

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

September 27, 2021

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

Subject: PRIA Label Amendment – Adding SARS-CoV-2 claims Product Name: OXIVIR® 1 Wipes EPA Registration Number: 70627-77 Application Date: 05/04/2021 Case Number: 299888

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.

Page 2 of 2 EPA Reg. No. 70627-77 Case Number. 00299888

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Stacey Grigsby by phone at 703.305.6440, or via email at grigsby.stacey@epa.gov

Sincerely,

Lorena Rivas

Lorena Rivas, Acting Product Manager 34 Regulatory Management Branch II Antimicrobials Division (7510P)

Enclosure: Accepted stamped label 09/20/2021 Efficacy Review





• [Bactericide] • [*Virucide] • [Fungicide] • [Mildewcide] • [Disinfectant] • [Cleaner]

Active Ingredient:	
Hydrogen Peroxide	0.5%
[Inert] [Other] Ingredients	
Total	100.0%

KEEP OUT OF REACH OF CHILDREN

See additional precautionary statements on [back] [left] [right] [panel] [of] label]. DO NOT FLUSH

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

EPA Reg. No. 70627-77 EPA Est. No. {*Insert EPA Est. No.*} Net Contents: {*Insert package contents*}

Manufactured [By] [For]: Diversey, Inc. PO Box 19747, Charlotte, NC 28219-0747 U.S.A. All Rights Reserved. [Manufactured in: *{insert country}* Accelerated Hydrogen Peroxide[®] and AHP[®] are trademarks of Diversey Inc.

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

{Features, Claims and Uses}

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{Product Descriptors}

- Active Ingredient is an Oxidizing Agent
- Bactericide
- Broad-Spectrum Disinfectant
- Cleaner
- Cleans, Deodorizes and Brightens in One Step¹
- Cleans, Disinfects, & Deodorizes (with Hydrogen Peroxide)
- Cleans Grout
- Cleans Hard, Non-porous Water Washable Surfaces!
- Deodorizer
- Disinfectant
- Easy to Use
- For (Industrial), (Institutional) & (Residential) Use
- Fungicide
- Fungicidal disinfectant against C. auris
- Hospital Disinfectant Cleaner
- Hydrogen Peroxide
- Meets Surface Recommendations from OSHA's Bloodborne Pathogens Standard for *HBV, *HCV & *HIV-1
- Mildewcide
- Multi-Surface²

(Marketing Statements)

1 Minute bactericidal, virucidal and fungicidal

- Multi-surface² Disinfectant Cleaner
- Multi-surface² [One-Step¹] Disinfectant
- Non-Dulling
- No Gloves Required, unless directed
- Odor Counteractant
- Odor Neutralizer
- One-step when used according to disinfection directions
- One-step Disinfectant (Cleaner) (& Deodorizer) (Wipes)
- Oxidizer
- Ready to Use
- Sanitizer
- Sanitizes
- Tuberculocide
- Tough on Pathogens, Not on People
- Towelette
- (Restroom) (&) (Bathroom) (Disinfectant Cleaner)
- Use Daily to Prevent the Buildup of Dirt and Grime.
- *Virucide
- Wipe

A disinfectant and cleaner (that cleans, disinfects and deodorizes in one labor saving step) when used according to disinfection directions for use.

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)

Alcohol Free

Always Ready to Use

An effective one-step¹ disinfectant cleaner for hard, nonporous surfaces

An effective one-step¹ sanitizer-cleaner on hard nonporous surfaces when used according to directions for use as a non-food contact sanitizer

Breaks down (removes) (eliminates 99.9% of) (removes) (the most common) allergens (found in dust)++

Broad-spectrum (Multi-surface²) (Bactericidal) (*Virucidal) (Tuberculocidal) (Fungicidal) (Sanitizer) (Disinfectant) (activity) Cleaning and disinfection in 1 minute

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

Cleans (and) disinfects (and deodorizes) hard, non-porous surfaces

Cleans fast

Cleans grout

Cleans hard, non-porous water washable surfaces!

Cleans, deodorizes and brightens in one step¹

Cleans (tough) soap scum

(Cleans) (Removes) (Eliminates 99.9% of) (Destroys) stains

Compatible with microfiber (cloths)

Compatible with (most) (virtually all) surfaces

Contains no phosphates Contains no VOC-emitting ingredients Controls (Eliminates 99.9% of) odor-causing bacteria Convenient, pre-wetted wipes on demand Deodorizer (Odor Counteractant) Deodorizes odor-causing bacteria Disinfects as it cleans when used according to disinfection directions for use Disinfects surfaces by killing [99.9%] SARS-Related Coronavirus 2 [SARS-CoV-2] [USA-WA1/2020] (the cause of COVID-19) [in one step¹] on hard non-porous surfaces Dual action formulation providing broad spectrum activity against; fungi, mycobacteria, *viruses, and bacteria Easy to use Effective - Cleans soap scum Effective cleaner Effective against Bloodborne Pathogens *HBV, *HCV & *HIV-1 Effective against SARS-Related Coronavirus 2 [SARS-CoV-2] [USA-WA1/2020] [in 1 minute] on hard non-porous surfaces [Effective against] [Disinfects] [Kills] [99.9%] SARS-CoV-2 [virus] (the cause of COVID-19) on hard non-porous surfaces (Eliminates) (Kills) 99.9% of (odor-causing) bacteria (from surfaces) Eliminates 99.9% of odors (caused by bacteria), (mold), (and) (mildew) Fast / Easy / Effective For (a) cleaner, fresher {insert use sites/surfaces from lists below} (or hard, non-porous washable surface where disinfection is required.) For non-food contact hard, non-porous surface where germs are a concern. For everyday use (in institutional (and) (industrial) facilities) For multiple cleaning tasks For non-scratch cleaning of showers and tubs, shower doors and curtains[†], fixtures and toilet bowls For use (in) (Hospitals), (and) (Health Care) (settings) (as a disinfectant cleaner) For terminal cleaning Formula utilizing by AHP. Formulated with patented hydrogen peroxide technology Fragrance Free Formula (Unscented) Gentle Enough for Use in Home Gentle on eyes, skin, and nose Good for most indoor cleaning tasks (Highly) compatible (formula) for most surfaces High (Frequently) touch[ed] surface(s) [disinfectant] [and] [cleaner] Intense cleaning action Keeps day care centers clean Kills (99.9% of) germs in 1 minute Kills (99.9% of) the cold and flu viruses (Kills) (Destroys) (Eliminates 99.9% of) (household) germs while it cleans (Kills) (Effective against) (the) cold (and) (flu) virus(es) on hard, nonporous surfaces Kills bacteria and sanitizes Kills coronavirus that causes COVID-19 on hard non-porous surfaces [Kills] [Effective against] the virus that causes COVID-19 on hard non-porous surfaces [Kills] [Eliminates] 99.9% SARS-Related Coronavirus [SARS-CoV-2] [USA-WA1/2020] [causative agent of COVID-19] [the virus that causes COVID-19] on hard non-porous surfaces Kills the virus (SARS-CoV-2) that causes COVID-19 on hard non-porous surfaces Kills [99.9% of] SARS-CoV-2, which causes COVID-19 on hard non-porous surfaces Kills *viruses on hard non-porous surfaces Kills bacteria and *viruses on (household) hard, non-porous surfaces in 1 minute Kills bacteria (in 1 minute) Kills odor-causing bacteria

Leaves {insert use sites/surfaces from lists below}-smelling clean (with a clean fresh scent) Leaves a fresh, clean scent Leaves no (dull) (sticky) residue. Leaves surfaces virtually streak-free No fragrance added No harsh (chemical) fumes No rinse required No streaking (or) (filming) (sticky residue) (formula) Non-corrosive (to eyes) (and) (skin) Non-tainting (leaves no unsightly residues) Not a skin (dermal) sensitizer Non-irritating to eyes Non-irritating to skin Non-irritating to respiratory tracts Not for use on skin **Odor Neutralizer** Oxivir[®] Clean Patented (Technology) (Phenol free) (No phenols) Powerful to remove (dried) (stuck on) dirt (grime) (food) (spills) (grease) (greasy messes) Powerful cleaning Powerful cleaning and disinfection in 1 minute. Powerful odor control (odor neutralizer) (deodorizer) (odor-counteractant) formula on hard non-porous surfaces Powers away tough stains (stuck on dirt) Proven "one-step1" disinfectant/cleaner/fungicide/mildewcide/virucide that is effective for hard, non-porous surfaces Proven to kill Candida auris (C. auris) (in one minute) Category IV Tox(icity) Rating (in all 6 toxicity categories) Quickly (eliminates 99.9% of) (removes) odors Reduces allergens++ Sanitizes Specially designed to dissolve (penetrate) the toughest (stubborn) soils (Step-saving), (Labor-saving,) (Time-saving,) (Cost-saving) formula Suitable for everyday use Surface cleaner with antibacterial formula This product kills germs and removes allergens++ while cleaning hard, nonporous surfaces ++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) 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 (pathogens) Use daily to prevent the build-up of dirt and grime Use only one product to get a streak-free shine plus antimicrobial action (Uses) (Harnesses) the cleaning power of hydrogen peroxide Versatile, Fast-acting, Convenient formula Will not leave grit or soap scum

BACTERICIDAL DISINFECTION: 1 MINUTE VIRUCIDAL DISINFECTION: 1 MINUTE (BROAD-SPECTRUM) NON-FOOD CONTACT SANITIZER: 10 SECONDS FUNGICIDAL: 30 SECONDS **FUNGICIDAL AGAINST C. AURIS: 1 MINUTE

(General Uses:)

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

This product is a one-step¹ (hospital-use) germicidal disinfectant (and) (deodorant) (odor-counteractant) (odor neutralizer) designed for general cleaning, (and) disinfecting (deodorizing) (of) hard, non-porous inanimate surfaces. It cleans by removing dirt, grime, and other common soils found (in) (on) *{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 surfaces from lists below*} (where disinfection is required). A potable water rinse is required for food contact surfaces. Do not use on glassware, dishes and utensils.

[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.

(This product [or product name] (Oxivir 1 Wipes) (This product) [or These] (are) (is a) non-woven, disposable (towelette(s)) (wipe(s)), pre-saturated with Hydrogen Peroxide (based) disinfectant cleaner.

(This product [or product name] (Oxivir 1 Wipes) (This product) is a one-step¹ (hospital-use) germicidal (disinfectant) cleaner and deodorant (odor-counteractant) (odor neutralizer) (towelette) designed for general cleaning, (and) disinfecting, (and) (deodorizing) (of) hard, non-porous environmental surfaces.

(This product's [or product name] (Oxivir 1 Wipes) (This product) (Its) (non-dulling) (cleaning) (convenient) (easy-to-use) (effective) formula eliminates the time and labor normally required for rinsing.

(This product's [or product name] (Oxivir 1 Wipes) (This product) (Its) (non-dulling) (cleaning) (convenient) (easy-to-use) (effective) formula is designed for use on (Use daily on) (Use daily to clean and disinfect) {*insert use sites/surfaces from lists below*}

(Oxivir 1 Wipes') (This product's) (Its) non-abrasive formula is designed for use on (Use daily on) (the following) {insert use sites/surfaces from lists below}

(Oxivir 1 Wipes') (This product's) (Its) non-abrasive formula is designed for use on (Use daily on) hard, non-porous environmental surfaces.

(Oxivir 1 Wipes) (This product) (It) cleans by removing dirt, grime, dead skin, blood, urine, fecal matter, body oils and other (organic matter) (common soils) found in *{insert use sites/surfaces from lists below}* (or – hard, non-porous washable surface where disinfection is required.)

(Oxivir 1 Wipes) (This product) (It) also eliminates odors, leaving (restroom) surfaces smelling clean and fresh. Use where odors are a problem.

(Oxivir 1 Wipes) (This product) cleans, disinfects and deodorizes hard, non-porous environmental (hospital) (medical) (dental) (laboratory) *(insert use sites/surfaces from lists below)* surfaces in one step (with no rinsing required).

(Oxivir 1 Wipes) (This product) cleans, disinfects and deodorizes surfaces by killing odor-causing microorganisms. Its (nondulling) (advanced) (efficient cleaning) (convenient) (easy-to-use) (effective) formula is designed for use on (Use it daily) on) *[insert use sites/surfaces from lists below]*

(Oxivir 1 Wipes) (This product) (It) (is designed for use on) (Use daily on) (the following) (hard, non-porous environmental (inanimate) surfaces): {*insert use sites/surfaces from lists below*} or –hard, non-porous washable surface where disinfection is

required.

(CLAIMS & USES:)

(This product) (Oxivir 1 Wipes) {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 1 Wipes) {marketed product name} kills ESKAPE organisms with a 1 minute kill time.

(This product) (Oxivir 1 Wipes) {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-step¹ (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 step¹ (with no rinsing required). [Its non-abrasive formula is designed for use on] [Use daily on] [(the 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.]

[This product can be used against bacteria, *viruses, fungi, mycobacteria and mildew on hard non-porous surfaces found in: {*insert use sites from list below*}]

{or}

[(Oxivir 1 Wipes) (This product) can be used (in) (on) hard non-porous surfaces (of the following items) or (in the following areas): {insert use sites/surfaces from lists below}]

{or}

[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: {insert use sites from list below}]

(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 step¹. [Its non-abrasive formula is designed for use on] [Use daily on] [Use daily to clean and disinfect] (hard, non-porous surfaces (of):) *{insert use sites/surfaces from lists below}* (where disinfection is required.) found in (barns, pens and stalls) animal housing facilities.]

{Use Sites}

AirplanesAirports

- Ambulances [Emergency Medical] Transport Vehicles
- Ambulatory Surgical Centers
 [(ASC)]
- Amusement Parks

- [Animal] (and) [Pet] Housing
- [Animal] (and) [Pet] Grooming Facilities
- Animal Care Facilities
- Animal Holding Areas
- Animal Housing Facilities
- Animal Life Science
 Laboratories
- Animal Transportation Vehicles
- Anesthesia Rooms or Areas
- [Assisted Living] (and) [Full Care] Nursing Homes
- [Athletic] (and) [Recreational] Facilities
- Banquet Halls
- Barber Shops
- Bars
- Basements
- Bathrooms
- Beauty Salons
- Bedrooms
- Bowling Alleys
- Breeding Establishments
- Buses
- Butcher Shops
- Cafeterias
- Changing Areas
- Colleges
- Convenience Stores
- Convention Centers
- Correctional Facilities
- Cruise Ships
- Cafeterias
- CAT Lab[oratories]
- Central Service Areas
- Central Supply [Rooms] (and) [Areas]
- Colleges
- Commercial (and)
 [Institutional] Kitchens
- C[ritical] C[are] U[nits]
- Dairy Farms
- Day Care [Centers]
- Deli[catessen]s
- Dental Operatories

- [Dental] [Dentist's] Offices
- Dining Halls
- Dialysis Clinics
- Doctors' Offices
- Dorm[itories]
- Elevators
- E[mergency] R[oom]s
- Emergency Vehicles
- Eye Surgical Centers
- Exam[ination] Rooms
- Factories
- Farms
- Food Preparation and
 Processing Areas
- [Food] Processing Plants
- Food Service Establishments
- [Food Serving] (and) [Storage Areas]
- Front of Restaurants
- Funeral Homes
- Garages
- Gas Stations
- General Merchandise Stores
- Greenhouses
- Grocery Stores
- Gym[nasium]s
- Health Clubs
- Health Care [Settings]
 [Facilities]
- Home Centers
- Home Health Care Settings
- Homes
- Hospices
- Hospitals
- Hotels
- Industrial Facilities
- Institutional Kitchens (and) [Bathrooms]
- [Institutional] Laundromats
- Institutions
- I[ntensive] C[are] U[nits] [areas]
- Isolation Areas
- Kennels
- Kitchens
- Laboratories

- Laundromats
- Laundry Rooms
- Lab[oratories]
- Lavatories
- Libraries
- Locker Room[s] [Facilities]
- Lodging Establishments
- Long Term Care Facilities
- Lounges
- Malls
- Manufacturing [Plants] [Facilities]
- Markets
- [Medical] Clinics
- Medical Facilities
- [Medical] [Doctor's] Offices
- [Newborn] [Neonatal] [Nursery] [Intensive] [Care] Units [NICU]
- Nurses' Stations
- Nursing Homes

Office Buildings

Patient Rooms

Orthopedics

[PICU]

Pet Shops

Pharmacies

O[perating] R[oom]s

Pet Animal Quarters

Physicians' Offices

Psychiatric Facilities

Public Facilities

Reception areas

Recovery Rooms

Recreational Facilities

Rehabilitation Centers

EPA Reg. No. 70627-77 September 22 ,2021 Page **7** of **23**

Radiology

Rental Cars

[Public] Restrooms

Physical Therapy Rooms

Play [Areas] (and) [Rooms]

[Police] (and) [Fire] Vehicles

Public [Areas] (and) [Places]

Public [Tele]phone [Booths]

Pediatric Intensive Care Units

NurseriesOffices

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- Respiratory Therapy Rooms
- Rest Stops
- Restaurants
- Restroom Areas
- Retail Businesses
- School Buses
- Schools
- Shelters
- Shops
- Shower Rooms

- Sports Stadiums
- Storage [Rooms] (and) [Areas]
- Subways
- Surgery Rooms [Centers]
- Tattoo Parlors
- Toilet Areas
- Transportation Terminals
- Trains
- Trolleys
- Universities

{Surface Materials}

Urgent Care [Centers]
 [Facilities]

- Veterinary [Offices] [Waiting Rooms]
- Waiting [Rooms] (and) [Areas]
- Work Stations
- X-Ray Rooms
- Zoos

[This Product (Product Name) can be used on the following hard, nonporous surfaces:]

- Amalgamators
- Anesthesia machines
- Animal equipment
- Apex locators
- Apheresis machines
- Appliance exterior(s) [surfaces][
- Appliance -or- cabinet knobs
- Autoclaves³
- Automatic feeders
- Bathroom doorknobs
- Baked enamel surfaces
- Bassinets
- [Bathroom] fixtures
- [Bathroom] (and) [Kitchen] faucets (and) [handles]
- Bathrooms sinks and faucets
- Bathroom surfaces
- [Bath]tubs
- Bed frames
- Bedpans
- Bedrails
- Commodes
- Bedside tables
- Blood pressure cuffs and monitors
- Booster chairs
- Bottoms of pots and pans
- Burner trays
- Cabinets
- Cages
- Call boxes

- Car interiors
- Chairs
- Changing tables
- Charging stations
- Chemotherapy hoods
- Furniture
- Closets
- Coated mattresses
- Coated pillows
- [Common] hard, nonporous [household] surfaces
- Compactors
- Computers
- [Computer] keyboards
- [Computer] monitors
- Computer mouse
- Computer screens
- Cooler exteriors
- Cords
- Counter[top]s
- [Crash] (and) [emergency] carts
- Cupboards
- Cribs
- Dental countertops
- Dental operatory surfaces
- Dental surfaces
- [Dentists'] [Dental] chairs
- Dental unit instrument trays
- Desk [tops]
- Diagnostic equipment

- Dialysis machines
- Dictating equipment [surfaces]
- Docking stations
- Door [handles] (and) [frames]
- Doorknobs
- Drainboards
- Drawers
- Dryers
- Dressing carts
- Elevator buttons

Exercise mats

Exhaust fans

equipment

[probes]

appliances

Feed racks

Faucets

- Endodontic equipment
- [Exam] [Examination] tables

Exterior surfaces of air vents

External surfaces of [medical]

[Ultrasound transducers] (and)

• Exercise] (and) [athletic] equipment

[External surfaces of]

Exterior (of) [toilet] (and)

[urinal] surfaces

External surfaces of

[veterinary] equipment

Fax machine [handles]

Exterior surfaces of watering

EPA Reg. No. 70627-77 September 22 ,2021 Page **8** of **23**

- [Filing] (and) [medicine] cabinets
- Finished hardwood
- [Finished] (and) [painted] walls
- Finished windowsills
- Fixtures
- Flower buckets
- Food cases
- Food trays
- Footboards
- Freezer exteriors³
- Furniture
- Garage surfaces
- [Garbage] disposals
- Garbage -or- trash cans
- Glucometers
- [Grocery] carts
- Gurneys
- Gym[nastic] equipment
- Hampers
- Handheld [electronic] devices
- [Hand] rail[ing]s
- High touch surfaces
- Headboards
- Headsets
- High chairs [(non-food contact)]
- High touch surfaces
- Hoods
- [Hospital] [Medical] surfaces
- [Hospital] [Patient] bed (springs) (railings) (frames)
- [Hospital] [Patient] [plastic] [vinyl] bed linings
- [Hospital] [Patient] [plastic] [vinyl] bed mattresses
- Common Household Surfaces
- Hydrotherapy Tubs
- Infant incubators and care cribs
- Infant warmers
- [Instrument] Stands
- Isolettes
- IV [stands] [pumps] [poles]
- Keyboards
- Kid's play [structures] [equipment]

- [Kitchen] appliance exteriors
- Kitchen surfaces
- Laminated surfaces
- Lamps
- Laptops
- Light [fixtures] [switches] [panels]
- Light lens covers
- Lockers
- Mammography equipment
- [Medicine] (and) [filing] cabinets
- Medication carts
- Mirrors
- Mobile devices
- Mobile electronic equipment
- Mobile workstations
- M[agnetic] R[esonance] I[maging] equipment
- Nurse-call devices] (and) [buttons]
- Office machinery
- Operating room lights
- Operating Room Tables
 (Surfaces) (Positioning Pads)
- Operatory light switches
- Outside of appliances
- Oxygen hoods
- Oven exteriors³
- Overbed tables
- Packing benches
- Paddles
- Pagers
- Painted surfaces
- Patient monitoring equipment
- Patient support and delivery equipment
- Pens
- Phlebotomy trays
- Physical therapy [(PT)] equipment surfaces
- Phone cradles
- Piano keys
- Plastic and painted surfaces
- Plastic laundry [hampers] [baskets]
- Plastic mattress covers

- Plastic salad bar sneeze guards
- Plastic shower curtains
- Plastic surfaces
- Playpens
- [plastic] [vinyl] Privacy screens
- Portable toilets
- Power cords
- Pulse oximeters
- PVC tubing
- Range hoods³
- Reception [counters] [desks]
- Recycling bins
- Refrigerator exteriors
- Respirators
- Respiratory therapy equipment
- Restroom fixtures

[stalls] [walls]

Sink [basins]

Stall doors

Staplers

Stools

Spine backboards

Sports equipment

Stereo consoles

Stethoscopes

Storage bins

Stove[top]s³

Support bars

Table[top]s

Tablet PCs

Telephones

Tiled walls

T[omography] equipment

EPA Reg. No. 70627-77 September 22 ,2021 Page **9** of **23**

Stretchers

Strollers

Stainless steel surfaces

Side rails

Signs

Shower fixtures

- Scales
- Seats
- Sequential compression
 devices

Shower(s) [curtains] [doors]

Shelves

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- Tools
- Towel dispensers
- Toys
- Traction devices
- Trash cans
- Tray tables
- Troughs
- Vanity tops

- Vending machine surfaces
- Veterinary care surfaces
- Vinyl tile
- Walkers
- Walls
- Wash basins
- Washable kitchen surfaces
- Washable walls

- Wastebaskets
- Wheelchairs
- Window blinds
- Windows
- Windshields
- Work benches
- X-ray equipment

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

(It is) (Designed) For (daily) (use) (cleaning) (disinfecting) (on) (of) (medical) hard, nonporous inanimate (environmental) surface(s) (materials) (Compatible with):

- Acrylic,
- baked enamel surfaces,
- Corian®,
- Chrome,
- non-food contact crystal,
- finished terrazzo,
- glass,
- glazed ceramic (tile),
- glazed porcelain,

- glazed tile,
- laminated surfaces,
- linoleum,
- metal (except copper and brass),
- painted surfaces,
- plastic (surfaces),
- glazed quarry tiles,
- rubber,

- sealed fiberglass,
- sealed granite,
- sealed marble,
- sealed mirror stone,
- stainless steel,
- synthetic marble,
- vinyl,

[Not recommended for use on] {or} [avoid contact with]: brass or copper.

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] [{product name}] is formulated to be used against the following soils and stains:

- Beverage stains
- Blood
- Body oils
- Body Fluids
- Coffee [stains]
- Common [soils] [stains]
- Cosmetics
- Dead skin
- Dirt
- Fecal matter
- Fingerprints

- Food spills
- Food residues
- Food stains
- Fruit [stains]
- Grease
- Grime
- Heel [marks] [scuffs]
- Ink [marks]
- Juice stains
- Laboratory stains
- Mold (and) [mildew] stains

- Mud
- Organic matter
- Pet stains
- Rust
- Smudges
- Soap Scum
- Tea [stains]
- Tough soils
- Urine [stains]
- Wine stains

EPA Reg. No. 70627-77 September 22 ,2021 Page **10** of **23**

{New and Improved Claims}

{Note to the reviewer: the following short claims might be inserted on the container label only for the period of 6 months after the launch}

- [Better] [Improved] [New] [New and improved] [packaging]
- [New and improved]
- [New Claims]
- [New Claims and Faster Contact Times]
- [New Kill Claims]
- [New Saves Time]

DIRECTIONS FOR USE:

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

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 list medical devices 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.)

{or}

This product is not for use on critical and semi-critical medical device surfaces

(CLAIMS AND ORGANISMS:)

When used as directed, this product is effective against (a 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.)

(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)
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(Bactericidal Activity):		
(Organism)	(ATCC Number)	(Contact Time)
Staphylococcus aureus	(ATCC 6538)	1 minute
Pseudomonas aeruginosa	(ATCC 15442)	1 minute
Salmonella enterica, formerly known as Salmonella choleraesuis	(ATCC 10708)	1 minute
Bordetella bronchiseptica,	(ATCC 10580)	1 minute
Burkholderia cepacia,	(ATCC 25416)	1 minute

Bordetella pertussis,	(ATCC 12743)	1 minute
Enterobacter aerogenes	(ATCC 12743)	1 minute
Enterococcus faecium.	(ATCC 51559)	1 minute
Escherichia coli,	(ATCC 11229)	1 minute
Escherichia coli O157:H7	(ATCC 35150)	1 minute
Klebsiella pneumonia	(ATCC 4352)	1 minute
Legionella pneumophila,	(ATCC 33153)	1 minute
Listeria monocytogenes,	(ATCC 19117)	1 minute
Pasteurella multocida	(ATCC 12947)	1 minute
Serratia marcescens	(ATCC 14756)	1 minute
Staphylococcus pseudintermedius	(ATCC 49444)	1 minute
Shigella dysenteriae	(ATCC 11835)	1 minute
Stenotrophomonas (Pseudomonas) maltophilia	(ATCC 25596)	1 minute
Streptococcus pyogenes	(ATCC19615)	1 minute
Citrobacter freundii	(ATCC 8090)	1 minute
Vibrio cholerae	(ATCC 39050)	1 minute
Campylobacter jejuni	(ATCC 29428)	1 minute
Streptococcus pneumonia	(ATCC 51936)	1 minute
Haemophilus influenzae	(ATCC 33930)	1 minute
Klebsiella oxytoca	(ATCC700324)	1 minute
([†] Antibiotic-Resistant (Strains of) Bacteria [<i>list below</i>]):	, , , , , , , , , , , , , , , , , , , ,	
Acinetobacter baumannii, (Multi-Drug Resistant (MDR)) (Ampicillin, Cefazolin, Cefepime, Gentamicin, Ertapenem, and Trimethoprim/Sulfa)	(ATCC 19606)	1 minute
Enterobacter cloacae, (New Delhi metallo-β-lactamase 1 positive (producing) (NDM 1))	(CDC 1000654)	1 minute
Enterococcus faecalis (Resistant to Vancomycin (VRE))	(ATCC 51575)	1 minute
Escherichia coli with extended beta-lactamase resistance (ESBL)	(ATCC BAA-196)	1 minute
Escherichia coli, (New Delhi metallo-β-lactamase 1 (NDM-1) producing (positive))	(CDC 1001728)	1 minute
Klebsiella pneumoniae, (Carbapenem Resistant (CRE))	(ATCC BAA 1705)	1 minute
Klebsiella pneumoniae, (Extended Spectrum beta-lactamase (ESBL) producing (positive))	(ATCC 700603)	1 minute
Klebsiella pneumoniae, (New Delhi metallo-β-lactamase 1(NDM-1) producing (positive))	(CDC 1000527)	1 minute
Pseudomonas aeruginosa, (Metallo-beta lactamase (MBL) positive	(CDC 2012059)	1 minute
Staphylococcus aureus (CA-MRSA), (Community Associated Methicillin Resistant) (NARSA NRS 123) (Genotype USA400)		1 minute
Staphylococcus aureus, (Methicillin Resistant (MRSA))	(ATCC 33592)	1 minute
Staphylococcus aureus, (Vancomycin Intermediate Resistant (VISA))	(HIP 5836)	1 minute
Staphylococcus aureus, (Vancomycin Resistant (VRSA)) [VRS1]	(VRS1)	1 minute
Staphylococcus epidermidis, (Methicillin Resistant (MRSE))	(ATCC 51625)	1 minute
Streptococcus pneumoniae, (Penicillin Resistant (PRSP))	(ATCC 700677)	1 minute
Multidrug-resistant Klebsiella aeogenes, (formerly Enterobacter aerogenes)	(ATCC BAA-2356)	1 minute
Carbapenem-resistant Escherichia coli	(ATCC BAA-2469)	1 minute
Multidrug-resistant Klebsiella pneumoniae	(ATCC BAA-1705)	1 minute
Klebsiella pneumoniae (NDM-1)	(ATCC BAA-2470)	1 minute
Multidrug-resistant Pseudomonas aeruginosa,	(ATCC BAA-2108)	1 minute
Multidrug-resistant Enterococcus faecium VIRUCIDAL: {Note to reviewer: Only one of the following statements will	(ATCC 51559)	1 minute
(in the presence of 5% serum load and 30 second contact time at 20°C (6 environmental surfaces.) {or} (30 second contact time) {or} (30 seconds)		-
(Viruses (Virucidal Activity)):	(ATCC Number)	(Contact Time)
(Viruses (Virucidal Activity)): (Organism)	(ATCC Number)	(Contact Time)
(Viruses (Virucidal Activity)): (Organism) Adenovirus Type 2, (strain: Adenoid 6)	(ATCC VR-846)	30 second
(Viruses (Virucidal Activity)): (Organism) Adenovirus Type 2, (strain: Adenoid 6) Adenovirus Type 7(, strain: Gomen)	(ATCC VR-846) (ATCC VR-7)	30 second 30 second
(Viruses (Virucidal Activity)): (Organism) Adenovirus Type 2, (strain: Adenoid 6) Adenovirus Type 7(, strain: Gomen) Adenovirus type 8	(ATCC VR-846) (ATCC VR-7) (ATCC VR-1368)	30 second30 second30 second
(Viruses (Virucidal Activity)): (Organism) Adenovirus Type 2, (strain: Adenoid 6) Adenovirus Type 7(, strain: Gomen) Adenovirus type 8 Cytomegalovirus,	(ATCC VR-846) (ATCC VR-7)	30 second30 second30 second30 second30 second
(Viruses (Virucidal Activity)): (Organism) Adenovirus Type 2, (strain: Adenoid 6) Adenovirus Type 7(, strain: Gomen) Adenovirus type 8 Cytomegalovirus, Hepatitis B Virus (HBV), Duck Hepatitis B Virus as surrogate (Acquired from Hepadnavirus Testing)	(ATCC VR-846) (ATCC VR-7) (ATCC VR-1368)	30 second 30 second 30 second 30 second 30 second 30 second
(Viruses (Virucidal Activity)): (Organism) Adenovirus Type 2, (strain: Adenoid 6) Adenovirus Type 7(, strain: Gomen) Adenovirus type 8 Cytomegalovirus, Hepatitis B Virus (HBV), Duck Hepatitis B Virus as surrogate (Acquired from	(ATCC VR-846) (ATCC VR-7) (ATCC VR-1368)	30 second30 second30 second30 second30 second

Herpes Simplex Virus, Type 2 (HSV-2)	(ATCC VR-734)	30 second
HIV-1 (AIDS Virus), Strain HTLV-III _B (HIV-1) (Acquired from Adv. Biotechnologies, Inc.)		30 second
Human Coronavirus,	(ATCC VR-740)	30 second
Influenza A Virus/Hong Kong,	(ATCC VR-544)	30 second
Influenza B Virus,	(ATCC VR-823)	30 second
Measles Virus, (strain: Edmonston, source)	(ATCC VR-24)	30 second
Middle East Respiratory Syndrome Coronavirus (MERS-CoV), (strain: EMC/2012)	BEI Resources	30 second
Norovirus, (Feline Calicivirus as the surrogate) (Feline Calicivirus, as the surrogate)	ATCC VR-782	30 second
Pandemic Influenza A Virus H1N1		30 second
Parainfluenza Virus Type 3,	(ATCC VR-93)	30 second
Poliovirus Type 1, Strain Brunhilde	(ATCC VR-1000)	30 second
Respiratory Syncytial Virus, (RSV)	(ATCC VR-26)	30 second
Rhinovirus Type 37, Strain 151-1,	(ATCC VR-1147)	30 second
Rotavirus WA (Acquired from University of Ottawa)		30 second
Vaccinia Virus,	(ATCC VR-119)	30 second
(Animal Viruses:)		
Avian Influenza A Virus (H7N9)		30 second
Avian Influenza A Virus (H3N2)	(ATCC VR-2072)	30 second
Avian Influenza A Virus (H5N1)		30 second
Bovine Viral Diarrhea Virus (BVDV)		30 second
Duck Hepatitis B Virus		30 second
Equine Influenza A Virus (H3N8) (EIV)		30 second
Feline Calicivirus, Strain F9	(ATCC VR-782)	30 second
Murine Norovirus		30 second
VIRUCIDAL: {Note to reviewer: Only one of the following statements w	ill be on the product l	abel}
{or} (1 minute)		
Enterovirus type D68, (Strain US/KY/14-18953)	(ATCC VR-1825)	1 minute
SARS-Related Coronavirus 2 [SARS-CoV-2] [cause of COVID-19] [USA-WA1/2020]		1 minute
(Animal Viruses:)		
Feline Infectious Peritonitis Virus, (FIPV)	(ATCC VR-2022)	1 minute
Feline Herpes Virus, (Feline Rhinotracheitis)	(ATCC VR-636)	1 minute
Murine Hepatitis Virus,	(ATCC VR-765)	1 minute
Minute Virus of Mouse, (Murine Parvovirus)	(ATCC VR-1346)	1 minute
TUBERCULOCIDAL: {Note to reviewer: Only one of the following state		
(in the presence of 5% serum load and 1 minute contact time at 20°C (environmental surfaces.) {or} (1 minute contact time) {or} (1 minute)	68°F) on hard, non-po	rous
		(Contrat There)
(Organism)	(ATCC Number)	(Contact Time)
Mycobacterium bovis (Tb) (OT 451C150) FUNGICIDAL: {Note to reviewer: Only one of the following statements		1 minute
(This product is fungicidal against the pathogenic fungi, <i>Trichophyton in mentagrophytes</i>) (ATCC 9533) (the fungus which causes Athlete's Foot	, terdigitale (formerly T	richophyton
porous surfaces.) {or} (in the presence of 5% serum load and 30 second contact time on hard {or} (30 second contact time)	, non-porous environn	nental surfaces.)

(30 second)		
(Organism)	(ATCC Number)	(Contact Time)
Trichophyton interdigitale (ATCC 9533) (formerly Trichophyton mentagrophytes)	(ATCC 9533)	30 seconds
FUNGICIDAL: {Note to reviewer: Only one of the following statements we (This product is fungicidal against the pathogenic fungi, <i>Candida albicans</i> <i>canis</i> (ATCC 10214) when used as directed on hard, non-porous surface {or} (in the presence of 5% serum load and 1 minute contact time on hard, non- {or} (1 minute contact time) {or} (1 minute) Candida albicans Microsporum canis **(FUNGICIDAL): {Note to reviewer: Only one of the following statements (in the presence of soil and 1 minute contact time on hard, non-porous er {or} (Using approved Standard Quantitative Disk Carrier Test Method (under the presence of soil and 1 minute contact time, against Candida auris (C (ATCC 26512)) {or} (1 minute contact time)	ill be on the product (ATCC 10231) and s.) n-porous environment (ATCC 10231) (ATCC 10231) (ATCC 10214) is will be on the product invironmental surfaces Good Laboratory Pra	Iabel} Microsporum ntal surfaces.) (Contact Time) 1 minute 1 minute uct label} s.) s.)
`{or}		
(1 minute)		
(1 minute)	(ATCC Number)	(Contact Time)
(1 minute) (Organism)	(ATCC Number) (ATCC 26512)	(Contact Time)
(1 minute) (Organism) Candida glabrata Candida auris	(ATCC 26512) (CDC AR-0381)	1 minute 1 minute
(1 minute) (Organism) Candida glabrata	(ATCC 26512) (CDC AR-0381) (Note to reviewer: O	1 minute 1 minute nly one of the orous
(1 minute) (Organism) Candida glabrata Candida auris Non-Food Contact Surface Sanitizer for hard non-porous surfaces: following statements will be on the product label} (in the presence of 5% serum load and 10 second contact time at 20°C (6 environmental surfaces.) {or} (in the presence of a 5% serum load and 10 second contact time (at 20°C environmental surfaces.) {or} (10 second contact time) - or - (10 seconds) (Organism)	(ATCC 26512) (CDC AR-0381) (Note to reviewer: O (58°F) on hard, non-po (68°F)) on hard, no (68°F)) on hard, no	1 minute 1 minute 1 minute nly one of the orous n-porous (Contact Time)
(1 minute) (Organism) Candida glabrata Candida auris Non-Food Contact Surface Sanitizer for hard non-porous surfaces: following statements will be on the product label} (in the presence of 5% serum load and 10 second contact time at 20°C (6 environmental surfaces.) {or} (in the presence of a 5% serum load and 10 second contact time (at 20°C environmental surfaces.) {or} (10 second contact time) - or - (10 seconds) Acinetobacter baumannii,	(ATCC 26512) (CDC AR-0381) (Note to reviewer: O (ATCC Number) (ATCC Number) (ATCC 19606)	1 minute 1 minute 1 minute nly one of the orous n-porous (Contact Time) 10 seconds
(1 minute) (Organism) Candida glabrata Candida auris Non-Food Contact Surface Sanitizer for hard non-porous surfaces: following statements will be on the product label} (in the presence of 5% serum load and 10 second contact time at 20°C (6 environmental surfaces.) {or} {or} (in the presence of a 5% serum load and 10 second contact time (at 20°C environmental surfaces.) {or} {or} (10 second contact time) - or - (10 seconds) (Organism) Acinetobacter baumannii, Campylobacter jejuni,	(ATCC 26512) (CDC AR-0381) (Note to reviewer: O (ATCC Number) (ATCC 19606) (ATCC 29428)	1 minute 1 minute 1 minute nly one of the orous n-porous (Contact Time) 10 seconds 10 seconds
(1 minute) (Organism) Candida glabrata Candida auris Non-Food Contact Surface Sanitizer for hard non-porous surfaces: following statements will be on the product label} (in the presence of 5% serum load and 10 second contact time at 20°C (6 environmental surfaces.) {or} (in the presence of a 5% serum load and 10 second contact time (at 20°C environmental surfaces.) {or} (10 second contact time) - or - (10 seconds) (Organism) Acinetobacter baumannii, Campylobacter jejuni, Enterobacter aerogenes,	(ATCC 26512) (CDC AR-0381) (Note to reviewer: O (ATCC Number) (ATCC 19606) (ATCC 19606) (ATCC 19048)	1 minute 1 minute 1 minute nly one of the orous n-porous (Contact Time) 10 seconds 10 seconds 10 seconds 10 seconds
(1 minute) (Organism) Candida glabrata Candida auris Non-Food Contact Surface Sanitizer for hard non-porous surfaces: following statements will be on the product label} (in the presence of 5% serum load and 10 second contact time at 20°C (6 environmental surfaces.) {or} (in the presence of a 5% serum load and 10 second contact time (at 20°C environmental surfaces.) {or} (10 second contact time) - or - (10 seconds) (Organism) Acinetobacter baumannii, Campylobacter jejuni, Enterobacter aerogenes, Enterococcus faecalis, (Resistant to Vancomycin [VRE])	(ATCC 26512) (CDC AR-0381) (Note to reviewer: O (ATCC number) (ATCC 19606) (ATCC 19606) (ATCC 13048) (ATCC 51575)	1 minute 1 minute 1 minute nly one of the orous n-porous 0 seconds 10 seconds
(1 minute) (Organism) Candida glabrata Candida auris Non-Food Contact Surface Sanitizer for hard non-porous surfaces: following statements will be on the product label} (in the presence of 5% serum load and 10 second contact time at 20°C (6 environmental surfaces.) {or} (in the presence of a 5% serum load and 10 second contact time (at 20°C environmental surfaces.) {or} (10 second contact time) - or - (10 seconds) (Organism) Acinetobacter baumannii, Campylobacter jejuni, Enterobacter aerogenes,	(ATCC 26512) (CDC AR-0381) (Note to reviewer: O (ATCC Number) (ATCC 19606) (ATCC 19606) (ATCC 19048)	1 minute 1 minute 1 minute nly one of the orous n-porous (Contact Time) 10 seconds 10 seconds 10 seconds 10 seconds 10 seconds
(1 minute) (Organism) Candida glabrata Candida auris Non-Food Contact Surface Sanitizer for hard non-porous surfaces: following statements will be on the product label} (in the presence of 5% serum load and 10 second contact time at 20°C (6 environmental surfaces.) {or} (in the presence of a 5% serum load and 10 second contact time (at 20°C environmental surfaces.) {or} (10 second contact time) - or - (10 seconds) (Organism) Acinetobacter baumannii, Campylobacter jejuni, Enterobacter aerogenes, Enterococcus faecalis, (Resistant to Vancomycin [VRE]) Escherichia coli 0157:H7	(ATCC 26512) (CDC AR-0381) (Note to reviewer: O (ATCC neviewer: O (68°F)) on hard, non-po (68°F)) on hard, no (68°F)) on hard, no (ATCC 19606) (ATCC 29428) (ATCC 13048) (ATCC 51575) (ATCC 35150) (ATCC 4352) (ATCC 19111)	1 minute 1 minute 1 minute nly one of the orous n-porous 0 seconds 10 seconds
(1 minute) (Organism) Candida glabrata Candida auris Non-Food Contact Surface Sanitizer for hard non-porous surfaces: following statements will be on the product label} (in the presence of 5% serum load and 10 second contact time at 20°C (6 environmental surfaces.) {or} {or} (in the presence of a 5% serum load and 10 second contact time (at 20°C environmental surfaces.) {or} {or} (10 second contact time) - or - (10 seconds) (Organism) Acinetobacter baumannii, Campylobacter jejuni, Enterobacter aerogenes, Enterobacter aerogenes, Enterococcus faecalis, (Resistant to Vancomycin [VRE]) Escherichia coli 0157:H7 Klebsiella pneumonia Listeria monocytogenes Pseudomonas aeruginosa	(ATCC 26512) (CDC AR-0381) (Note to reviewer: O (ATCC 1000 hard, non-point) (ATCC 19606) (ATCC 19606) (ATCC 19428) (ATCC 13048) (ATCC 13048) (ATCC 35150) (ATCC 35150) (ATCC 19111) (ATCC 15442)	1 minute 1 minute 1 minute 1 minute nly one of the orous n-porous More of the 10 seconds
(1 minute) Candida glabrata Candida glabrata Candida auris Non-Food Contact Surface Sanitizer for hard non-porous surfaces: following statements will be on the product label} (in the presence of 5% serum load and 10 second contact time at 20°C (6 environmental surfaces.) {or} (in the presence of a 5% serum load and 10 second contact time (at 20°C environmental surfaces.) {or} (10 second contact time) - or - (10 seconds) (Organism) Acinetobacter baumannii, Campylobacter jejuni, Enterobacter aerogenes, Enterobacter aerogenes,	(ATCC 26512) (CDC AR-0381) (Note to reviewer: O (ATCC neviewer: O (68°F)) on hard, non-po (68°F)) on hard, no (68°F)) on hard, no (ATCC 19606) (ATCC 29428) (ATCC 13048) (ATCC 51575) (ATCC 35150) (ATCC 4352) (ATCC 19111) (ATCC 15442) (ATCC 10708)	1 minute 1 minute 1 minute 1 minute nly one of the orous n-porous 10 seconds 10 seconds
(1 minute) (Organism) Candida glabrata Candida auris Non-Food Contact Surface Sanitizer for hard non-porous surfaces: following statements will be on the product label} (in the presence of 5% serum load and 10 second contact time at 20°C (6 environmental surfaces.) {or} {or} (in the presence of a 5% serum load and 10 second contact time (at 20°C environmental surfaces.) {or} {or} (10 second contact time) - or - (10 seconds) (Organism) Acinetobacter baumannii, Campylobacter jejuni, Enterobacter aerogenes, Enterobacter aerogenes, Enterococcus faecalis, (Resistant to Vancomycin [VRE]) Escherichia coli 0157:H7 Klebsiella pneumonia Listeria monocytogenes Pseudomonas aeruginosa	(ATCC 26512) (CDC AR-0381) (Note to reviewer: O (ATCC 1000 hard, non-point) (ATCC 19606) (ATCC 19606) (ATCC 19428) (ATCC 13048) (ATCC 13048) (ATCC 35150) (ATCC 35150) (ATCC 19111) (ATCC 15442)	1 minute 1 minute 1 minute 1 minute nly one of the orous n-porous More of the 10 seconds

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.

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).

{Claims against Emerging Viral Pathogens}

This product qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral categories:

- 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 virus	Enterovirus type D68 (Strain US/KY/14-18953)
Large, Non-Enveloped Viruses Small, Non-Enveloped Viruses	 Enterovirus type D68 (Strain US/KY/14-18953) Canine Parvovirus

{The statements shall be made only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.}

{Acceptable claim language:}

{Product name} has demonstrated effectiveness against viruses similar to {name of emerging virus} on hard, non-porous surfaces. Therefore, (this product) ({Product name}) can be used against {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 {pathogen-specific website address} for additional information.

{or}

{*Name of illness/outbreak*} is caused by {*name of emerging virus*}. {*Product name*} kills similar viruses and therefore can be used against {*name of emerging virus*}. when used in accordance with the directions for use against [Enterovirus type D68 (Strain US/KY/14-18953)] [Canine Parvovirus] on hard, non-porous surfaces. Refer to the [CDC or OIE] website at {*website address*} for additional information.

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 treated surfaces to remain visibly wet for 1 minute, additional towelettes if needed to ensure the correct visibly wet surfacecontact time. 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 treated surfaces to remain visibly wet for 1 minute, additional towelettes if needed to ensure the correct visibly wet surfacecontact time.. (For certain listed viruses, Allow treated surfaces to remain visibly wet for 1 minute, additional towelettes if needed to ensure the correct visibly wet surfacecontact time. 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. Allow treated surfaces to remain visibly wet 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. Allow treated surfaces to remain visibly wet for 1 minute. and rinse with potable water. (For certain listed viruses, Allow treated surfaces to remain visibly wet for 1 minute, additional towelettes if needed to ensure the correct visibly wet surfacecontact time. 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 treated surfaces to remain visibly wet for 1 minute, additional towelettes if needed to ensure the correct visibly wet surfacecontact time.. (For certain listed viruses, Allow treated surfaces to remain visibly wet for 1 minute, additional towelettes if needed to ensure the correct visibly wet surfacecontact time. for 30 seconds.)
- 4. Rinse with sterile water.
- 5. Wipe with a dry, clean cloth and let air dry.

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. Allow treated surfaces to remain visibly wet 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 treated surfaces to remain visibly wet for 1 minute, additional towelettes if needed to ensure the correct visibly wet surfacecontact time.

Change towelettes frequently to avoid re-deposition of soil. Use additional towelettes if needed to ensure the correct visibly wet surface 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) Protective Gloves (latex, nitrile, or vinyl) gloves, gowns, face masks, and eye coverings, 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, and chutes) 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 treated surfaces to remain visibly wet for 1 minute, additional towelettes if needed to ensure the correct visibly wet surfacecontact time. 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.

To Kill Fungi:

For Candida auris, please see special instructions.

Pre-clean heavily soiled areas. Wipe hard, non-porous environmental surfaces with towelette (wipe). Allow treated surfaces to remain visibly wet for 1 minute, additional towelettes if needed to ensure the correct visibly wet surfacecontact time. for 1 minute. Use additional towelettes (wipes) 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 treated surfaces to remain visibly wet for 1 minute, additional towelettes if needed to ensure the correct visibly wet surfacecontact time. for 1 minute. Use additional towelettes (wipes) 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 treated surfaces to remain visibly wet for 1 minute, additional towelettes if needed to ensure the correct visibly wet surfacecontact time. 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.

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

(Packaging Opening Instructions:)

(Rigid Can with EZ-Open Lid)

Dispenser Directions: Do Not Remove Lid. Lift Lid to expose dispenser and seal film. Using finger, push through film at vent hole and remove film. Pull wipe up from center of roll and pull towards you to insert in single wipe dispenser. Simply pull wipe at angle towards you to dispense one wipe at a time. To dispense multiple wipes, pull wipe away from you, out of single wipe dispenser and pull up. Separate wipe at perforation. When finished, close lid to retain moisture.

To Open New Package: No Need to Remove Lid. Lift lid to expose dispenser and seal film, which covers wipe roll. Simply puncture and tear film at the vent holes and remove film from canister.

To Open Package: Open lid/flap and pull out wipe at an angle from center of roll. When finished, close lid to retain moisture.

(Rigid Can with Traditional-Open Lid)

Dispenser Directions: Remove lid to expose dispenser and seal film. Remove film. Pull wipe up from center of roll and thread through lid. Replace lid. Pull wipe at angle towards you to dispense one wipe at a time. Separate wipe at perforation. When finished, close lid to retain moisture.

To Open New Package: Remove lid to expose dispenser and seal film, which covers wipe roll. Remove film. Thread wipe through lid. Replace lid.

To Open Package: Open lid/flap and pull out wipe at an angle from center of roll. When finished, close lid to retain moisture.

(Stand Up Pouch)

Dispenser Directions: Remove film seal from wipe access port. Pull first wipe from center of roll. Insert first wipe in to easy thread dispenser. Insert easy thread dispenser into port and make a 1/4 turn clockwise to lock in place. Pull wipes at an angle to dispense. Dispense as many as required for job and break off at perforation. After use, store next wipe in easy thread dispenser cavity and snap lid closed to retain moisture.

To Open New Package: Remove film seal (from orifice) (over/from cap). Twist dispenser counterclockwise and remove to access wipe roll. Grab first wipe from center of roll. Insert wipe in dispenser orifice. Insert dispenser, twist clockwise until it locks.

To Open Package: Open lid/flap and pull out wipe at an angle from center of roll. When finished, close (click) (snap) lid/flap (closed) to retain moisture.

(FlatPack)

[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].

(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).

[Storage and Disposal for Institutional Use Products]

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. Do not allow product to freeze.

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:

Store in original container in areas inaccessible to small children. Keep securely closed.

Container Disposal:

NONREFILLABLE READY-TO-USE FORMULATIONS: {Note to reviewer: The following text will be used on

nonrefillable RTU container labels:}

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

REFILLABLE CONTAINERS: {Note to reviewer: The following paragraph will be used on labels for refillable containers:}

Refillable container. Refill this container with *{insert one of the following brand names*: Oxivir Wipes, Oxivir 1 Wipes*}* 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.

{Note to reviewer: One of the following statements will be used, depending on the type of container}

{For product supplied in refillable or non-refillable containers}

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

{For product supplied in resealable packages:}

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

(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.)

[Storage and Disposal for Residential Only Use Products]

Storage and Disposal

PESTICIDE [PRODUCT] STORAGE: Store in original container in areas inaccessible to small children. Keep securely closed.

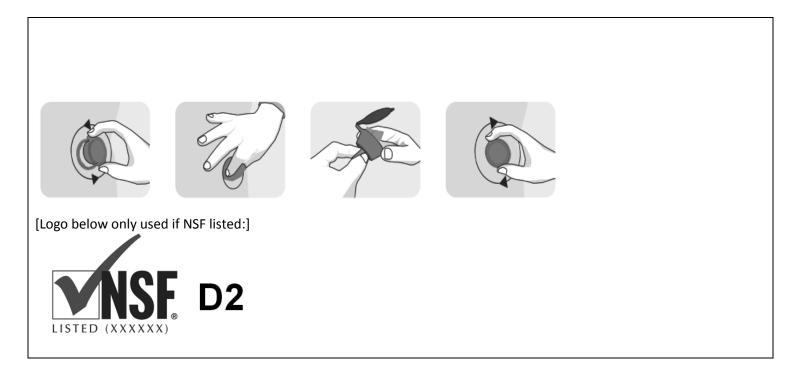
CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. Wrap [container] and put in trash or offer for recycling if available.

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.



EPA Reg. No. 70627-77 September 22 ,2021 Page **21** of **23**



{Footnotes for Symbols Mentioned in Label}		
++ Claims against non-living allergens	* Viruses	
** Candida auris Use Directions	¹ When used according to Disinfectant Directions	
² Hard,non-porous surfaces	³ at room temperature	

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, (First Aid,) (Precautionary Statements,) (Environmental Hazards) (and) (Storage and Disposal).

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