carts, chairs, counters, door knobs and handles, drawer pulls, exam tables, examination gurneys, incubators, infant incubators care cribs, IV poles, lighting fixtures, machines, mammography equipment compressor plates, pails, patient monitoring equipment, physical therapy respiratory shower stalls, stethoscopes, stools, stretchers, telephones, toilet exteriors seats, ultrasound transducers probes, walkers, wheelchairs, water sensitive, nonfood contact surfaces, Hospital

operating rooms, emergency departments, medical settings, medical related facilities, ambulatory surgical centers, surgery centers (ASC), Life Science Laboratories, surgical, surgery suites, out-patient (OPSC), central services department, isolation areas, Cath labs, ICU, Central Supply, laboratories, clinics, patient areas, nursing homes, ophthalmic offices, home health care, hospices, laboratory, hard nonporous laundry room surfaces, Newborn nursery optometric facilities, Orthopedics, centers, pediatrics, Pediatric (PICU), physical therapy, Physicians' offices, Radiology, Recovery, Rehabilitation, Respiratory Therapy, X-Ray and dialysis centers, blood, plasma, semen and milk donation centers, aphaeresis vehicles, ambulances settings, Emergency Rooms, ER, police fire vehicles, morgue, cadaver and other critical care areas where control of cross contamination between treated surfaces is important.

**Emergency and First Responder Applications: Mixed AXENIPLEX SD** is for use in the disinfection of hard, nonporous surfaces in **Ambulances, Police, and Fire, Emergency and First Responder Vehicles and other areas where control of cross contamination of treated surfaces is required.** **Use Sites:** CBRN PPE's, SCBA's, ventilation and airway equipment, monitoring defibrillation resuscitators, immobilization devices, communication wheeled hard, nonporous cots, folding stretchers, stair chairs, injury prevention IV poles, roof hooks, intravenous arm boards, cardiac nebulizers, cellular phones other electronics, hard, nonporous extrication equipment and additional hard nonporous surfaces, water sensitive surfaces listed on this label.

**Mixed AXENIPLEX SD** is for use in the disinfection of hard, nonporous surfaces in Schools, Transport vehicles, buses, cruise ships, **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, nonporous surfaces contaminated with the 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, nonporous surfaces listed on this label.

**School and University Applications: AXENIPLEX SD** is for use in the disinfection of hard, nonporous 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, nonporous surfaces contaminated with the pathogens listed on this label. **Use Sites:** Personal protective safety equipment, athletic helmets, wrestling headgear, boxing half mask respirators, full face breathing apparatus, gas masks, goggles, spectacles, shields, hearing protectors, hard, nonporous ear muffs, hard nonporous mats, gymnastic exercise weight machines, aerobic 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, nonporous surfaces listed on this label.

**Home Applications: Mixed AXENIPLEX SD** is for daily use in the cleaning and disinfection of hard, nonporous surfaces in the home. **Homes, Condominiums and Apartments: Use Sites:** Sealed Hardwood floors, tile floors and linoleum floors, Kitchen and Bathroom countertops, Bathroom shower, Bathroom tub, sinks, sink handles, toilets, cabinets, glass windows, window sills, Computers, Computer keyboards, television remote(s), door knobs, trash cans, refrigerator, and other hard, nonporous surfaces listed on this label.

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

**Veterinary Applications: Mixed AXENIPLEX SD** is for use in the disinfection of hard, nonporous 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, instruments, kennels, stables, stalls, catteries, furniture, walls, floors and animal transportation vehicles will deodorize those areas that are generally hard to keep fresh smelling such as garbage storage areas, empty bins and cans, and any other hard, nonporous areas which are prone to odors caused by microorganisms.

**Mixed AXENIPLEX SD** is for use in the disinfection of hard, nonporous surfaces in **Livestock Premises, Poultry Premises, Poultry Hatcheries and Animal Housing Facilities. Use Sites:** Egg receiving area, tray dumping egg holding chick setter room, hatchery trays, buggies, racks, flats, processing loading poultry buildings, ceilings, sidewalls and floors.

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

**Mixed AXENIPLEX SD** is for use in the sanitation of hard, nonporous 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, all other hard, nonporous in barns, pens, and stalls, chutes facilities fixtures occupied or traversed by animals.

**Morgue and Mortuary Applications: Mixed AXENIPLEX SD** is for use in the disinfection of hard, nonporous surfaces in **Morgues, Mortuaries, Funeral Homes and Funeral Parlors.**

**Refrigeration Applications: Equipment surfaces must be cooled to 20° C for disinfection: AXENIPLEX SD** is for use in the disinfection of hard, nonporous surfaces on **Coils and Drain Pans of Air Conditioning and Refrigeration Equipment and Heat Pumps.**

**Mixed AXENIPLEX SD** is effective and for use as directed on hard, nonporous 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.

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

## **AXENIPLEX® SD (Part A)**

### **DIRECTIONS FOR USE**

(Part A must be Mixed with Part B. There are no stand-alone claims)

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

#### **MIXING DIRECTIONS FOR ACTIVATION**

AXENIPLEX SD (Part A) is formulated as one component of a two-part system and therefore must not be used alone as a disinfectant without activating. Activate AXENIPLEX SD prior to use by pouring the contents of the AXENIPLEX SD Activator (Part B) small container into the AXENIPLEX SD (Part A) large container as instructed below:

<b>TOTAL MIXED SOLUTION</b>	<b>129.8 fl. oz.</b>
AXENIPLEX SD Part A	128 fl. oz.
AXENIPLEX SD Part B	1.28 fl. oz.



1. Using appropriate personal protective equipment (PPE), remove the cap on the AXENIPLEX SD (Part A) large container to expose the opening;
2. Obtain the AXENIPLEX SD Activator (Part B) small container and remove the child protective cap. CAREFULLY pour the entire content of the AXENIPLEX SD Activator (Part B) small container into Part A large container.
3. Replace cap on the empty AXENIPLEX SD Activator (Part B) small container and discard as directed;
4. Replace cap on the AXENIPLEX SD (Part A) large container and shake or mix for approximately 15 seconds to combine the solution. AXENIPLEX SD Mixed Solution is now Ready-to-Use as directed.
5. Mark the activation date on the product use container using a permanent marker. Once Part A and Part B are Mixed, the Mixed solution can be used as a disinfectant for eight (8) days. Dispose of any Solution that has exceeded this timeframe post activation.

### **GENERAL CLEANING & DEODORIZING DIRECTIONS**

**Mixed AXENIPLEX SD** is for use in general cleaning and deodorizing. Apply a generous amount of AXENIPLEX SD, the mixed AXENIPLEX 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.

### **DISINFECTION DIRECTIONS**

**Mixed AXENIPLEX SD** is for use in disinfecting hard, nonporous surfaces against, to kill, the following pathogens:

- **Mixed AXENIPLEX SD** is for use in disinfecting hard, nonporous surfaces to kill the following pathogens: *Staphylococcus aureus* (ATCC 6538), *Pseudomonas aeruginosa* (ATCC 15442), *Salmonella enterica* (ATCC 10708).
- **BACTERICIDAL HEALTHCARE ACTIVITY – Mixed AXENIPLEX 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),

**TO CLEAN, DISINFECT, AND DEODORIZE IN ONE STEP:** Apply mixed AXENIPLEX SD 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:** <sup>††</sup> 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 mixed AXENIPLEX SD. Apply mixed AXENIPLEX SD 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.

**TO DISINFECT WATER SENSITIVE EQUIPMENT HARD, NONPOROUS 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 mixed AXENIPLEX SD. Carefully apply mixed AXENIPLEX SD 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, nonporous, non-critical instruments and objects compatible with Ultrasonic cleaning units. Pour mixed AXENIPLEX SD directly into bath chamber. Place objects into unit and operate for 5 minutes, according to the Ultrasonic manufacturers use directions. Remove objects and allow to air dry or rinse with sterile water (sterile water for injection) and allow to air dry. Use freshly mixed AXENIPLEX SD for each bath cycle.

**TO CLEAN, DISINFECT, AND DEODORIZE BEAUTY, HAIR, SALON, BARBER SHOP, SPA AND NAIL MANICURE, SALON HARD, NONPOROUS 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 mixed AXENIPLEX SD 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 mixed AXENIPLEX SD 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 PATHOGENS 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 mixed AXENIPLEX SD and rinse with water. For hard, nonporous surfaces, apply 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.

<sup>++</sup>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.

#### **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 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:**

## STORAGE AND DISPOSAL

### AXENIPLEX SD (Part A)

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. Dispose of container into an approved trash receptacle. Offer for recycling if available or reconditioning if appropriate.

# AXENIPLEX® SD Activator (Part B)

Disinfectant Cleaner

AXENIPLEX SD is a two-part system and when Part A and Part B are combined, creates an effective Bactericide,  
One-Step Cleaner, Disinfectant & Deodorizer

*IDEAL FOR WATER SENSITIVE EQUIPMENT & AREAS*

For Pharmaceutical Manufacturing, Hospital, Emergency, First Responder,  
Institutional, Industrial and Home Use

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

ACTIVE INGREDIENT:

Hydrogen Peroxide	.....22.00%
Peroxyacetic acid	.....15.00%
Inert Ingredients	.....63.00%
Total	.....100.00%

KEEP OUT OF REACH OF CHILDREN

**DANGER**

Read Entire Label and Supplemental Pamphlet for  
Complete Directions and Additional Precautionary Statements

<b>FIRST AID FOR STERIPLEX SD ACTIVATOR (PART B) SOLUTION ONLY</b>	
<b>IF IN EYES</b>	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 physician for treatment advice.
<b>IF ON SKIN OR CLOTHING</b>	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.
<b>IF SWALLOWED</b>	Call 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 to an unconscious person.
<b>IF INHALED</b>	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.	
Have the product container with you when calling a poison control center or going for treatment.	
<b>FOR EMERGENCY MEDICAL INFORMATION CALL TOLL FREE: 1-800-222-1222</b>	

## DIRECTIONS FOR USE

(Part B must be Mixed with Part A. There are no stand-alone claims)

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

### MIXING DIRECTIONS FOR ACTIVATION

AXENIPLEX SD (Part B) is formulated as one component of a two-part system and therefore must not be used alone as a disinfectant without activating. Activate AXENIPLEX SD prior to use by pouring the contents of the AXENIPLEX SD Activator (Part B) small container into the AXENIPLEX SD (Part A) large container. Refer to AXENIPLEX SD part A for complete directions for use.

1. Using appropriate personal protective equipment (PPE), remove the cap on the AXENIPLEX SD (Part A) large container to expose the opening;
2. Obtain the AXENIPLEX SD Activator (Part B) small container and remove the child protective cap. CAREFULLY pour the entire content of the AXENIPLEX SD Activator (Part B) small container into Part A large container.
3. Replace cap on the empty AXENIPLEX SD Activator (Part B) small container and discard as directed;
4. Replace cap on the AXENIPLEX SD (Part A) large container and shake or mix for approximately 15 seconds to combine the solution. AXENIPLEX SD Mixed Solution is now Ready-to-Use as directed.

Mark the activation date on the product use container using a permanent marker. Once Part A and Part B are Mixed, the Mixed solution can be used as a disinfectant for eight (8) days. Dispose of any Solution that has exceeded this timeframe post activation.

### PRECAUTIONARY STATEMENTS FOR AXENIPLEX SD ACTIVATOR (PART B) ONLY

#### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**DANGER. CORROSIVE.** Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through the skin. Harmful if swallowed. Do not breathe vapors or spray mist. Do not get in eyes, on skin or on clothing. Wear goggles and/or face shield and rubber gloves when handling. Do not enter an enclosed area without proper respiratory protection. 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 before reuse.

#### PHYSICAL OR CHEMICAL HAZARDS FOR AXENIPLEX SD ACTIVATOR (PART B) ONLY

**STRONG OXIDIZING AGENT.** Corrosive. Mix only with AXENIPLEX SD Part A solution. Product must be diluted in accordance with label directions prior to use. At temperatures exceeding 156°F, decomposition occurs, releasing oxygen. The oxygen released could initiate combustion.

#### ENVIRONMENTAL HAZARDS FOR AXENIPLEX SD ACTIVATOR (PART B) ONLY

This pesticide is toxic to birds, fish, and aquatic invertebrates.

#### PERSONAL PROTECTIVE EQUIPMENT (PPE) FOR AXENIPLEX SD ACTIVATOR (PART B) ONLY User Safety

Some active ingredients of this product can cause eye damage or skin irritation. Prolonged exposure to spray mist or vapor may cause allergic reactions to some individuals. User should wash hands before eating, drinking, or using the toilet. User should be familiar with prescribed safety and usage instructions prior to using this product.

##### Eyes and Face

Use cup type chemical goggles. Full-face shield should be used when mixing and applying this product to the intended surfaces.

**Protective Clothing** Use of rubber or neoprene footwear is recommended. Rubber or neoprene aprons or full protective clothing should be used. Hydrogen peroxide is an ingredient of this product. Completely submerge hydrogen peroxide contaminated clothing or other materials in water prior to drying. Residual hydrogen peroxide, if allowed to dry on materials such as fabrics, cotton, leather, wood, paper, or other combustibles can cause the material to ignite and result in a fire.

**Gloves**

Rubber or neoprene gloves are recommended when mixing and applying product. Thoroughly wash the outside of gloves with soap and water prior to removal. Inspect regularly for leaks.

**Respiratory**

For normal use as directed, respiratory protection is not required. However, if exposures are anticipated to be above normal limits or if concentrations are unknown (e.g., significant spill or other emergencies), or if they are anticipated to be above 5 ppm for hydrogen peroxide or 50 ppm for Peroxyacetic acid, the use of a self-contained breathing apparatus (SCBA) is recommended.

## STORAGE AND DISPOSAL

### AXENIPLEX SD (Part B)

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

**Pesticide Storage**

Store in original container in dry, cool area and away from direct sunlight. Keep container closed at all times when not in use. Never return AXENIPLEX SD Activator (Part B) to the original container after it has been removed. To maintain product quality, do not allow product to become overheated in storage. Avoid all contaminants, especially dirt, caustic reducing agents, and metals. Contamination and impurities will reduce shelf life and can induce decomposition.

In case of spill or decomposition, isolate container, douse container with cool water and dilute AXENIPLEX SD Activator (Part B) with large volumes of water. Do not store in a manner where cross-contamination with other pesticides could occur. Avoid damage to containers. Do not double stack pallets. Use first in, first out storage system.

**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. If material has been spilled, an acceptable method of disposal is to dilute with at least 20 volumes of water followed by discharge into suitable treatment system in accordance with all local, state, and Federal environmental laws, rules, regulations, standards, and other requirements. Because acceptable methods of disposal may vary by location, regulatory agencies should be contacted prior to disposal. AXENIPLEX SD Activator (Part B), which is to be discarded, should be disposed of as hazardous waste after contacting the appropriate local, state, or Federal agency to determine proper procedures

**Container Handling and Disposal**

Nonrefillable container. Do not reuse or refill this container. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container  $\frac{1}{4}$  full of water and recap and shake for 10 seconds, then uncap and discard rinsate. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times, and then discard container and cap into an approved trash receptacle. Offer for recycling, if available.