



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 9, 2014

Rebecca Mannion
Diversey, Inc.
8310 16th ST, MS 707
Sturtevant, WI 53177

Subject: PRIA Label Amendment – Add soft surface sanitization claims
Product Name: OXIVIR Tb
EPA Registration Number: 70627-56
Application Date: July 15, 2014
Decision Number: 493250

Dear Ms. Mannion

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, 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. 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 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.

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

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with FIFRA section 6. If you have any questions, please contact Zebora Johnson by phone at (703) 308-7080, or via email at johnson.zebora@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "SEIICHI MURASAKI". The signature is stylized with a large initial "S" and a cursive "M".

Seiichi Murasaki
Acting Product Manager 33
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

(Note to Agency: Text appearing in parenthesis is done to show optional text.)

OXIVIR Tb

(Ready to Use)
(One-Step Disinfectant) (and) (Deodorizer)
(General) (*Virucide), (Bactericide), (Tuberculocide), (Fungicide), (Sanitizer)
(Cleaner) (Disinfectant) (Deodorizer)
(One-step cleaner spot sanitizer on soft surfaces[†])

(Hydrogen Peroxide)

For (Industrial) (&) (Institutional) Use

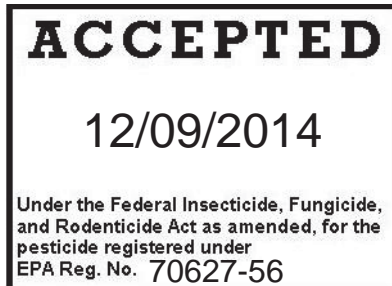
ACTIVE INGREDIENT:	
Hydrogen Peroxide.....	0.5%
OTHER (INERT) INGREDIENTS:	<u>99.5%</u>
TOTAL:	100.0%

KEEP OUT OF REACH OF CHILDREN CAUTION

(See additional precautionary statements on (back) (side) (left) (right) (panel) (label) (below).)

(See reference sheet (enclosed in each case) for (a complete list of organisms) (additional (features) (claims) (directions for use)) (for this product).)

Net Contents:



(Product of XXXXXXXXX)

(Note to Agency: Text appearing in parenthesis is done to show optional text.)

(FEATURES, CLAIMS & USES:)

(General Uses:)

For Use in Health Care, Veterinary, Animal Housing, Dental, (Life Science) Laboratory, Medical, Industrial & Institutional Facilities, Food Processing Establishments, and Hospitals.

This product is a one-step (hospital-use) germicidal (disinfectant) cleaner and deodorant (odor-counteractant) (odor neutralizer) designed for general cleaning, (and) disinfecting (deodorizing) (of) hard, non-porous inanimate surfaces. It cleans quickly by removing dirt, grime, and other common soils found in hospitals, nursing homes (long-term care), (medical) (dental) offices, schools & colleges, correctional facilities, transportation terminals (airports, train stations, bus stations, truck stops, rest (stops) areas), hotels, motels, casinos, cruise ships, other institutional/commercial buildings, homes cleaned by (home cleaning services,)(professional cleaning services,)(medical assistance services,) office buildings, veterinary clinics, pet shops, equine farms, and animal & life science laboratories.

This product's non-dulling formula eliminates the time and labor normally required for rinsing. It is designed for use on (Use daily on) (the following) (hard, non-porous inanimate surfaces): (vinyl), (Naugahyde), painted surfaces, plastic (surfaces), glazed ceramic, glazed porcelain, chrome, stainless steel, aluminum, laminated surfaces and baked enamel surfaces associated with floors, walls, ceilings, tables, chairs, countertops, telephones, fixtures, glazed tile, sinks – almost any washable (non-food contact) surface where disinfection is required. A potable water rinse is required for food contact surfaces. Do not use on glasses, dishes and utensils.

(Soft Surface Spot Sanitization:)

- A proven spot sanitizer on soft surfaces[†]
- An effective soft surface[†] spot sanitizer
- Spot sanitizes soft surfaces[†] (in one step) (in 30 seconds)

(Great) For use (as a spot sanitizer) on soft surfaces[†] (composed of cotton or polyester). (This product) Kills (removes) (sanitizes) microorganisms on soft surfaces[†] or fabric[†] including: blinds, bedding, blankets, chairs, couches, curtains, drapes, exercise mats, gym bags, headrests, linens, mats, mattresses, seat (soft) cushions, shades, sheets, sofas, sports equipment (lining), towels, upholstered furniture, upholstery, washcloths, and window treatments. Removes (and) (or) (eliminates) odors by killing odor-causing bacteria on soft surfaces[†] or fabrics[†]. A cost effective solution compared to laundering or dry cleaning curtains.

[Note: Prior to first use on a particular surface, it is recommended to test in a small, discreet area if there is concern of incompatibility.]

[†]plain cotton weave and 100% polyester fabric

(Hospitals/Health Care Facilities/Dental Offices/Life Science Laboratories:)

This product is a one-step (hospital-use) (laboratory-use) germicidal (disinfectant) cleaner and deodorant (odor-counteractant) (odor neutralizer) designed for general cleaning, (and) disinfecting, (deodorizing) (of) hard, non-porous inanimate surfaces. This product cleans quickly by removing dirt, grime, food residue, dead skin, blood and other organic matter commonly found in hospitals, (in health care facilities), ambulances, emergency vehicles, clinics, surgical centers, neonatal care units, physician offices, (laboratory settings). It also eliminates odors, leaving (restroom) surfaces smelling clean and fresh. Use where odors are a problem.

This product cleans, disinfects and deodorizes hard, non-porous inanimate (hospital) (medical) (dental) (laboratory) surfaces in one step (with no rinsing required). Its non-abrasive formula is designed for use on (Use daily on) (the following) (hard, non-porous inanimate surfaces:) (vinyl), (Naugahyde), painted surfaces, plastic (surfaces), glazed ceramic, glazed porcelain, chrome, stainless steel, laminated surfaces (and baked enamel surfaces associated with floors), walls, ceilings, tables, chairs, countertops, telephones, fixtures, glazed tile, toilet exteriors, urinal exteriors, sinks found in (health care facilities), (hospitals), (dental offices), (patient rooms), (operating rooms), (ICU areas), (shower rooms), and (locker rooms) (fume hoods and animal cages [found in laboratory settings]). (It can be used to pre-clean and disinfect hospital items: wheelchairs, (hospital) (patient) bedrails and linings (patient bed linings) (vinyl mattress covers), wash basins, bed pans, non-critical medical equipment surfaces – almost any washable (food and non-food contact) surface (where disinfection is required). A potable water rinse is required when disinfecting food contact surfaces. Do not use on glasses, dishes and utensils.

(Note to Agency: Text appearing in parenthesis is done to show optional text.)

(Animal Housing Facilities:)

This product cleans by removing dirt, grime, blood, urine, fecal matter and other common soils found in animal housing facilities, grooming facilities, farms, kennels, pet stores, veterinary clinics, laboratories or other small animal facilities. It (also) eliminates odors leaving surfaces smelling clean and fresh.

This product cleans, disinfects and deodorizes hard, non-porous environmental surfaces in one step. Its non-abrasive formula is designed for use on (Use daily on) (Use daily to clean and disinfect) (hard, non-porous surfaces:) plated or stainless steel, chrome, glazed porcelain, glazed tile, laminated surfaces (associated with floors, walls, countertops, cages, kennels, animal equipment), found in (barns, pens and stalls) animal housing facilities.

(Refill)

To Transfer This Product Into Smaller Containers:

[This product may be transferred into clean, properly labeled containers for use elsewhere within your facility.] The small container and transfer items (funnels or hand pumps) must be clean and dry. Pour (or pump) product directly into a properly labeled smaller container being careful not to spill any product. Keep containers sealed when not in use. Refill in a well ventilated area.

(CLAIMS:)

When used as directed, this product is highly effective against a wide variety (broad-spectrum) of pathogenic microorganisms (including bacteria, antibiotic resistant bacteria, viruses, and fungi). (See reference sheet (enclosed in each case) for a complete list of organisms.)

Using approved AOAC test methods (under Good Laboratory Practices, [GLP's]), 5% serum load and 1 minute contact time this product kills the following on hard non-porous inanimate surfaces:

Bactericidal Activity:

Staphylococcus aureus, (ATCC 6538)
Salmonella enterica, (ATCC 10708)
Formerly known as *Salmonella choleraesuis*
Pseudomonas aeruginosa, (ATCC 15442)

Acinetobacter baumannii, (ATCC 19606)
Escherichia coli O157:H7, (ATCC 35150)
Escherichia coli with extended beta-lactamase resistance (ESBL), (ATCC BAA-196)

Klebsiella pneumoniae, (ATCC 4352)
Shigella dysenteriae, (ATCC 11835)

Antibiotic-Resistant (Strains of) Bacteria (Antibiotic-Resistant Bactericidal Activity):

Enterococcus faecalis, (ATCC 51575)
(Resistant to Vancomycin [VRE])

Staphylococcus aureus (CA-MRSA),
(NARSA NRS 384)(Genotype USA300)
Community Associated Methicillin Resistant

Staphylococcus aureus (CA-MRSA),
(NARSA NRS 123)(Genotype USA400)
Community Associated Methicillin Resistant

Staphylococcus aureus, (ATCC 33592)
(Resistant to Methicillin [MRSA])

***Viruses (*Virucidal Activity):**

*Adenovirus type 8, (ATCC VR-1368)
*Hepatitis B Virus (HBV), Duck Hepatitis B Virus (DHBV) as surrogate
(Acquired from Hepadnavirus Testing)
*Hepatitis C Virus (HCV), Bovine Viral Diarrhea Virus (BVDV) as surrogate
(Acquired from National Veterinary Services Laboratories)

*Herpes Simplex Virus, Type 1 (HSV-1), (ATCC VR-733)
*Herpes Simplex Virus, Type 2 (HSV-2), (ATCC VR-734)
*HIV-1 (AIDS Virus), Strain HTLV-III_B (HIV-1), (Acquired from Adv. Biotechnologies, Inc.)
*Human Coronavirus, (ATCC VR-740)
*Influenza A/Hong Kong, (ATCC VR-544)

*Norovirus, (Feline Calicivirus, ATCC VR-782 as the surrogate)
*Poliovirus Type 1, Strain Brunhilde, (ATCC VR-1000)
*Rhinovirus Type 37, Strain 151-1, (ATCC VR-1147)
*Rotavirus WA, (Acquired from University of Ottawa)

(*Veterinary Viruses:)

*Avian Influenza A (H3N2), (ATCC VR-2072)

*Feline Calicivirus, Strain F9, (ATCC VR-782)

TUBERCULOCIDAL in the presence of a 5% serum load and 5 minute contact time at 20°C (68°F) on hard, non-porous environmental surfaces.

Mycobacterium bovis (Tb) (OT 451C150)

(Note to Agency: Text appearing in parenthesis is done to show optional text.)

FUNGICIDAL: This product is fungicidal against the pathogenic fungi *Trichophyton mentagrophytes* (ATCC 9533) (the fungus which causes Athlete's Foot) in the presence of a 5% serum load and 10 minute contact time when used as directed on hard surfaces found in bathrooms, shower stalls, locker rooms, or other clean, non-porous, hard surfaces commonly contacted by bare feet.

Trichophyton mentagrophytes (ATCC 9533)

Non-Food Contact Surface Sanitizer for hard non-porous surfaces in the presence of a 5% serum load and 30 second contact time on hard, non-porous environmental surfaces.

Enterococcus faecalis, (ATCC 51575)
(Resistant to Vancomycin [VRE])

Pseudomonas aeruginosa, (ATCC 15442)

Staphylococcus aureus, (ATCC 6538)

Escherichia coli O157:H7, (ATCC 35150)

Salmonella enterica, (ATCC 10708)

Staphylococcus aureus, (ATCC 33592)
(Resistant to Methicillin [MRSA])

Klebsiella pneumoniae, (ATCC 4352)

Soft Surface Spot Sanitizer in the presence of 5% soil with a 30 second contact time on cotton or polyester fabrics (surfaces) against the following bacteria:

Staphylococcus aureus, (ATCC 6538)

Acinetobacter baumannii, (ATCC 19606)
(Multi-Drug Resistant [MDR], Resistant to Cefazolin, Gentamicin, Trimethoprim/Sulfa, and Ertapenem)

Klebsiella pneumoniae, (ATCC BAA-1705)
(Carbapenem-Resistant)

Enterobacter aerogenes, (ATCC 13048)

Enterococcus faecalis, (ATCC 51575)
(Resistant to Vancomycin [VRE])

Staphylococcus aureus, (ATCC 33592)
(Resistant to Methicillin [MRSA])

Malodor(s) (Activity) (Counteractancy) – eliminates (destroys) odors and odor-causing bacteria on hard, nonporous surfaces in restroom areas, behind and under sinks and counters, and storage areas (and other places where bacterial growth can cause malodors).

DIRECTIONS FOR USE:

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

(Note to Reviewer: For labels that list medical devices as defined by the FDA.)

(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 blood stream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.)

For Use as a One-Step Cleaner/Disinfectant Product:

1. Pre-clean heavily soiled areas.
2. Apply product by coarse trigger sprayer to hard, non-porous inanimate surfaces. Spray 6 – 8 inches from surface, making sure to wet surfaces thoroughly.
3. All surfaces must remain wet for 1 minute. Use a 5 minute contact time for Tb and a 10 minute contact time for fungi.
4. Wipe surfaces dry (or rinse) (or allow to air dry).

Note: Rinsing is not necessary unless floors are to be coated with finish or restorer. All food contact surfaces must be rinsed with potable water. Do not use on glassware, utensils, or dishes.

For Use as a Tuberculocide:

1. Pre-clean heavily soiled areas.
2. Apply product by coarse trigger sprayer to hard, non-porous inanimate surfaces. Spray 6 – 8 inches from surface, making sure to wet surfaces thoroughly.
3. Allow the surface to remain wet for 5 minutes.
4. Wipe surfaces dry (or rinse) (or allow to air dry).
5. Change solution after each use (application).

To Kill Fungi:

1. Pre-clean heavily soiled areas.
2. Apply product by coarse trigger sprayer to hard, non-porous inanimate surfaces. Spray 6 – 8 inches from surface, making sure to wet surfaces thoroughly.
3. Allow surface to remain wet for 10 minutes.
4. Wipe surfaces dry (or rinse) (or allow to air dry).

***KILLS HIV AND HCV and HBV ON PRE-CLEANED INANIMATE SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in health care settings (Hospitals, Nursing Homes) and other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood/body fluids, and in which the surfaces/objects likely to be soiled with blood/body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS) Hepatitis B Virus (HBV), or Hepatitis C Virus (HCV).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATING AGAINST HIV-1 (AIDS Virus), HBV OR HCV OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

Personal Protection: Disposable latex or vinyl gloves, gowns, face masks, and eye coverings as appropriate, must be worn during all cleaning of body fluids, blood, and decontamination procedures.

Cleaning Procedures: Blood/Body Fluids must be thoroughly cleaned from surfaces/objects before application of this product.

Contact Time: Allow surface to remain wet for 1 minute to kill HIV-1, HBV and HCV. Use a 5 minute contact time for Tb and a 10 minute contact for fungi.

Disposal of Infectious Material: Blood/Body Fluids must be autoclaved and disposed according to Federal, State and local regulations for infectious waste disposal.

Animal Housing Facilities (Including Veterinary Clinics, (Equine) Farms, Livestock, Swine and Poultry Houses): For cleaning and disinfecting the following hard, non-porous surfaces: feeding and watering equipment, utensils, instruments, cages, kennels, stables, catteries, etc.

1. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc.
2. Remove all litter, droppings and manure from floors, walls and surfaces of facilities (including pens, chutes, and barns) occupied or traversed by animals.
3. Empty all troughs, racks, and other feeding or watering appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with potable water. Saturate surfaces by spraying with product for a period of 1 minute. Use a 5 minute contact time for TB and a 10 minute contact time for fungi.
5. Spray handling and restraining equipment such as leashes, muzzles, halters or ropes, as well as forks, shovels, and scrapers used for removing litter and manure.
6. Ventilate buildings and other closed spaces.
7. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub treated feed racks, troughs, mangers, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

For Use to Clean and Disinfect Life Science Laboratory Surfaces:

1. Pre-clean heavily soiled areas.
2. Apply product by coarse trigger sprayer to hard, non-porous inanimate surfaces. Spray 6 – 8 inches from surface, making sure to wet surfaces thoroughly.
3. Allow the surface to remain wet for 1 minute. Use a 5 minute contact time for Tb and a 10 minute contact time for fungi.
4. Wipe surfaces dry (or rinse) (or allow to air dry).

(Note to Agency: Text appearing in parenthesis is done to show optional text.)

For use as a Non-Food Contact Sanitizer:

1. Pre-clean heavily soiled areas.
2. Apply Solution with spray, cloth, disposable wipe or mop to hard, non-porous environmental surfaces.
3. Allow the surface to remain wet for 30 seconds.
4. Wipe surfaces dry (or rinse) (or allow to air dry).
5. Change solution after each use (application).

To Spot Sanitize Soft Surfaces:

1. Remove gross filth prior to sanitization.
2. Hold bottle upright 6 – 8" from surface. Spray until fabric is wet. DO NOT SATURATE.
3. Allow surface to remain wet for 30 seconds.
4. (Gently blot with a clean (damp) (color-safe) cloth) (and) (or) Let air dry. [For difficult odors or heavy fabrics, repeat application.] [Repeat as needed.]

[Note: Prior to first use on a particular surface, it is recommended to test in a small, discreet area if there is concern of incompatibility.]

For Use as a Cleaner and/or Deodorizer:

Apply product by coarse trigger sprayer to hard, non-porous inanimate surfaces. Wipe surfaces dry (or rinse) (or allow to air dry).

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. Store in original container in areas inaccessible to small children. Keep securely closed.

PESTICIDE STORAGE

Store in a dry, well-ventilated area away from chemicals, direct light, heat or open flame. Do not mix with other cleaning or disinfecting products.

PESTICIDE DISPOSAL

Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. For more information on the disposal of unused, unwanted product and the clean up of spills, contact the EPA Regional Office of the Manufacturer for guidance.

CONTAINER DISPOSAL (Note to reviewer – One or more of the following paragraphs for Container Disposal will be selected, depending on packaging type:)

NONREFILLABLE SEALED OR SMALL CONTAINERS: (Note to reviewer: Several of our packaging options are sealed containers or bottles designed to reduce worker exposure to the concentrate. None of these can be triple rinsed because they are closed, sonically welded, sealed containers. The following text will be used on these sealed container types or containers 5 gallons or smaller:)

Nonrefillable container. Do not reuse or refill this container. Wrap empty container and put in trash (or offer for recycling if available).

NONREFILLABLE NON-RIGID CONTAINERS: Note to reviewer: Several of our packaging options are Bag-in-Box containers (a plastic bag liner supported inside a box) or are flexible bag-type containers (such as ACCUPACK™ Containers). These flexible containers are exempt from the triple rinsing requirements. The following text will be used on these container types:

Nonrefillable container. Do not reuse or refill this container. Wrap empty container and put in trash.

LARGE NONREFILLABLE CONTAINERS: Note to reviewer: One of the following paragraphs will be used on labels for rigid, nonrefillable containers too large to shake (larger than 5 gallons):

Nonrefillable container. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for at least 30 seconds. Stand the container on its end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Offer container for reconditioning, if appropriate.

(Note to Agency: Text appearing in parenthesis is done to show optional text.)

OR

Nonrefillable container. Clean container promptly after emptying. Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or a mix tank or collect rinsate for later use or disposal. Insert pressure-rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip. Offer for reconditioning, if appropriate.

REFILLABLE CONTAINERS: *Note to reviewer: One of the following paragraphs will be used on labels for refillable containers:*

Refillable container. Refill this container with (this brand or brand name) pesticide only. Do not reuse this container for any other purpose.

Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller.

OR

Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller.

To clean the container prior to final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times.

ENVIRONMENTAL HAZARDS *(for labels with veterinary use patterns)*

This product is toxic to birds, fish and aquatic invertebrates. Caution should be used when applying indoors because pets may be at risk.

ENVIRONMENTAL HAZARDS *(for containers of 5 gallons or 50 lbs. or more)*

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting agency has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

IN CASE OF EMERGENCY, CALL A POISON CONTROL CENTER OR DOCTOR FOR TREATMENT ADVICE.

(Insert Emergency Number Here)

Have the product container or label with you when calling a Poison Control Center or doctor or going in for treatment.

EPA Reg. No. 70627-56

EPA Est. No.

(Lot code letters indicate establishment number.)

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(Note to Agency: Text appearing in parenthesis is done to show optional text.)

OXIVIR Tb REFERENCE SHEET

Using approved AOAC test methods (under Good Laboratory Practices, [GLP's]), 5% serum load and 1 minute contact time this product kills the following on hard non-porous inanimate surfaces:

Bactericidal Activity:

Staphylococcus aureus, (ATCC 6538)
Salmonella enterica, (ATCC 10708)
Formerly known as *Salmonella choleraesuis*
Pseudomonas aeruginosa, (ATCC 15442)

Acinetobacter baumannii, (ATCC 19606)
Escherichia coli O157:H7, (ATCC 35150)
Escherichia coli with extended beta-lactamase resistance (ESBL), (ATCC BAA-196)

Klebsiella pneumoniae, (ATCC 4352)
Shigella dysenteriae, (ATCC 11835)

Antibiotic-Resistant (Strains of) Bacteria (Antibiotic-Resistant Bactericidal Activity):

Enterococcus faecalis, (ATCC 51575)
(Resistant to Vancomycin [VRE])

Staphylococcus aureus (CA-MRSA),
(NARSA NRS 384)(Genotype USA300)
Community Associated Methicillin Resistant

Staphylococcus aureus (CA-MRSA),
(NARSA NRS 123)(Genotype USA400)
Community Associated Methicillin Resistant

Staphylococcus aureus, (ATCC 33592)
(Resistant to Methicillin [MRSA])

*Viruses (*Virucidal Activity):

*Adenovirus type 8, (ATCC VR-1368)
*Hepatitis B Virus (HBV), Duck Hepatitis B Virus (DHBV) as surrogate
(Acquired from Hepadnavirus Testing)
*Hepatitis C Virus (HCV), Bovine Viral Diarrhea Virus (BVDV) as surrogate
(Acquired from National Veterinary Services Laboratories)

*Herpes Simplex Virus, Type 1 (HSV-1), (ATCC VR-733)
*Herpes Simplex Virus, Type 2 (HSV-2), (ATCC VR-734)
*HIV-1 (AIDS Virus), Strain HTLV-III_B (HIV-1),
(Acquired from Adv. Biotechnologies, Inc.)
*Human Coronavirus, (ATCC VR-740)
*Influenza A/Hong Kong, (ATCC VR-544)

*Norovirus, (Feline Calicivirus, ATCC VR-782 as the surrogate)
*Poliovirus Type 1, Strain Brunhilde, (ATCC VR-1000)
*Rhinovirus Type 37, Strain 151-1, (ATCC VR-1147)
*Rotavirus WA, (Acquired from University of Ottawa)

(*Veterinary Viruses:)

*Avian Influenza A (H3N2), (ATCC VR-2072)

*Feline Calicivirus, Strain F9, (ATCC VR-782)

TUBERCULOCIDAL in the presence of a 5% serum load and 5 minute contact time at 20°C (68°F) on hard, non-porous environmental surfaces.

Mycobacterium bovis (Tb) (OT 451C150)

FUNGICIDAL: This product is fungicidal against the pathogenic fungi *Trichophyton mentagrophytes* (ATCC 9533) (the fungus which causes Athlete's Foot) in the presence of a 5% serum load and 10 minute contact time when used as directed on hard surfaces found in bathrooms, shower stalls, locker rooms, or other clean, non-porous, hard surfaces commonly contacted by bare feet.

Trichophyton mentagrophytes (ATCC 9533)

Non-Food Contact Surface Sanitizer for hard non-porous surfaces in the presence of a 5% serum load and 30 second contact time on hard, non-porous environmental surfaces.

Enterococcus faecalis, (ATCC 51575)
(Resistant to Vancomycin [VRE])
Escherichia coli O157:H7, (ATCC 35150)

Pseudomonas aeruginosa, (ATCC 15442)
Salmonella enterica, (ATCC 10708)

Klebsiella pneumoniae, (ATCC 4352)

Staphylococcus aureus, (ATCC 6538)

Staphylococcus aureus, (ATCC 33592)
(Resistant to Methicillin [MRSA])

(Note to Agency: Text appearing in parenthesis is done to show optional text.)

Soft Surface Spot Sanitizer in the presence of 5% soil with a 30 second contact time on cotton or polyester fabrics (surfaces) against the following bacteria:

Staphylococcus aureus, (ATCC 6538)

Acinetobacter baumannii, (ATCC 19606)
(Multi-Drug Resistant [MDR], Resistant to
Cefazolin, Gentamicin, Trimethoprim/Sulfa,
and Ertapenem)

Klebsiella pneumoniae, (ATCC BAA-1705)
(Carbapenem-Resistant)

Enterobacter aerogenes, (ATCC 13048)

Enterococcus faecalis, (ATCC 51575)
(Resistant to Vancomycin [VRE])

Staphylococcus aureus, (ATCC 33592)
(Resistant to Methicillin [MRSA])

Malodor(s) (Activity) (Counteractancy) – eliminates (destroys) odors and odor-causing bacteria on hard, nonporous surfaces in restroom areas, behind and under sinks and counters, and storage areas (and other places where bacterial growth can cause malodors).

DIRECTIONS FOR USE:

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

(Note to Reviewer: For labels that list medical devices as defined by the FDA.)

(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 blood stream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.)

For Use as a One-Step Cleaner/Disinfectant Product:

1. Pre-clean heavily soiled areas.
2. Apply product by coarse trigger sprayer to hard, non-porous inanimate surfaces. Spray 6 – 8 inches from surface, making sure to wet surfaces thoroughly.
3. All surfaces must remain wet for 1 minute. Use a 5 minute contact time for Tb and a 10 minute contact time for fungi.
4. Wipe surfaces dry (or rinse) (or allow to air dry).

Note: Rinsing is not necessary unless floors are to be coated with finish or restorer. All food contact surfaces must be rinsed with potable water. Do not use on glassware, utensils, or dishes.

For Use as a Cleaner and/or Deodorizer:

Apply to hard non-porous surfaces by spray, cloth, sponge, or mop. Wipe surfaces dry (or rinse) (or allow to air dry).

For Use as a Tuberculocide:

1. Pre-clean heavily soiled areas.
2. Apply product by coarse trigger sprayer to hard, non-porous inanimate surfaces. Spray 6 – 8 inches from surface, making sure to wet surfaces thoroughly.
3. Allow the surface to remain wet for 5 minutes.
4. Wipe surfaces dry (or rinse) (or allow to air dry).
5. Change solution after each use (application).

To Kill Fungi:

1. Pre-clean heavily soiled areas.
2. Apply product by coarse trigger sprayer to hard, non-porous inanimate surfaces. Spray 6 – 8 inches from surface, making sure to wet surfaces thoroughly.
3. Allow surface to remain wet for 10 minutes.
4. Wipe surfaces dry (or rinse) (or allow to air dry).

***KILLS HIV AND HCV and HBV ON PRE-CLEANED INANIMATE SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in health care settings (Hospitals, Nursing Homes) and other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood/body fluids, and in which the surfaces/objects likely to be soiled with blood/body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS) Hepatitis B Virus (HBV), or Hepatitis C Virus (HCV).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATING AGAINST HIV-1 (AIDS Virus), HBV OR HCV OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

Personal Protection: Disposable latex or vinyl gloves, gowns, face masks, and eye coverings as appropriate, must be worn during all cleaning of body fluids, blood, and decontamination procedures.

Cleaning Procedures: Blood/Body Fluids must be thoroughly cleaned from surfaces/objects before application of this product.

Contact Time: Allow surface to remain wet for 1 minute to kill HIV-1, HBV and HCV. Use a 5 minute contact time for Tb and a 10 minute contact for fungi.

Disposal of Infectious Material: Blood/Body Fluids must be autoclaved and disposed according to Federal, State and local regulations for infectious waste disposal.

For use as a Non-Food Contact Sanitizer:

1. Pre-clean heavily soiled areas.
2. Apply Solution with spray, cloth, disposable wipe or mop to hard, non-porous environmental surfaces.
3. Allow the surface to remain wet for 30 seconds.
4. Wipe surfaces dry (or rinse) (or allow to air dry).
5. Change solution after each use (application).

To Spot Sanitize Soft Surfaces:

5. Remove gross filth prior to sanitization.
6. Hold bottle upright 6 – 8" from surface. Spray until fabric is wet. DO NOT SATURATE.
7. Allow surface to remain wet for 30 seconds.
8. (Gently blot with a clean (damp) (color-safe) cloth) (and) (or) Let air dry. [For difficult odors or heavy fabrics, repeat application.] [Repeat as needed.]

Animal Housing Facilities (Including Veterinary Clinics, (Equine) Farms, Livestock, Swine and Poultry Houses): For cleaning and disinfecting the following hard, non-porous surfaces: feeding and watering equipment, utensils, instruments, cages, kennels, stables, catteries, etc.

1. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc.
2. Remove all litter, droppings and manure from floors, walls and surfaces of facilities (including pens, chutes, and barns) occupied or traversed by animals.
3. Empty all troughs, racks, and other feeding or watering appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with potable water. Saturate surfaces by spraying with product for a period of 1 minute. Use a 5 minute contact time for TB and a 10 minute contact time for fungi.
5. Spray handling and restraining equipment such as leashes, muzzles, halters or ropes, as well as forks, shovels, and scrapers used for removing litter and manure.
6. Ventilate buildings and other closed spaces.
7. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub treated feed racks, troughs, mangers, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

(Note to Agency: Text appearing in parenthesis is done to show optional text.)

For Use to Clean and Disinfect Life Science Laboratory Surfaces:

1. Pre-clean heavily soiled areas.
2. Apply product by coarse trigger sprayer to hard, non-porous inanimate surfaces. Spray 6 – 8 inches from surface, making sure to wet surfaces thoroughly.
3. Allow the surface to remain wet for 1 minute. Use a 5 minute contact time for Tb and a 10 minute contact time for fungi.
4. Wipe surfaces dry (or rinse) (or allow to air dry).

Read the label affixed to the container for this product (product brand name) before applying.

Use of this product (product brand name) according to this label is subject to the use precautions and limitations imposed by the label affixed to the container for this product (product brand name).

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