

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

June 29, 2023

Brian Hogan KRK Consulting LLC

Authorized Agent for Berkshire Management Incorporated

Electronic Transmittal: <u>brianhogan330@gmail.com</u>

Subject: Label Amendment – Minor label changes along with changing the primary brand

name from "AXENIPLEX SD" to "TRUSEPTA" while removing the ABN.

Product Name: TRUSEPTA

EPA Registration Number: 96194-1

Received Date: 9/9/2021

Action Case Number: 00321559

# Dear Brain Hogan:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. Pursuant to 40 CFR 156.10(a)(6) you must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

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 FIFRA and is subject to review by the Agency. See FIFRA section 2(p)(2). 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) lists 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, FIFRA section 12(a)(1)(B). 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 Assurance.

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Additionally, the company has asked to withdraw their alternate brand name (ABN) and change the primary brand name from "AXENIPLEX SD" to "TRUSEPTA". The ABN has been removed and primary brand name changed in the official record.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Steven Snyderman by phone at (202) 564-0910, or via email at <a href="mailto:snyderman.steven@epa.gov">snyderman.steven@epa.gov</a>.

Sincerely,

Steven Snyderman, Product Manager 33

Regulatory Management Branch II Antimicrobials Division (7510M)

Office of Pesticide Programs

Steven Inyderman

Enclosure: Stamped Final Label

# ACCEPTED

06/29/2023

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 2010 4

96194-1

# **TRUSEPTA**

(Part A & Part B)

Disinfectant and Cleaner
TRUSEPTA is a two-part system and when Part A and Part B are combined, creates an
effective Bactericide,
Cleans, Disinfectants & Deodorizes in one step

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 TRUSEPTA Part A and TRUSEPTA Part B can be found in subsequent pages of this master label document.

# TRUSEPTA (Part A)

ACTIVE INGREDIENT:	Silver0.0155%
Inert Ingredients	99.9845%
Total	100.0000%

#### KEEP OUT OF REACH OF CHILDREN

Net Contents: 0.85, 45 Gallons

## **ACTIVE INGREDIENTS:**

# TRUSEPTA (Part B)

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

# KEEP OUT OF REACH OF CHILDREN DANGER [/ PELIGRO]

[Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)]

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

{Note to Reviewer: In accordance with 40 CFR 156.68(d), all first aid statements, as prescribed, will appear on the front panel of the product label.}

# PRECAUTIONARY STATEMENTS FOR TRUSEPTA 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 TRUSEPTA ACTIVATOR (PART B) ONLY

**STRONG OXIDIZING AGENT.** Corrosive. Mix only with TRUSEPTA 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. 96194-1 EPA Est. No. XXXXX-XX-X

Berkshire Management Incorporated 4306 W. Harvey Blvd. Cedar Hills, UT 84062 801-362-2135

# **TRUSEPTA**

# (Mixed Solution)

**Pharmaceutical Manufacturing Applications:** Mixed TRUSEPTA 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
- [Two in one] cleaning and disinfecting for hard, non-porous surfaces
- Clean and disinfect in one step
- Broad Spectrum [Disinfectant] [Antibacterial] [Cleaner and Disinfectant] for hard, non-porous surfaces [for Hospital Use] [for Pharmaceutical Use], proven to [kill 99.9%] [destroy 99.9%] [eliminate 99.9%] [deodorize] bacteria [in 5 minutes] on Hard, Non-porous Surfaces [without Bleach] For [Pharmaceutical] [Hospital] [First Responder] Use
- Broad Spectrum [Disinfectant] [One-Step Cleaner and Disinfectant] on hard, non-porous surfaces [for Pharmaceutical Use] [for Hospital Use]
- Cleaner and Disinfectant for hard, non-porous surfaces [for Pharmaceutical Use] [for Hospital Use]
- Cleans [and], Disinfects hard, non-porous surfaces, [& Deodorizes] in [without Bleach] [for Pharmaceutical Use] [for Hospital Use]
- Hospital [Use] Pharmaceutical [Use] [Cleaner and] Disinfectant for hard, non-porous surfaces
- Disinfects as it Cleans in One Operation on hard, non-porous surfaces [without Bleach]
- Meets AOAC Use-Dilution Test Standards for Hospital Use [Cleaner &] Disinfectants on hard, nonporous surfaces
- Meets AOAC Use-Dilution Test Standards for Pharmaceutical Use [Cleaner &] Disinfectants on hard, non-porous surfaces
- Cleaning and Disinfecting on hard, non-porous surfaces [without Bleach] [for Hospital Use] [for Pharmaceutical Use]
- Broad Spectrum Hospital and Medical Environment Use [Cleaner and] Disinfectant for hard, nonporous surfaces
- Kills 99.9% of 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 99.9%] [destroy 99.9%] [eliminate 99.9%] [deodorize] bacteria, [in 5 minutes] on Hard, Nonporous Surfaces [without Bleach]
- [Disinfectant] [for Hospital Use] [for Pharmaceutical Use]
- Hospital [Use] Pharmaceutical [Use] Disinfectant x
   Contains No [Bleach] [or] [Sodium Hypochlorite] x
   Clean, Fresh Smell [with No Bleach Fumes]
- Bleach Free
- Does Not Contain Bleach
- [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 hard, non-porous surfaces, [& 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 hard, non-porous surfaces [without Bleach] [for Hospital Use]
- Deodorizes by Killing the Germs that Cause Odors
- Disinfects hard, non-porous surfaces [without Bleach]
- Disinfecting Formula [without Bleach] [for Hospital Use] [for Pharmaceutical Use]
- Broad Spectrum Hospital and Medical Environment Use Disinfectant for hard, non-porous surfaces [without Bleach]
- Broad Spectrum Pharmaceutical Manufacturing Use Disinfectant on hard, non-porous surfaces [without Bleach]
- Disinfects hard, non-porous surfaces and Deodorizes by Killing 99.9% of Bacteria and their Odors
- Convenient Disinfecting on hard, non-porous surfaces [without Bleach]
- Cleaning and Disinfecting of hard, non-porous surfaces [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 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 of hard, non-porous surfaces
- Formulated for Effective [Pharmaceutical Manufacturing] Disinfection on hard, non-porous surfaces [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 TRUSEPTA, Kills, Destroys, Eliminates, 99.9% bacteria, in 5 Minutes,

Pseudomonas aeruginosa, Salmonella enterica, Staphylococcus aureus.

\*\*Hospital and Healthcare Applications: Mixed TRUSEPTA 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 TRUSEPTA 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 TRUSEPTA 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: TRUSEPTA 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 TRUSEPTA** 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 TRUSEPTA** 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 TRUSEPTA** 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 TRUSEPTA** 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 TRUSEPTA** 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 TRUSEPTA** is for use in the sanitation of hard, nonporous surfaces in **Animal Farms. Use Sites:** Mangers, nonfood 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 TRUSEPTA 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: TRUSEPTA 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 TRUSEPTA** 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 TRUSEPTA** 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.

# TRUSEPTA (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

**TRUSEPTA** (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 TRUSEPTA prior to use by pouring the entire contents of the **TRUSEPTA** Activator (Part B) small container (red label) into the **TRUSEPTA** (Part A) large container as instructed below:

TOTAL MIXED SOLUTION	109.8 fl. oz.	45.45 Gallons
TRUSEPTA Part A	108 fl. oz.	45 Gallons
TRUSEPTA Part B	1.08 fl. oz.	0.45 Gallons



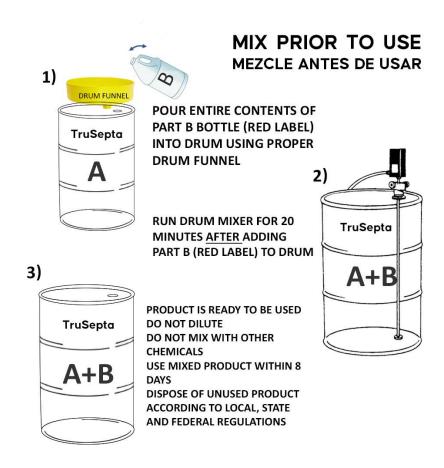




- 1. Using appropriate personal protective equipment (PPE), remove the cap on the TRUSEPTA (Part A) large container to expose the opening;
- 2. Obtain the TRUSEPTA Activator (Part B) small container (red label) and remove the child protective cap. CAREFULLY pour the entire content of the TRUSEPTA Activator (Part B) small container (red label) into Part A large container.
- 3. Replace cap on the empty TRUSEPTA Activator (Part B) small container (red label) and discard as directed;
- 4. Replace cap on the TRUSEPTA (Part A) large container and shake or mix for approximately 15 seconds to combine the solution. TRUSEPTA Mixed Solution is now Readyto-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 TRUSEPTA** is for use in general cleaning and deodorizing. Apply a generous amount of TRUSEPTA, the mixed TRUSEPTA 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 TRUSEPTA** is for use in disinfecting hard, nonporous surfaces against, to kill, the following pathogens:

- Mixed TRUSEPTA 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 TRUSEPTA 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:** Apply mixed TRUSEPTA 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 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 mixed TRUSEPTA. Apply mixed TRUSEPTA 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 TRUSEPTA. Carefully apply mixed TRUSEPTA 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 TRUSEPTA 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 TRUSEPTA 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 TRUSEPTA 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 TRUSEPTA 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 TRUSEPTA 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: Berkshire Management Incorporated 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, Berkshire Management Incorporated or the seller makes no other express or implied warranty of merchantability. To the extent consistent with applicable law, in no case shall Berkshire Management Incorporated or the seller be liable for consequential, special or indirect damages resulting from the use or handling of this product. Berkshire Management Incorporated 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 Berkshire Management Incorporated.

**Lot Number:** 

Mix Activation, Date:

# STORAGE AND DISPOSAL

# **TRUSEPTA (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.

# TRUSEPTA Activator (Part B)

Disinfectant and Cleaner

TRUSEPTA is a two-part system and when Part A and Part B are combined, creates an effective Bactericide, Cleans, Disinfectants & Deodorizes in one step

### 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 [/ PELIGRO]

[Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)]

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

{Note to Reviewer: In accordance with 40 CFR 156.68(d), all first aid statements, as prescribed, will appear on the front panel of the product label.}

FIRST AID FOR TRUSEPTA ACTIVATOR		
(PART B) SOLUTION ONLY		
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 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.	
IF SWALLOWED	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.	
IF INHALED	Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.	
	Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.	
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		

# **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

TRUSEPTA (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 TRUSEPTA prior to use by pouring the entire contents of the TRUSEPTA Activator (Part B) small container (red label) into the TRUSEPTA (Part A) large container. Refer to TRUSEPTA part A for complete directions for use.

- 1. Using appropriate personal protective equipment (PPE), remove the cap on the TRUSEPTA (Part A) large container to expose the opening;
- 2. Obtain the TRUSEPTA Activator (Part B) small container (red label) and remove the child protective cap. CAREFULLY pour the entire content of the TRUSEPTA Activator (Part B) small container (red label) into Part A large container.
- 3. Replace cap on the empty TRUSEPTA Activator (Part B) small container (red label) and discard as directed;
- 4. Replace cap on the TRUSEPTA (Part A) large container and shake or mix for approximately 15 seconds to combine the solution. TRUSEPTA 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 TRUSEPTA 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 TRUSEPTA ACTIVATOR (PART B) ONLY

**STRONG OXIDIZING AGENT.** Corrosive. Mix only with TRUSEPTA 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 TRUSEPTA ACTIVATOR (PART B) ONLY**

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

# PERSONAL PROTECTIVE EQUIPMENT (PPE) FOR TRUSEPTA 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

# TRUSEPTA (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 TRUSEPTA 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 TRUSEPTA 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. TRUSEPTA 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 ¼ 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.