



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 18, 2019

Sara Seltzer
Registration Specialist
Diversey, Inc.
P.O. Box 19747
Charlotte, NC 28219

Subject: PRIA Label Amendment – Adding Candida Auris Claim
Product Name: Oxivir 1 Wipes
EPA Registration Number: 70627-77
Application Date: 02/14/2019
Decision Number: 548951

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

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

Sincerely,

A handwritten signature in black ink that reads "Zenon V. Montano for". The signature is written in a cursive style with a large initial 'Z' and a long horizontal stroke at the end.

Zeno Bain, Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: Approved label

(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.)

OXIVIR 1 WIPES

(ALL-IN-ONE) (MULTI-SURFACE) (ONE-STEP) (HOSPITAL) (DISINFECTANT) (AND DEODORIZING) (WIPES)
(SANITIZER) (SANITIZING WIPES) • (CLEANER) • (*VIRUCIDE) • (BACTERICIDE) • (TUBERCULOCIDE) •
(FUNGICIDE) • (MILDEWCIDE) • (DEODORANT) • (DEODORIZER) • (**Fungicidal disinfectant against *C. auris*)
(Meets OSHA Bloodborne Pathogen Standard for *HBV, *HCV & *HIV)
(READY TO USE) (EASY TO USE) (TOWELETTE) (MULTI-SURFACE) (WIPE)

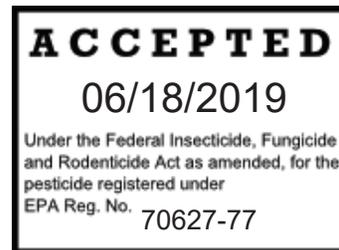
(For (Hospital) (Health Care) (Industrial) (&) (Institutional) Use)

Active Ingredient:

Hydrogen Peroxide0.5%

Other Ingredients:.....99.5%

Total:.....100.0%



KEEP OUT OF REACH OF CHILDREN

Net Contents: _____

[Made in (Product of) _____]

(MARKETING CLAIMS: *These may be used partially, in their entirety, or may be combined appropriately with commas, changes in capitalization, and addition of "and" as necessary, or not at all.*)

(See reference sheet [enclosed in each case] for [a complete list of pathogenic organisms] [additional features, claims] [claimed for this product] [and] [additional] [directions for use][or *insert product name*]).

(General)

- A Hydrogen Peroxide solution impregnated in a wiping cloth
- Acute Oral Toxicity (LD50>5,000 mg/kg) (Category IV)
- Acute Inhalation Toxicity (LC50>2.08 mg/L) (Category IV)
- Acute Dermal Toxicity (LD50>5,050 mg/kg) (Category IV)
- Always ready to use
- Compatible with most hard, nonporous surfaces
- Contains no VOC-emitting ingredients
- Contains no phosphates
- Compatible with (Suitable for) (Will not harm) most hard non-porous surfaces.
- Convenient
- Deodorizer (Odor Counteractant) (Odor Neutralizer)
- Disposable
- Easy flip-top lid
- Easy to use – just wipe (and) (walk away)
- Eliminates buckets
- Formulated with patented hydrogen peroxide technology
- For everyday use (in institutional (and) (industrial) facilities)
- Fragrance Free Formula (Unscented)
- Help make your (the) {*insert any use site from pages 5 and 6*} Oxivir Clean
- Just pull, wipe & toss!

- Leaves a fresh, clean scent
- Leaves no (dull) (sticky) residue

(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.)

Leaves office (washroom) (restroom) (bathroom) smelling clean (with a clean fresh scent)
Leaves surfaces virtually streak-free
No fragrance added
No harsh (chemical) fumes
No mixing, measuring or rinsing required
No need to spray!
No rinse required
No streaking (or) (filming) (sticky residue) (formula)
Non-corrosive (to eyes) (and) (skin)
Non-tainting (leaves no unsightly residues)
Non-woven disposable cloth
Not a skin (dermal) sensitizer (non-sensitizer)
Phenol free (No phenols)
Powerful odor control (odor neutralizer) (deodorizer) (odor-counteractant) formula (on hard non-porous surfaces)
Pre-measured (towelette) (wipe)
Pre-moistened (towelette) (wipe)
Pre-soaked (towelette) (wipe)
Primary Eye Irritation Category IV
Primary Skin Irritation Category IV
Quick drying
Quickly (eliminates) (removes) odors
Stay-moist package
Step-saving, (Labor-saving,) (Time-saving,) (Cost-saving) formula
Strong (towelette) (wipe)
Suitable for everyday use
Use on non-food contact surfaces, including: (grocery cart handles) (cash registers) (telephones) (doorknobs)
Versatile, Fast-acting, Convenient (formula)
Wipe down grocery (or shopping) cart handles

(Allergens)

Breaks down (destroys (eliminates) (removes) (the most common) allergens (found in dust)**

(Note: the sentence above will be used with this claim qualifier):

Reduces allergens**

**This product removes the following (non-living) allergens: (cat dander), (cockroach matter), (cockroach debris), (cockroach particles), (dog dander), (dust mite debris), (pet dander), (pollen particles)

This product kills germs and destroys allergens** while cleaning hard, nonporous surfaces

(Cleaning)

An effective counter cleaner

Built-in scrubbing fibers

Clean you expect

Cleans, deodorizes and brightens in one step

Cleans effectively

Cleans fast

Cleans sealed grout

Cleans hard, non-porous water washable surfaces!

Cleans (removes) (eliminates) (destroys) stains

Cleans (tough) grease and grime (and) (institutional) (soils) (fast)

Cleans (tough) soap scum

Compatible with (equipment) and (hard) (non-porous) surfaces

Convenient, quick & easy cleaning

Effective – Cleans soap scum

Effective daily cleaner

For a cleaner, fresher {insert any use site from pages 5 and 6}

For multiple cleaning tasks

(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.)

For non-scratch cleaning of showers and tubs, shower doors and (nonporous) curtains, fixtures and toilet bowls
Good for most indoor cleaning tasks
Grease cutting formula
Great for grease cutting
Great for on-the-go cleaning
Intense cleaning action
Keeps day care centers clean
Powerful cleaning
Powers away tough stains (stuck on dirt)
Quick and easy cleaning
Removes tough stains
Specially designed to dissolve (penetrate) the toughest (stubborn) soils
Use daily to prevent the build-up of dirt and grime
Uses (harnesses) the cleaning power of hydrogen peroxide
Will not leave grit or soap scum

(Antimicrobial-related statements)

A disinfectant (and) cleaner (that cleans, disinfects and deodorizes in one labor saving step)
A disinfectant cloth for use on telephone surfaces and other telecommunications equipment surfaces
Aids in reducing [or in the reduction of] cross contamination between treated surfaces
An effective one-step sanitizer-cleaner (wipe) (towelette) for use on hard non-food contact surfaces
An effective way to clean, deodorize against odor-causing organisms and disinfect hard, non-food contact surfaces
Antibacterial cellphone wipe (towelette)
Antibacterial (surface) cleaner (cloth) (wipe) (towelette)
Antimicrobial cleaner (cloth) (wipe) (towelette)
Anti-viral* (Anti-Virus*) (Surface) Cleaner
Assures proper dilution strength for product effectiveness
Broad-Spectrum (Multi-Purpose) (Multi-Surface) (Bactericidal) (*Virucidal) (Tuberculocidal) (Fungicidal) (Sanitizer)
(Disinfectant) (Activity) (Cleaner)
Clean & disinfect any room, any time
Cleaner and disinfectant towel (cloth) (towelette)
Cleans and disinfects (and deodorizes) hard, non-porous surfaces (easily)
Cleans and disinfects (cell phone surfaces) (telephone equipment) (telephone equipment surfaces) (dictating equipment surfaces) (telecommunications equipment surfaces) (devices) (headsets)
Controls the spread of listed bacteria on treated (hard, non-porous environmental) surfaces
Controls (Eliminates) odor-causing bacteria
Disinfects as it cleans
Disinfects (Deodorizes) (and) (Sanitizes) as it cleans
Disinfects - kills germs for a deep down clean
Deodorizes odor-causing bacteria
Dual action formulation providing broad spectrum activity against; fungi, mycobacteria, *viruses, and bacteria
Each pre-moistened towelette (disposable) (wipe) cleans, deodorizes and kills listed bacteria all around the {insert any use site from pages 5 and 6}
Effective against *Candida auris* (*C. auris*) in one minute
Effective daily cleaner
Effective in 1 minute against *Staphylococcus aureus*, *Salmonella enterica*, and *Pseudomonas aeruginosa*
Effectively disinfects hard, non-porous surfaces (in the presence of organic soil)
Eliminates (Kills) (odor-causing) bacteria (from surfaces)
Eliminates odors (caused by bacteria), (mold), (mildew)
Every day, every room disinfectant
Fast / Easy / Effective
For use (in) (Hospitals), (Health Care) (settings) (as a multi-purpose disinfectant cleaner)
For any non-food contact hard, non-porous surface where germs are a concern
Great on-the-go disinfectant (cloth)
Help control listed bacteria on treated surfaces while keeping your office (or workstation or workplace or business) clean

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and dust-free
Kills antibiotic resistant organisms[‡]
Kills bacteria (and sanitizes)
Kills bacteria (and *viruses) (on hard, non-porous surfaces) in 1 minute
Kills (Destroys) (Eliminates) germs while it cleans
Kills (Effective against) cold (flu) virus (on hard, nonporous surfaces)
Kills odor-causing bacteria
Kills *viruses (in 30 seconds)
Kills (99.9% of) germs in 1 minute
Kills (99.9% of) (cold) (and) (flu) (viruses) in 30 seconds
(Kills) (Inactivates) *Candida auris* on hard, non-porous surfaces.
Kills a minimum of 99.999% or five logs of *Candida auris* on hard, non-porous surfaces.
Proven to kill *Candida auris* (*C. auris*) in one minute
Restroom disinfectant wipes
Sanitizes
Surface cleaner with antibacterial formula
Telephone (cleaner) (and) (disinfectant) wipes
These wipes are a convenient way to disinfect surfaces
To be used in sanitizing and disinfecting of hard, non-porous non-food contact surfaces and non-critical equipment which may harbor or spread germs
Tough on germs
Use only one product to get a streak-free shine plus antimicrobial action
Use to disinfectant (wipe down) shopping (or grocery) cart handles
*Virus killing cleaner

BACTERICIDAL: 1 MINUTE

VIRUCIDAL: 30 SECONDS

ANIMAL PREMISE *VIRUCIDAL: 1 MINUTE

(BROAD-SPECTRUM) NON-FOOD CONTACT SANITIZER: 10 SECONDS

FUNGICIDAL: 30 SECONDS

****FUNGICIDAL AGAINST *C. AURIS*: 1 MINUTE**

(CLAIMS & USES:)

This product cleans, disinfects, and deodorizes hard, nonporous inanimate (environmental) surfaces (and patient care equipment) in one step with no rinsing required. This product is a (one-step,) (broad spectrum,) (hospital,) disinfectant (germicidal) cleaner and deodorizer (odor counteractant) designed for general cleaning, disinfection and deodorizing of hard, nonporous surfaces. (Designed for (non-critical) hard, nonporous surfaces in healthcare.) (It quickly) Removes (bathtub ring,) blood, body fluids, body oils, dirt, fungus, food residue, fecal matter, grime, laboratory stains, mold stains, soils, stains, urine and other organic matter commonly found (on hard, nonporous, inanimate (environmental) surfaces) (patient care equipment)) (in hospitals and healthcare facilities) (where housekeeping is of prime importance in controlling the hazard of cross-contamination between treated surfaces). It (also) eliminates odors leaving (restroom) surfaces smelling clean and fresh. Use where odors are a problem.

(Destroys bacteria, *viruses, fungi, mycobacteria and mildew on hard non-porous surfaces found in:) – or-
(This product can be used in the following areas:)

(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.)

(Medical Facilities:)

- alternative care facilities,
- ambulances or (emergency medical) transport vehicles,
- ambulatory care centers (ASCs); ambulatory surgery centers,
- anesthesia rooms,
- assisted living facilities,
- CAT laboratories,
- central service areas,
- central supply rooms,
- clinics,
- critical care units,
- dental clinics (offices),
- dialysis clinics (facilities),
- (blood) (plasma) donation centers,
- examination (exam) rooms (areas),
- emergency rooms (ERs) (areas),
- eye surgical centers,
- home health care (settings),
- hospices,
- hospitals,
- (medical) (neonatal) (pediatric) (surgical) intensive care units (ICUs) (MICUs) (NICUs) (PICUs) (SICUs),
- isolation rooms (areas),
- laboratories,
- laundry rooms,
- long-term care facilities (homes),
- medical facilities,
- (medical) (physicians') (doctors') offices,
- (neonatal) (newborn) nurseries,
- nursing homes,
- nurses stations,
- operating rooms (theaters),
- ophthalmic offices,
- outpatient (surgical) centers (clinics) (OPSCs) (facilities),
- patient rooms (areas),
- pharmacies,
- (physical) (patient) therapy rooms,
- procedure rooms,
- psychiatric facilities,
- radiology (X-Ray) rooms (areas),
- reception areas,
- recovery rooms,
- rehabilitation centers,
- respiratory therapy rooms,
- skilled nursing facilities,
- surgery rooms,
- waiting rooms (areas)

(General Institutional Facilities:)

(Cross-contamination is a major Infection Prevention concern.) (This product has been developed to aid in the reduction of cross-contamination between treated surfaces (not only in hospitals (and healthcare facilities), but also) in:)

- airports,
- animal hospitals,
- animal housing facilities,
- animal treatment facilities,
- animal life science laboratories,
- athletic facilities,
- bathrooms,
- bus (depots) (stations),
- casinos,
- convenience stores,
- convention centers,
- correctional facilities,
- crises scene
- cruise ships,
- day care centers,
- dormitories,
- elevators,
- food service,
- funeral homes,
- general merchandise stores,
- health clubs,
- hotels (motels),
- institutions,
- Laundromats,
- libraries,
- locker rooms,
- lounges,
- military installations,
- office buildings,
- pet shops,
- playgrounds,
- public buildings,
- public restrooms,
- recreational facilities,
- rest stops,
- retail businesses,
- schools (colleges, and universities),
- shopping centers,
- spas,
- sports arenas (stadiums)
- train (depots) (stations),
- transportation terminals (facilities),
- veterinary clinics

(It is designed) For (daily) (use) (cleaning) (disinfecting) (on) (of) (medical) (hard, nonporous inanimate (environmental) surface (materials)) (Compatible with): acrylic, baked enamel surfaces, Corian[®], chrome, non-food contact crystal, glass, glazed ceramic (tile), glazed porcelain, glazed tile, laminated surfaces, linoleum, metal (except copper and brass), sealed mirror stone, painted surfaces, plastic (surfaces), sealed quarry tiles, sealed fiberglass, sealed granite, sealed marble, stainless steel, synthetic marble, sealed terrazzo and vinyl.

Not recommended for use on (or) (avoid contact with): brass or copper.

(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.)

Note: This product is compatible with the listed materials. If product is intended to be used on other surfaces, it is recommended to test product by applying to a small discrete area to determine compatibility before proceeding with its use.

This product cleans, disinfects and deodorizes (common) hard, nonporous (hospital) (non-critical) (semi-critical) (medical) surfaces (patient care equipment) in one step (with no rinsing required). (Designed for (daily) use on (common) hard, nonporous (materials) (inanimate) (environmental) surfaces (patient care equipment) found in hospitals and other healthcare facilities.) (May be used to clean and disinfect sinks, faucets, fixtures, bathrooms, restrooms, tubs, and showers.) (For non-scratch cleaning of showers, tubs, shower doors and nonporous curtains, and fixtures, urinals, and exterior surfaces of toilets.)

It can be used on the following (hard, nonporous surfaces):

(Medical Surfaces/Items:)

*[**Note to Reviewer: When this product is manufactured and listed as an FDA Medical Device General Purpose Disinfectant, it can be used to disinfect the following noncritical medical items and the **paragraph on page 12 will appear on the label:]*

- amalgamators,
- exterior surfaces of autoclaves,
- backboards,
- (hospital) (patient) beds, bedrails, bedframes, bed springs,
- bedpans,
- bedside (overbed) tables,
- blood pressure cuffs,
- blood pressure monitors,
- cabinets,
- (nurse) call buttons (boxes) (devices),
- (crash) (medication) carts,
- computerized axial tomography equipment (CATs),
- chemotherapy hoods,
- cellular phones,
- chairs,
- closets,
- (bedside) commodes,
- coated (removable) (plastic) covers for mattresses and pillows,
- computer mouse, keyboards, peripherals, screens, tables,
- remote (portable) controls (controllers),
- counters (countertops),
- desktops,
- dental chairs,
- dental curing lights,
- dental operatory surfaces,
- diagnostic equipment,
- exterior surfaces of dialysis machines,
- docking stations,
- doors,
- exterior surfaces of (medical) equipment,
- faucets,
- fixtures,
- footboards,
- exterior of glucometers,
- gurneys,
- handheld electronic devices,
- handles,
- headboards,
- high touch surfaces,
- infant incubators and care cribs,
- instrument trays,
- isolettes,
- IV stands (poles) and exterior surfaces of pumps,
- laptops,
- light lens covers,
- loupes,
- mammography equipment,
- Manikins used in CPR training,
- exterior surfaces of medical equipment,
- exterior surfaces of magnetic resonance imaging equipment (MRIs),
- mobile devices (electronic equipment),
- mobile workstations,
- operating room tables, (lights,) (light switches,) (wall mounted controls), (and exterior surfaces of equipment,)
- orthopedics,
- oxygen hoods,
- paddles,
- pagers,
- patient care (monitoring) equipment,
- patient support and delivery equipment,
- phlebotomy trays,
- phones, phone cradles and phone accessories,
- physical therapy equipment,
- powercords
- hard, nonporous edges of privacy curtains,
- pulse oximeters,
- remote controls,
- scales,
- sequential compression devices,
- side rails,
- sinks,
- slit lamps,
- (mayo) (instrument) (ring) stands,
- stethoscopes,
- stools,

(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.)

- stretchers,
- support bars,
- tables, (exam tables),
- tablet PCs,
- telephones,
- exterior surfaces of toilets, (portable toilets,)
- toilet grab bars (handholds),
- traction devices and patient slings,
- exterior surfaces of (PVC) (equipment) tubing,
- urinals,
- walls,
- wash basins,
- wheelchairs,
- weighing devices/equipment,
- X-ray equipment,

*[Note to Reviewer: When this product is manufactured and listed as an FDA Medical Device General Purpose Disinfectant, it can be used to pre-clean and/or disinfectant the following semi-critical items prior to terminal sterilization and the **paragraph on page 12 will appear on the label:]*

- anesthesia equipment,
- respirators, respiratory equipment, respiratory therapy equipment,
- ultrasound transducers (and/or probes).

(General Surfaces Items:)

- exterior surfaces of air vents covers,
- cabinets,
- cages,
- chairs,
- changing tables,
- closets,
- coated (removable) (plastic) covers for mattresses and pillows,
- computer mouse, keyboards, peripherals, screens, tables,
- counters (countertops),
- desktops,
- docking stations,
- doors,
- drawers,
- exercise equipment,
- faucets,
- feeding and watering equipment,
- fixtures,
- floors (flooring),
- handheld electronic devices,
- handles,
- hand rails (railings),
- high touch surfaces,
- kennel runs,
- laptops,
- light fixtures, switches,
- lockers,
- mobile devices (electronic equipment),
- mobile workstations,
- pagers,
- phones, phone cradles and accessories,
- shelves,
- showers,
- shower fixtures,
- sinks,
- stools,
- tables,
- tablet PCs,
- telephones,
- tubs,
- exterior surfaces of toilets,
- urinals,
- walls,
- wash basins

(Animal/Veterinary Items:)

- animal equipment,
- animal crates,
- automatic feeders,
- buckets,
- brushes,
- cages,
- carts,
- counters,
- desks,
- dog runs,
- examination tables,
- exterior surfaces of fountains,
- external surfaces of (veterinary) equipment,
- exterior surfaces of watering appliances,
- farm vehicles (trucks),
- feed racks,
- fencing,
- food baths,
- gates,
- gathering (guiding) equipment
- grooming equipment,
- handling equipment,
- harnesses & leashes,
- pens,
- (wash) stalls,
- transportation crates,
- troughs,
- veterinary care surfaces.

(found in (health care facilities) (and) (hospitals).) Do not use on glasses, dishes and utensils. In addition, this product will deodorize those areas that are generally hard to keep fresh smelling, such as garbage storage areas, empty garbage bins and cans, and any other areas that are prone to odors caused by microorganisms. (Disinfects, cleans, and deodorizes hard, nonporous surfaces in (restrooms,) (bathrooms,) (toilet areas,) (finished nonporous surfaces behind and

(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.)

under sinks and counters,) (garbage cans and garbage storage areas), and other places where bacterial growth can cause malodors.)

Note: Prior to use on electronic equipment or components, (please) refer to manufacturer's instructions (for appropriate use).

(For Use in Mold Remediation:)

This product kills the growth of mold and mildew and the odors caused by (associated with) them on hard, non-porous surfaces such as sealed (concrete) floors, sealed walls; sealed drywall and gypsum board, tabletops, bench-tops, drain troughs, drip pans, desks, locker room benches, and hard non-porous bath mats (e.g., rubber or plastic).

DIRECTIONS FOR USE:

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

Not recommended for use on (or) (avoid contact with): brass or copper.

(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).) Using approved AOAC test methods (under Good Laboratory Practices, [GLPs]), in the presence of 5% serum load and 1 (one) minute contact time, unless otherwise noted, this product kills the following on hard nonporous (inanimate) (environmental) surfaces:

Bacteria (Bactericidal Activity):

Pseudomonas aeruginosa, (ATCC 15442)

Staphylococcus aureus, (ATCC 6538)

Salmonella enterica, (ATCC 10708)

formerly known as *Salmonella choleraesuis*

Bordetella bronchiseptica, (ATCC 10580)

Burkholderia cepacia, (ATCC 25416)

Bordetella pertussis, (ATCC 12743)

Enterobacter aerogenes, (ATCC 13048)

Enterococcus faecium, (ATCC 51559)

Escherichia coli, (ATCC 11229)

Escherichia coli O157:H7, (ATCC 35150)

Klebsiella pneumoniae, (ATCC 4352)

Legionella pneumophila, (ATCC 33153)

Listeria monocytogenes, (ATCC 19117)

Pasteurella multocida, (ATCC 12947)

Serratia marcescens, (ATCC 14756)

Staphylococcus pseudintermedius,
(ATCC 49444)

Shigella dysenteriae, (ATCC 11835)

Stenotrophomonas (Pseudomonas)
maltophilia, (ATCC 25596)

Streptococcus pyogenes, (ATCC19615)

([±])Antibiotic-Resistant (Strains of) Bacteria (Antibiotic-Resistant Bactericidal Activity):

Acinetobacter baumannii,

(Multi-Drug Resistant (MDR)) (ATCC 19606)

Ampicillin, Cefazolin, Cefepime, Gentamicin,
Ertapenem, and Trimethoprim/Sulfa)

Enterobacter cloacae, (New Delhi metallo-β-
lactamase 1 positive (producing) (NDM 1))
(CDC 1000654)

Enterococcus faecalis, (ATCC 51575)
(Vancomycin Resistant (VRE))

Escherichia coli, (Extended Spectrum Beta-
lactamase producing (positive (ESBL))
(ATCC BAA-196)

Escherichia coli, (New Delhi metallo-β-
lactamase 1(NDM-1) producing (positive))
(CDC 1001728)

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

Klebsiella pneumoniae, (Extended Spectrum
beta-lactamase (ESBL) producing (positive))
(ATCC700603)

Klebsiella pneumoniae, (New Delhi metallo-β-
lactamase 1(NDM-1) producing (positive))
(CDC 1000527)

Pseudomonas aeruginosa, (Metallo-beta
lactamase (MBL) positive (CDC 2012059))

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

Staphylococcus aureus, (Methicillin Resistant
(MRSA)) (ATCC 33591)

Staphylococcus aureus, (ATCC 33592)
(Methicillin Resistant (MRSA))

Staphylococcus aureus, (Vancomycin
Intermediate Resistant (VISA)) [HIP 5836]

Staphylococcus aureus,
(Vancomycin Resistant (VRSA))[VRS1]

Staphylococcus epidermidis, (Methicillin
Resistant (MRSE)) (ATCC 51625)

Streptococcus pneumoniae, (Penicillin
Resistant (PRSP)) (ATCC 700677)

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***Virucidal** (using approved AOAC methods) (under Good Laboratory Practices, (GLP's)), in the presence of 5% serum load with a 30 second contact time(, unless otherwise noted).

***Viruses:**

*Adenovirus Type 8, (ATCC VR-1368)	*Herpes Simplex Virus, Type 2 (HSV-2), (ATCC VR-734)	*Pandemic Influenza A Virus H1N1
*Cytomegalovirus, (ATCC VR-538)	*HIV-1 (AIDS Virus), Strain HTLV-III _B (HIV-1), (Acquired from Adv. Biotechnologies, Inc.)	*Parainfluenza Virus Type 3, (ATCC VR-93)
*Hepatitis B Virus (HBV), Duck Hepatitis B Virus as surrogate (Acquired from Hepadnavirus Testing)	*Human Coronavirus, (ATCC VR-740)	*Respiratory Syncytial Virus, (RSV) (ATCC VR-26)
*Hepatitis C Virus (HCV), Bovine Viral Diarrhea Virus as surrogate (Acquired from National Veterinary Services Laboratories)	*Influenza A Virus (Hong Kong Strain), (ATCC VR-544)	*Rhinovirus Type 37, Strain 151-1, (ATCC VR-1147)
*Herpes Simplex Virus, Type 1 (HSV-1) (ATCC VR-733)	*Influenza B Virus, (ATCC VR-823)	*Rotavirus, (WA strain) (Acquired from University of Ottawa)
	*Norovirus, (Feline Calicivirus, ATCC VR-782 as the surrogate)	*Vaccinia Virus, (ATCC VR-119)

***Animal Viruses:**

*Avian Influenza A Virus (H7N9)	*Bovine Viral Diarrhea Virus (BVDV)	*Feline Calicivirus, Strain F9 (ATCC VR-782)
*Avian Influenza A Virus (H3N2), (ATCC VR-2072)	*Duck Hepatitis B Virus	*Murine Norovirus
	*Equine Influenza A Virus (H3N8) (EIV)	

***Animal Viruses with a 1 minute contact time:**

*Feline Infectious Peritonitis Virus, (FIPV) (ATCC VR-2022)	*Feline Herpes Virus, (Feline Rhinotracheitis) (ATCC VR-636)	*Minute Virus of Mouse, (Murine Parvovirus) (ATCC VR-1346)
*Murine Hepatitis Virus, (ATCC VR-765)		

TUBERCULOCIDAL (determined by the AOAC Tuberculocidal Activity of Disinfectant Towelette) against *Mycobacterium bovis* (Tb) (BCG) (OT 451C150) in the presence of a 5% serum load and 1 minute contact time at 20°C (68°F) on hard, non-porous environmental surfaces.

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% soil and 30 second 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.

FUNGICIDAL against *Candida albicans* (ATCC 10231) and *Microsporium canis* (ATCC 10214) in the presence of 5% soil with a 1 minute contact time.

****FUNGICIDAL** against *Candida auris* (CDC AR-0381) with a 1 minute contact time.

Mold/Mildew (Mildewcidal Activity): Kills the growth of mold and mildew with a 4 minute contact time: *Aspergillus brasiliensis* (formerly known as *Aspergillus niger*) (ATCC 16404) (and the odors caused by them) when applied to hard, non-porous environmental surfaces.

Mold/Mildew (Mildewstatic Activity): Controls and prevents the growth of mold and mildew: *Aspergillus brasiliensis* (formerly known as *Aspergillus niger*) (and the odors caused by them) when applied 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.)

Non-Food Contact Surface Sanitizer in the presence of a 5% serum load and 10 second contact time on hard, non-porous environmental surfaces.

Acinetobacter baumannii, (ATCC 19606)

Campylobacter jejuni, (ATCC 29428)

Enterobacter aerogenes, (ATCC 13048)

Enterococcus faecalis, (Vancomycin Resistant (VRE)) (ATCC 51575)

Escherichia coli O157:H7, (ATCC 35150)

Klebsiella pneumoniae, (ATCC 4352)

Listeria monocytogenes, (ATCC 19117)

Pseudomonas aeruginosa, (ATCC 15442)

Salmonella enterica, (formally known as

Salmonella choleraesuis) (ATCC 10708)

Staphylococcus aureus, (ATCC 6538)

Staphylococcus aureus, (Methicillin Resistant (MRSA)) (ATCC 33592)

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).

(Optional Pandemic Influenza Statements)

- Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by Influenza A virus. (This product or product name) is a broad-spectrum hard surface disinfectant that has been shown to be effective against Influenza Type A2 (Hong Kong), (VR-544), and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- This product has demonstrated effectiveness against Influenza A virus and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 Influenza A virus.
- This product has demonstrated effectiveness against Influenza Type A2 (Hong Kong), (VR-544), and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- Kills Pandemic 2009 H1N1 Influenza A virus (formerly called swine flu).
- Kills Pandemic 2009 H1N1 Influenza A virus.

OPTIONAL Packaging Related Statements – Appropriate language can be selected depending on packaging.

[For canisters and buckets:]

[To open the package:]

[To pull wipes through lid]: Remove lid. [Then remove and discard induction seal [from the canister]]. Pull out corner of first sheet [wipe] from center of roll and push ½” to ¾” (1 to 2 cm) through “X” opening on lid. DO NOT push finger through opening. Replace lid and pull wipe at an angle. The next sheet pops up automatically. When finished, close [lid] [flap] to retain moisture.

[For re-fill pouch where the wet roll is left in the pouch when placed in the canister:]

[Look for product expiration date on back of refill pouch.] [Remove the new [lot number/][expiry date] from pouch and place it on top of the old [lot number/][expiry date] sticker on the canister]. Open [Remove lid from] empty canister [bucket]. [Place] [Put] [Insert] refill [pouch] into bucket [canister]. [Use scissors] [to] [Cut] [Rip] [Tear] [Pull] [Open] refill pouch. DO NOT remove wipe roll from refill pouch. Pull out corner of first sheet [wipe] from center of roll and push ½” to ¾” (1 to 2 cm) through “X” opening on lid. DO NOT push finger through opening. Replace lid and pull wipe [towel] at an angle. The next [sheet] [wipe] [towel] pops up automatically. When finished, close [lid] [flap] to retain moisture. If bucket becomes contaminated [or] [damaged] replace immediately. Replace bucket immediately if tabs below [lid] [flap] become damaged.

[For re-fill pouch where the wet roll is placed directly in the canister:]

[Remove the new [lot number/][expiry date] from pouch and place it on top of the old [lot number/][expiry date] sticker on the canister.] Open [Remove lid from] empty canister [bucket]. [Use scissors] [to] [Cut] [Rip] [Tear] [Pull] [Open] refill pouch. Place saturated towelettes in empty canister [by] [invert[ing] contents of the pouch into empty canister]. Pull out corner of first sheet [wipe] from center of roll and push ½” to ¾” (1 to 2 cm) through “X” opening on lid. DO NOT push finger through opening. Replace lid and pull wipe [towel] at an angle. The next [sheet] [wipe] [towel] pops up automatically. When finished, close [lid] [flap] to retain moisture. If bucket becomes contaminated [or] [damaged] replace immediately. Replace bucket immediately if tabs below [lid] [flap] become damaged.

[For re-sealable flatpack, transport pack or softpack, flexible package:]

[To Open Package:]

1. Open [click-lock] [closure] and peel back [or] [remove] seal.
2. Pull out [one] wipe [sheet] [at a time][, use as directed].
3. [When finished,] [firmly] close [click-lock] [closure] to retain moisture [to prevent drying between uses].

[For re-sealable soft pack:]

1. Remove the seal (from the place shown on the label).
2. Remove one sheet at a time.
3. Close the seal (to prevent drying between uses).

[For single count pack:]

To Open: Tear open packet. Unfold and use as directed. Discard after single use.
Not for personal cleansing. This is not a baby wipe. [Do not flush in toilet].

(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.)

Not for personal cleansing. This is not a baby wipe. Do not flush in toilet.

*(**Note to reviewer: The following paragraph will be used on labels that state non-critical and semi-critical medical devices listed on pages 6 and 7, as defined by the FDA, and is manufactured accordingly.)*

(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.)

To Use as a One-Step Cleaner/Disinfectant:

1. Pre-clean heavily soiled areas.
2. Wipe hard, non-porous environmental surfaces with towelette.
3. Allow surface to remain wet for 1 minute. (For certain listed viruses, allow to remain wet for 30 seconds.)
4. Allow to air dry (or rinse (with potable water if necessary)).

Note: All food contact surfaces must be rinsed with potable water. Do not use on glassware, utensils, or dishes.

To Use as a (Daily) (Bathroom) (Restroom) (Shower Room) (Locker Room) (Athletic Equipment) Cleaner/Disinfectant:

1. Pre-clean heavily soiled areas.
2. Wipe hard, non-porous environmental surfaces with towelette.
3. Allow surfaces to remain wet for 1 minute. (For certain listed viruses, allow to remain wet for 30 seconds.)
4. Rinse surfaces thoroughly (and) (or) let air dry.

(The below sentence is optional language:)

(Note: Floors will be slippery when wet or contaminated with foreign materials.)

[Note to Reviewer: When this product is manufactured and listed as an FDA Medical Device General Purpose Disinfectant, the final product label can state the following instructions to disinfect noncritical medical items:]

To Disinfect Non-Critical, Pre-cleaned Instruments:

1. Instruments must be thoroughly pre-cleaned to remove excess organic debris, rinsed, and rough dried. (Clean and rinse lumens of hollow instruments before wiping with this product).
2. Wipe hard, non-porous environmental surfaces with towelette.
3. Let stand for 1 minute (at room temperature).
4. Wipe with a clean, damp cloth or paper towel and allow to air dry.

Note: Non-critical medical items are those that only come into contact with intact skin.

To Clean and Disinfect Manikins Used in CPR Training:

Manikins should be cleaned as soon as possible at the end of each class to avoid drying of contaminants on surfaces. Disassemble the manikin as directed by manufacturer's instructions. Wipe all surfaces with towelette until thoroughly wet. Let stand for 1 minute and rinse with potable water. (For certain listed viruses, allow to remain wet for 30 seconds.)

To Disinfectant Hard, Non-Porous Surfaces in Pharmaceutical and Cosmetic Processing Facilities:

1. Pre-clean heavily soiled areas.
2. Wipe hard, non-porous environmental surfaces with towelette.
3. Allow surfaces to remain wet for 1 minute. (For certain listed viruses, allow to remain wet for 30 seconds.)
4. Rinse with sterile water.
5. Wipe with a dry, clean cloth and let 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.)

To Clean and Disinfect Barber and Beauty/Manicure Instruments and Tools:

1. Pre-clean heavily soiled items.
2. Wipe all surfaces of pre-cleaned combs, brushes, scissors, clipper blades, razors, manicure implements and other hard, non-porous instruments with this product until thoroughly wet.
3. Let stand for 1 minute.
4. Rinse the surfaces thoroughly with water.
5. Let air dry before reuse.

To Disinfect Hard, Non-Porous Surfaces of Non-Circulating Footbaths:

1. Drain: Drain the water (from) (the) (unit) (basin) (bowl) and remove any visible debris.
2. Clean: Thoroughly clean all surfaces with (this product) (or) (soap) (detergent), then rinse with water and drain.
3. Apply: Wipe all hard non-porous (inanimate) (environmental) surfaces with the towelette. Allow surfaces to remain wet for 1 minute. Change towelettes frequently to avoid re-deposition of soil. Use additional towelettes if needed to ensure the correct wet contact time.
4. Rinse (cleaned) (treated) (surfaces) with fresh water and drain.

***KILLS HIV, HCV and HBV ON PRE-CLEANED ENVIRONMENTAL 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 C Virus (HCV) or Hepatitis B Virus (HBV).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (AIDS VIRUS), HCV OR HBV 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 30 seconds to kill HIV-1, HCV and HBV, 4 minutes for mold, and 1 minute to kill other organisms cited on label.

Disposal of Infectious Material: Blood/body fluids must be autoclaved and disposed of 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 barns, pens, stalls, chutes, and barns) occupied or traversed by animals.
3. Empty (or cover) all troughs, racks, and other feeding and watering appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with potable water.
5. Wipe hard, non-porous environmental surfaces with towelettes. To disinfect, all surfaces must remain wet for 1 minute. (For certain listed viruses, allow to remain wet for 30 seconds.)
6. Allow to air dry (or rinse with potable water if necessary).
7. Ventilate buildings and other closed spaces.
8. Do not house animals or employ equipment until treatment has been absorbed, set or dried.
9. 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 which can be used partially or in its entirety. Commas may be added where needed.)

To Kill Fungi:

For Candida auris, please see special instructions. Pre-clean heavily soiled areas. Wipe hard, non-porous environmental surfaces with towelette. Allow to remain wet for 1 minute. Use additional towelettes if needed to ensure the correct wet contact time. Wipe surfaces or let air dry.

****Special Instructions for Cleaning Prior to Disinfection against *Candida auris***

Personal Protection: Wear appropriate barrier protection such as gloves, gowns, masks or eye covering.

Cleaning Procedure: Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection by application with a clean cloth, mop, and/or sponge saturated with the product. Pre-cleaning is to include vigorous wiping and/or scrubbing and all visible soil is removed. Surfaces in patient rooms are to be cleaned in an appropriate manner, such as from right to left or left to right, on horizontal surfaces, and top to bottom, on vertical surfaces, to minimize spreading the organism. Restrooms are to be cleaned last. Do not reuse soiled cloths.

Infectious Materials Disposal: Materials used in the cleaning process that may contain feces/wastes are to be disposed of immediately in accordance with local regulations for infectious materials disposal.

Disinfection Procedure: Pre-clean heavily soiled areas. Wipe hard, non-porous environmental surfaces with towelette. Allow to remain wet for 1 minute. Use additional towelettes if needed to ensure the correct wet contact time. Wipe surfaces or let air dry.

To Use as a Non-Food Contact Sanitizer:

1. Pre-clean heavily soiled areas.
2. Wipe hard, non-porous environmental surfaces with towelette.
3. Allow the surface to remain wet for 10 seconds.
4. Wipe surfaces dry (or rinse) (or allow to air dry).

To Kill Mold and Mildew:

Pre-clean surfaces. Wipe hard, nonporous surfaces with towelettes until completely wet. Allow to remain wet for 4 minutes. Let air dry (or) (wipe surface dry) (or) (rinse).

To Control Mold and Mildew:

Wipe hard, nonporous surfaces with towelettes until completely wet. Let air dry (or wipe surface dry) (or rinse). Repeat application weekly or when growth reappears.

Mold Remediation:

1. Repair the source of moisture (stop leaks, etc.) to eliminate conditions favorable to mold growth such as moisture ingress and high relative humidity and to prevent further mold growth and/or re-growth.
2. Wipe (the wall) with a clean cloth wetted with clean water or with this product. Dispose of the cleaning cloth in a well-sealed plastic bag.
3. Wipe the contaminated, hard, non-porous surfaces with towelettes until completely wet.
4. Allow to remain wet for 4 minutes. Use additional towelettes if needed to ensure the correct wet contact time.

To Clean (and/or Deodorize):

Wipe hard, non-porous environmental surfaces with towelette. (Wipe surfaces dry) (or rinse) (or allow to air dry). Repeat for heavily soiled areas. For stubborn stains or heavily soiled areas or tougher jobs, allow product to penetrate (dirt) before wiping.

(Allergen Destruction)

To Clean and Destroy Specified Allergens: Wipe, wait 1 minute, and wipe with a second towelette to remove excess. (Allow to air dry) (or) (rinse). (If streaking is observed, wipe with a clean, damp (cloth or) paper towel.)

Allergens:

- Cockroach matter -or- particles
- Dust mite matter -or- particles
- Pet dander -or- dog and cat dander

(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.)

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in original container in areas inaccessible to small children in a cool, dry area (away from direct sunlight and heat). Keep securely closed.

Towelette Storage/Disposal: Dispose of (wipe) (towelette) (cloth) in trash after use. Do not flush. (Tightly close lid) (Reseal) between uses to retain moisture.

Container Disposal:

[Note to reviewer: The following statement will be used on containers that cannot be refilled by the end-user but are recyclable:]

Nonrefillable container. Do not reuse or refill this container. Offer empty container for recycling. If recycling is not available, discard container in trash.

[Note to reviewer: The following statement will be used on containers that cannot be refilled by the end-user and are NOT recyclable such as refill bags/soft packs:]

Nonrefillable container. Do not reuse or refill this container. Discard container in trash.

[Note to reviewer: The following statement will be used on containers (canisters, buckets) that are designed to be refilled by the end-user:]

Refillable container. Refill this container with this brand name pesticide only. Do not reuse or refill this container for any other purpose. After final use, offer empty container for recycling. If recycling is not available, discard container in trash.

EPA Reg. No. 70627-77

EPA Est. No.

(Lot code letters indicate establishment number.)

[Manufactured][Distributed][by][for]:

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[Graphics:]



Hydrogen Peroxide (logo) patent pending

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.)

REFERENCE SHEET

OXIVIR 1 WIPES

(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 use, storage and disposal.

EPA Reg. No. 70627-77

[Manufactured][Distributed][by][for]:

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