



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 16, 2019

Sara Seltzer
Registration Specialist
Diversey, Inc.
PO Box 19747
Charlotte, NC 28219-0747

Subject: PRIA Label Amendment – Adding Efficacy Claims
Product Name: Oxivir TB
EPA Registration Number: 70627-56
Application Date: 07/31/2019
Decision Number: 553938

Dear Ms. Seltzer:

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.

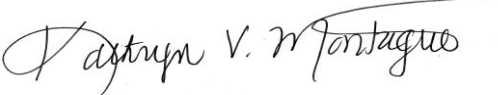
Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded 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

Page 2 of 2
EPA Reg. No. 70627-56
Decision No. 553938

with FIFRA section 6. If you have any questions, please contact Terria Northern by phone at 703-347-0265, or via email at northern.terria@epa.gov.

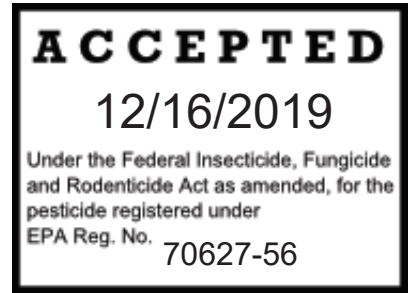
Sincerely,

A handwritten signature in black ink that reads "Kathryn V. Montague". The signature is written in a cursive style with a long horizontal flourish extending from the top of the "g" in "Montague".

Kathryn Montague, Acting Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure

(Note to Agency: Text appearing in parenthesis is done to show optional text which can be used partially or in its entirety. Commas may be added where needed. Text in brackets is a note to the Reviewer.)



OXIVIR Tb

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

(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 (USA)(Candada))

(Note to Agency: Text appearing in parenthesis is done to show optional text which can be used partially or in its entirety. Commas may be added where needed. Text in brackets is a note to the Reviewer.)

(FEATURES, CLAIMS & USES:)

(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 and deodorant (odor-counteractant) (odor neutralizer) designed for cleaning, (and) disinfecting (deodorizing) (of) hard, non-porous inanimate surfaces. It cleans by removing dirt, grime, and other common soils found in *[insert use sites/surfaces from lists below]* (or –hard, non-porous washable surface where disinfection is required.)

It is designed for use on (Use daily on) (the following) (hard, non-porous inanimate surfaces): *-[insert use sites/surfaces from lists below]* – (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 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[†].

[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

(This product) (Oxivir Tb) *[insert marketed product name]* cleans and disinfects *[insert organism name(s) from list in Efficacy Claims section]* including ESKAPE pathogens - *Enterococcus faecium, Staphylococcus aureus, Klebsiella pneumonia, Acinetobacter baumannii, Pseudomonas aeruginosa, and Enterobacter aerogenes*

(This product) (Oxivir Tb) *[insert marketed product name]* kills ESKAPE organisms with a 1 minute kill time.

(This product) (Oxivir Tb) *[insert marketed product name]* cleans and disinfects, killing ESKAPE organisms with a 1-minute dwell time.

Kills ESKAPE bacteria in 1 minute

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

This product is a one-step (hospital-use) (laboratory-use) germicidal disinfectant and deodorant (odor-counteractant) (odor neutralizer) designed for cleaning, (and) disinfecting, (deodorizing) (of) hard, non-porous inanimate surfaces. This product cleans by removing dirt, grime, food residue, dead skin, blood and other organic matter commonly found in *[insert use sites/surfaces from lists below]*. 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

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following) (hard, non-porous inanimate surfaces:)-[insert use sites/surfaces from lists below] (or –hard, non-porous washable surface where disinfection is required.) found in [insert use sites/surfaces from lists below] (It can be used to pre-clean and disinfect hospital items: [insert use sites/surfaces from lists below] – (where disinfection is required). A potable water rinse is required when disinfecting food contact surfaces. Do not use on glasses, dishes and utensils.

(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:) [insert use sites/surfaces from lists below] (where disinfection is required.) found in (barns, pens and stalls) animal housing facilities.

(USE SITES:)

(Oxivir Tb) (This product) can be used (in) (on) hard non-porous surfaces of the following items or in the following areas:

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

<ul style="list-style-type: none"> • alternative care facilities, • ambulances or (emergency medical) transport vehicles, • ambulatory care centers (ASCs); ambulatory surgery centers, • anesthesia rooms, • assisted living facilities, • (acute) (and) (long-term) care facilities, • backboards, • (hospital) (patient) bedrails and linings (patient bed linings), (vinyl mattress covers), • bedpans, • (hospital) (patient) bedrails, bedframes, bed springs, side rails, • bedside (overbed) table, • (bedside) commodes, • blood pressure cuffs (for use on hard, non-porous surfaces) • blood pressure monitors, • CAT laboratories, • (crash) (medication) carts, • cabinets, • (nurse) call buttons (boxes) (devices), • central service areas, • central supply rooms, 	<ul style="list-style-type: none"> • diagnostic equipment, • dialysis clinics (facilities), • (blood) (plasma) donation centers, • examination (exam) rooms (areas), • exam tables • emergency rooms (ERs) (areas), • eye surgical centers, • footboards, • gurneys, • health care facilities, • hospices, • hospitals, • infant incubators, • instrument trays, • IV stands (poles) and exterior surfaces of pumps, • (medical) (neonatal) (pediatric) (surgical) intensive care units (ICUs) (MICUs) (NICUs) (PICUs) (SICUs) (areas), • isolation rooms (areas), • laboratories, • laboratory settings • laundry rooms, • long-term care facilities (homes), • (medical assistance services), 	<ul style="list-style-type: none"> • (neonatal) (newborn) nurseries, • nursing homes, • nurses stations, • operating rooms (theaters), • ophthalmic offices, • outpatient (surgical) centers (clinics) (OPSCs) (facilities), • paddles, • patient rooms (areas), • patient care (monitoring) equipment, • pharmacies, • phlebotomy trays, • (physical) (patient) therapy rooms, • physical therapy equipment, • procedure rooms, • psychiatric facilities, • radiology (X-Ray) rooms (areas), • reception areas, • recovery rooms, • rehabilitation centers, • respiratory therapy rooms, • skilled nursing facilities, • stethoscopes, • stretchers, • surgery rooms, • traction bars, devices and patient slings,
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<ul style="list-style-type: none"> • clinics, • critical care units, • dental chairs, • dental clinics, • dental curing lights, • dental offices, • dental operatory surfaces, 	<ul style="list-style-type: none"> • medical facilities, • (medical) (physicians') (doctors') offices, 	<ul style="list-style-type: none"> • waiting rooms (areas) • wash basins, • wheelchairs, • x-ray equipment,
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(USE SITES, continued)

(Oxivir Tb) (This product) can be used (in) (on) hard non-porous surfaces in the following areas:

(Animal/Veterinary Facilities/Animal Housing Facilities:)

<ul style="list-style-type: none"> • animal equipment, • animal crates, • animal hospitals, • animal housing facilities, • animal treatment facilities, • animal life science laboratories, • automatic feeders not for food contact, • barns, pens, and stalls, • bathrooms, • brushes, • buckets, • bus (depots) (stations), • cages, • carts, • non food contact counters, 	<ul style="list-style-type: none"> • crates, • dog runs, • examination tables • exercise facilities, • exercise equipment, • farm vehicles (trucks), • fencing, • fume hoods and animal cages (found in laboratory settings), • farms, • gates, • gathering (guiding) equipment, • merchandise stores, • grooming equipment, • grooming facilities, 	<ul style="list-style-type: none"> • health clubs, • handling equipment, • harnesses & leashes, • kennels, • kennel runs, • laboratories or other small animal facilities, • office buildings, • pens, • pet shops (equine farms), • shower rooms (areas), • troughs, • veterinary clinics • veterinary equipment, • veterinary care surfaces, • (wash) stalls,
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(Areas:)

<ul style="list-style-type: none"> • Airplanes, • airports, • aluminum • athletic equipment, • athletic facilities, • baked enamel surfaces associated with floors, • barber/beauty (salons) (shops), • exterior surfaces of air vents covers, • cabinets, • cages, • carts, • casinos, • ceilings • chairs , • changing tables, • chrome • closets, 	<ul style="list-style-type: none"> • convention centers, • correctional facilities, • counters † , • cruise ships, • day care centers † , • desks, ¥ • desktops , • docking stations, ¥ • doors , • drawers, • elevators, • exercise equipment, • exercise facilities, • faucets, • fixtures, • floors (flooring), • funeral homes, • glass, • glazed ceramic, 	<ul style="list-style-type: none"> • hand rails (railings), • hotels (motels), • institutions, • laminated surfaces • laptops, • laundromats, • libraries, • light fixtures, switches, • lockers, • locker rooms (areas), • lounges, • mirrors, • military installations, • mobile devices (electronic equipment), • mobile workstations, • Naugahyde, • train (depots) (stations), • transportation terminals (facilities),
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<ul style="list-style-type: none"> • coated (removable) (plastic) covers for mattresses and pillows, • computer mouse, keyboards, peripherals, screens, tables, convenience stores, • non-food contact countertops, • non-food contact surfaces, • office buildings • pagers, • painted surfaces, • phones, phone cradles and accessories, • plastic (surfaces), • plated steel • playgrounds, • public buildings, • public restrooms, • recreational facilities, • restrooms, • rest stops (public restrooms), • retail businesses 	<ul style="list-style-type: none"> • glazed ceramic (restroom) tile, • glazed porcelain, • glazed tile, • handheld electronic devices, • schools (colleges, and universities), • shelves, • shopping centers, • showers, • shower fixtures, • shower rooms (areas) • sinks, • sink basins, • sinks found in (health care facilities), • (hospitals), (dental offices), (patient rooms), (operating rooms), (ICU areas), (shower rooms), and (locker rooms) • stainless steel, • stools, • spas, • sports arenas (stadiums) 	<ul style="list-style-type: none"> • tables, • tablet PCs, • telephones, • tubs, • exterior surfaces of toilets, • toilet exteriors, • exterior surfaces of urinals, • urinal exteriors, • walls, • wash basins, • vinyl
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† Non-Food Contact Surfaces

* Except Wood Surfaces

(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.

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.)

(CLAIMS:)

When used as directed, this product is effective against a wide variety (broad-spectrum) of pathogenic microorganisms (including bacteria, antibiotic resistant bacteria, *[list of antibiotic resistant organisms is below, in Efficacy Claims section, under subheading Antibiotic-Resistant (Strains of) Bacteria]*, viruses, and fungi). (See reference sheet (enclosed in each case) for a complete list of organisms.)

(Note to Agency: Text appearing in parenthesis is done to show optional text which can be used partially or in its entirety. Commas may be added where needed. Text in brackets is a note to the Reviewer.)

(HOSPITAL DISINFECTANT:)

BACTERICIDAL:

[Note to reviewer: Only one of the following statements will be on the product label]

(in the presence of 5% serum load and 1 minute contact time at 20°C (68°F) on hard, non-porous environmental surfaces.)

- or -

(1 minute contact time)

- or -

(1 minute)

(Bactericidal Activity):

(Organism)	(ATCC Number)	(Contact Time)
<i>Staphylococcus aureus</i>	(ATCC 6538)	1 minute
<i>Pseudomonas aeruginosa</i>	(ATCC 15442)	1 minute
<i>Salmonella enterica</i> , formerly known as <i>Salmonella choleraesuis</i>	(ATCC 10708)	1 minute
<i>Acinetobacter baumannii</i>	(ATCC 19606)	1 minute
<i>Enterococcus faecium</i>	(ATCC 51559)	1 minute
<i>Escherichia coli</i> O157:H7	(ATCC 35150)	1 minute
<i>Klebsiella aerogenes</i> , (formerly <i>Enterobacter aerogenes</i>)	(ATCC 13048)	1 minute
<i>Klebsiella pneumoniae</i>	(ATCC 4352)	1 minute
<i>Legionella pneumophila</i>	(ATCC 33153)	1 minute
<i>Listeria monocytogenes</i>	(ATCC 19111)	1 minute
<i>Shigella dysenteriae</i>	(ATCC 11835)	1 minute

(Antibiotic-Resistant (Strains of) Bacteria [list below]):

<i>Enterococcus faecalis</i> (Resistant to Vancomycin (VRE))	(ATCC 51575)	1 minute
<i>Escherichia coli</i> , carbapenem resistant (CRE)	(ATCC BAA-2469)	1 minute
<i>Escherichia coli</i> with extended beta-lactamase resistance (ESBL)	(ATCC BAA-196)	1 minute
<i>Klebsiella aerogenes</i> , (formerly <i>Enterobacter aerogenes</i>), Ceftazidime resistant	(ATCC BAA-2356)	1 minute
<i>Klebsiella pneumoniae</i> , carbapenem resistant (CRKP/CRE)	(ATCC BAA-1705)	1 minute
Extended spectrum beta-lactamase <i>Klebsiella pneumoniae</i> (NDM-1)	(ATCC 700603)	1 minute
<i>Streptococcus pneumoniae</i> , Penicillin-resistant (PRSP)	(ATCC 70067)	1 minute
Multidrug-resistant (MDR) <i>Pseudomonas aeruginosa</i>	(ATCC BAA -2108)	1 minute
<i>Staphylococcus aureus</i> (Resistant to Methicillin (MRSA))	(ATCC 33592)	1 minute
<i>Staphylococcus aureus</i> (CA-MRSA), (Community Associated Methicillin Resistant)	(NARSA NRS 384)(Genotype USA300)	1 minute
<i>Staphylococcus aureus</i> (CA-MRSA), (Community Associated Methicillin Resistant)	(NARSA NRS 123)(Genotype USA400)	1 minute

VIRUCIDAL:

[Note to reviewer: Only one of the following statements will be on the product label]

(in the presence of 5% serum load and 1 minute contact time at 20°C (68°F) on hard, non-porous environmental surfaces.)

- or -

(1 minute contact time)

- or -

(1 minute)

(Viruses (Virucidal Activity)):

(Organism)	(ATCC Number)	(Contact Time)
Adenovirus type 8	(ATCC VR-1368)	1 minute
Hepatitis B Virus (HBV)	(Acquired from Hepadnavirus Testing)	1 minute

(Note to Agency: Text appearing in parenthesis is done to show optional text which can be used partially or in its entirety. Commas may be added where needed. Text in brackets is a note to the Reviewer.)

Hepatitis C Virus (HCV)	(Acquired from National Veterinary Services Laboratories)	1 minute
Herpes Simplex Virus, Type 1 (HSV-1)	(ATCC VR-733)	1 minute
Herpes Simplex Virus, Type 2 (HSV-2)	(ATCC VR-734)	1 minute
HIV-1 (AIDS Virus), Strain HTLV-III _B (HIV-1)	(Acquired from Adv. Biotechnologies, Inc.)	1 minute
Human Coronavirus, (ATCC VR-740)	(ATCC VR-740)	1 minute
Influenza A/Hong Kong, (ATCC VR-544)	(ATCC VR-544)	1 minute
Middle Eastern Respiratory Syndrome Coronavirus (MERS-CoV)	(Strain EMC/2012)	1 minute
Norovirus, (Feline Calicivirus as the surrogate)	(Feline Calicivirus, ATCC VR-782 as the surrogate)	1 minute
Poliovirus Type 1, Strain Brunhilde	(ATCC VR-1000)	1 minute
Respiratory Syncytial virus (RSV)	(ATCC VR-26)	1 minute
Rhinovirus Type 14	(ATCC VR-284)	1 minute
Rotavirus WA	(Acquired from University of Ottawa)	1 minute
Vaccina Virus	(ATCC VR-156)	1 minute
(Veterinary Viruses:)		
Avian Influenza A (H3N2)	(ATCC VR-2072)	1 minute
Feline Calicivirus, Strain F9	(ATCC VR-782)	1 minute

TUBERCULOCIDAL:

[Note to reviewer: Only one of the following statements will be on the product label]

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

- or -

(5 minute contact time)

- or -

(5 minutes)

(Organism)	(ATCC Number)	(Contact Time)
<i>Mycobacterium bovis</i> (Tb) (OT 451C150)	<i>Mycobacterium bovis</i> (Tb) (OT 451C150)	5 minutes

FUNGICIDAL:

[Note to reviewer: Only one of the following statements will be on the product label]

Trichophyton interdigitale (ATCC 9533) (formerly *Trichophyton mentagrophytes*) (the fungus which causes Athlete's Foot) and *Candida albicans* (ATCC 10321) in the presence of a 5% serum load and 3 minute contact time at 20°C (68°F) when used as directed on hard, non-porous surfaces found in bathrooms, shower stalls, locker rooms, or other clean, hard, non-porous, surfaces commonly contacted by bare feet.)

- or -

(This product is fungicidal against the pathogenic fungi, *Trichophyton interdigitale* (ATCC 9533) (formerly *Trichophyton mentagrophytes*) (the fungus which causes Athlete's Foot) and *Candida albicans* (ATCC 10321) when used as directed on hard, non-porous surfaces found in bathrooms, shower stalls, locker rooms, or other clean, hard, non-porous, surfaces commonly contacted by bare feet.)

- or -

(This product is fungicidal against the pathogenic fungi, *Trichophyton interdigitale* (ATCC 9533) (formerly *Trichophyton mentagrophytes*) (the fungus which causes Athlete's Foot) and *Candida albicans* (ATCC 10321) when used as directed on hard, non-porous surfaces.)

- or -

(in the presence of 5% serum load and 3 minute contact time at 20°C (68°F) on hard, non-porous environmental surfaces.)

- or -

(3 minute contact time)

- or -

(3 minutes)

(Note to Agency: Text appearing in parenthesis is done to show optional text which can be used partially or in its entirety. Commas may be added where needed. Text in brackets is a note to the Reviewer.)

(Organism)	(ATCC Number)	(Contact Time)
<i>Trichophyton interdigitale</i> (ATCC 9533) (formerly <i>Trichophyton mentagrophytes</i>)	(ATCC 9533)	3 minutes
<i>Candida albicans</i>	(ATCC 10231)	3 minutes

Non-Food Contact Surface Sanitizer for hard non-porous surfaces:

[Note to reviewer: Only one of the following statements will be on the product label]

(in the presence of 5% serum load and 30 second contact time at 20°C (68°F) on hard, non-porous environmental surfaces.)

- or -

(in the presence of a 5% serum load and 30 second contact time (at 20°C (68°F)) on hard, non-porous environmental surfaces.)

- or -

(30 second contact time)

- or -

(30 seconds)

(Organism)	(ATCC Number)	(Contact Time)
<i>Enterococcus faecalis</i> , (Resistant to Vancomycin [VRE])	(ATCC 51575)	30 seconds
<i>Escherichia coli</i> O157:H7, (ATCC 35150)	(ATCC 35150)	30 seconds
<i>Klebsiella pneumoniae</i> , (ATCC 4352)	<i>Klebsiella pneumoniae</i> , (ATCC 4352)	30 seconds
<i>Pseudomonas aeruginosa</i> , (ATCC 15442)	<i>Pseudomonas aeruginosa</i> , (ATCC 15442)	30 seconds
<i>Salmonella enterica</i> , (formerly known as <i>Salmonella choleraesuis</i>)	<i>Salmonella enterica</i> , (ATCC 10708)	30 seconds
<i>Staphylococcus aureus</i> , (ATCC 6538)	<i>Staphylococcus aureus</i> , (ATCC 6538)	
<i>Staphylococcus aureus</i> , (ATCC 33592), (Resistant to Methicillin [MRSA])	<i>Staphylococcus aureus</i> , (ATCC 33592)	

Soft Surface Spot Sanitizer [Note to reviewer: Only one of the following statements will be on the product label]

- (in the presence of 5% serum load and 30 second contact time on cotton or polyester fabrics (surfaces))

- or -

(30 second contact time)

- or -

(30 seconds)

(Organism)	(ATCC Number)	(Contact Time)
<i>Staphylococcus aureus</i> ,	(ATCC 6538)	30 seconds
<i>Enterobacter aerogenes</i>	(ATCC 13048)	30 seconds
<i>Enterococcus faecalis</i> , (Resistant to Vancomycin [VRE])	(ATCC 51575)	30 seconds
<i>Staphylococcus aureus</i> , (Resistant to Methicillin [MRSA])	(ATCC 33592)	30 seconds
<i>Acinetobacter baumannii</i> , (Multi-Drug Resistant [MDR], Resistant to Cefazolin, Gentamicin, Trimethoprim/Sulfa, and Ertapenem)	(ATCC 19606)	30 seconds
<i>Klebsiella pneumoniae</i> , (Carbapenem-Resistant)	(ATCC BAA-1705)	30 seconds

ALL SURFACES MUST REMAIN WET FOR:

1 minute – Bacteria & Viruses

5 minutes – Tuberculosis

3 minutes - Fungi

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).

(Note to Agency: Text appearing in parenthesis is done to show optional text which can be used partially or in its entirety. Commas may be added where needed. Text in brackets is a note to the Reviewer.)

(Emerging Pathogens Claims)

(Oxivir Tb) (This product) meets the criteria to make claims against certain emerging viral pathogens from the following viral category:

- Enveloped Viruses
- Large, Non-Enveloped Viruses
- Small, Non-Enveloped Viruses

For an emerging viral pathogen that is a/an...	...follow the directions for use for the following organisms on the label:
Enveloped Viruses	<ul style="list-style-type: none"> • Feline Calicivirus (ATCC VR-782) / Norovirus • Rhinovirus Type 37 (ATCC VR-1147) • Adenovirus Type 8 (ATCC VR-1368) • Rotavirus, Strain WA • Poliovirus type 1 (ATCC VR-1000), Strain Brunhilde
Large, Non-Enveloped Viruses	<ul style="list-style-type: none"> • Feline Calicivirus (ATCC VR-782) / Norovirus • Rhinovirus Type 37 (ATCC VR-1147) • Poliovirus type 1 (ATCC VR-1000), Strain Brunhilde
Small, Non-Enveloped Viruses	

(Oxivir Tb) (This product) has demonstrated effectiveness against viruses similar to [insert name of emerging virus] on hard, non-porous surfaces. Therefore, Oxivir Tb (this product) can be used against [insert name of emerging virus] when used in accordance with the directions for use against [insert name of supporting virus(es) from list above] on [hard, non-porous surfaces]. Refer to the [CDC or OIE] website at [insert pathogen-specific website address] for additional information.

[Insert name of illness / outbreak] is caused by [insert name of emerging virus]. Oxivir Tb kills similar viruses and therefore can be used against [insert name of emerging virus] when used in accordance with the directions for use against [insert name of supporting virus(es)] on [hard, non-porous surfaces]. Refer to the [CDC or OIE] website at [website address] for additional information.

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

1. Pre-clean heavily soiled areas.
2. Spray evenly over hard, non-porous inanimate surface to be cleaned, 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 3 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. Spray evenly over hard, non-porous inanimate surface to be cleaned, 6 – 8 inches from surface, making sure to wet surfaces thoroughly.
3. Allow the surface to remain visibly wet for 5 minutes.
4. Wipe surfaces dry (or rinse) (or allow to air dry).

(Note to Agency: Text appearing in parenthesis is done to show optional text which can be used partially or in its entirety. Commas may be added where needed. Text in brackets is a note to the Reviewer.)

5. Change solution after each use (application).

To Kill Fungi:

1. Pre-clean heavily soiled areas.
2. Spray evenly over hard, non-porous inanimate surface to be cleaned, 6 – 8 inches from surface, making sure to wet surfaces thoroughly.
3. Allow surface to remain visibly wet for 3 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) Protective Gloves (latex, nitrile, 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 visibly wet for 1 minute to kill HIV-1, HBV and HCV. Use a 5 minute contact time for Tb and a 3 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 3 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. Spray evenly over hard, non-porous inanimate surface to be cleaned, 6 – 8 inches from surface, making sure to wet surfaces thoroughly.
3. Allow the surface to remain visibly wet for 1 minute. Use a 5 minute contact time for Tb and a 3 minute contact time for fungi.
4. Wipe surfaces dry (or rinse) (or allow to air dry).

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.

(Note to Agency: Text appearing in parenthesis is done to show optional text which can be used partially or in its entirety. Commas may be added where needed. Text in brackets is a note to the Reviewer.)

3. Allow the surface to remain visibly 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 visibly 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:

Spray evenly over hard, non-porous inanimate surface to be cleaned, 6 – 8 inches from surface, making sure to wet surfaces thoroughly. 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 which can be used partially or in its entirety. Commas may be added where needed. Text in brackets is a note to the Reviewer.)

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.

(1-800-851-7145)

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

Optional Graphics:



(Note to Agency: Text appearing in parenthesis is done to show optional text which can be used partially or in its entirety. Commas may be added where needed. Text in brackets is a note to the Reviewer.)

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OXIVIR Tb REFERENCE SHEET

(Insert verbatim any Claims statements from the Claims sections from above.)

DIRECTIONS FOR USE:

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

(Insert verbatim any set(s) of Directions For Use from above)

See the container label for use directions and additional required information for First Aid, Precautionary Statements, and Storage and Disposal.

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