



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

May 3, 2021

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

Subject: Label Amendment: Adding Efficacy Claims-SARS-CoV-2
Product Name: OXIVIR® 1
EPA Registration Number: 70627-74
Application Date: 12/17/2020
Action Case Number: 00216848

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.

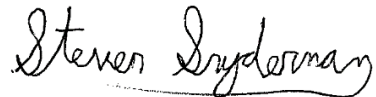
A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or 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.

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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, you may contact Lorena Rivas at Rivas.lorena@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "Steven Snyderman". The signature is written in a cursive style with a horizontal line underneath the name.

Steven Snyderman, Product Manager 33
Regulatory Management Branch II
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: Approved label

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OXIVIR[®] 1

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

Active Ingredient:

| | |
|--|--------|
| Hydrogen Peroxide | 0.5% |
| [Inert] [Other] Ingredients | 99.5% |
| Total | 100.0% |

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

See additional precautionary statements on [back] [left] [right] [panel] [of] label].

EPA Reg. No. 70627-74

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) ({Product name})].]

ACCEPTED

05/03/2021

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under

EPA Reg. No. 70627-74

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{Features, Claims and Uses}

{Product Descriptors}

-
- Active Ingredient is an Oxidizing Agent
 - Bactericide
 - Broad-Spectrum Disinfectant
 - Cleaner
 - Cleans, Deodorizes and Brightens in One Step when used according to disinfection/sanitization directions
 - Cleans, Disinfects, & Deodorizes
 - Cleans Grout
 - Cleans Hard, Non-porous Water Washable Surfaces!
 - Cleaner spot sanitizer on soft surfaces[†]
 - Deodorizer
 - Disinfectant
 - For (Hospital) (Health Care) (Industrial) (Institutional) (& (Residential) Use
 - Fungicide
 - Fungicidal disinfectant against *C. auris*
 - Hospital Disinfectant Cleaner
 - Hydrogen Peroxide
 - Meets surface disinfection recommendations from OSHA's Bloodborne Pathogens Standard for *HBV, *HCV & *HIV-1
 - Mildewcide
 - Hard nonporous Multi-Surface
 - Hard nonporous Multi-surface Disinfectant Cleaner
 - Hard nonporous Multi-surface [One-Step] Disinfectant [when used according to disinfection]
 - Non-Dulling
 - Odor Counteractant
 - Odor Neutralizer
 - One-step when used according to disinfection (and sanitizing) directions
 - One-step Disinfectant (Cleaner) (& Deodorizer) when used according to disinfection directions
 - Oxidizer
 - (Restroom) (& (Bathroom) (Disinfectant Cleaner)
 - Ready to Use
 - Sanitizer
 - Sanitizes
 - Tuberculocide
 - Use Daily to Prevent the Buildup of Dirt and Grime.
 - *Virucide

(Marketing Statements)

1 Minute bactericidal, *virucidal, and fungicidal

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

A proven spot sanitizer on soft surfaces[†]

Acute Dermal Toxicity (LD50>5,050 mg/kg) (Category IV)

Acute Inhalation Toxicity (LC50>2.08 mg/L) (Category IV)

Acute Oral Toxicity (LD50>5,000 mg/kg) (Category IV)

Alcohol Free

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

An effective one-step disinfectant cleaner for hard, nonporous surfaces when used according to disinfection directions

An effective soft surfaces[†] spot sanitizer

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

Broad-spectrum (Multi-purpose) (hard nonporous Multi-surface) (Bactericidal) (*Virucidal) (Tuberculocidal) (Fungicidal) (Sanitizer) (Disinfectant) (activity)

Category IV Tox(ico)logy Rating (in all 6 tox categories)

Cleaning and disinfection in 1 minute

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

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 step when used according to disinfection/sanitization directions

Cleans (tough) soap scum

(Cleans) (Removes) (Kills Up to 99.9% of) (Destroys) stains

Compatible with microfiber (cloths)

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Compatible with (most) (virtually all) surfaces
Contains no phosphates
Contains no VOC-emitting ingredients
Controls (Kills Up to 99.9% of) odor-causing bacteria
Deodorizer (Odor Counteractant)
Deodorizes odor-causing bacteria
Disinfects as it cleans when used according to disinfection directions for use
Disinfects hard nonporous surfaces by killing [99.9%] SARS-Related Coronavirus 2 [SARS-CoV-2] [USA-WA1/2020] [in one step]
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 Candida auris (C. auris) in one minute
Effective against SARS-Related Coronavirus 2 [SARS-CoV-2] [USA-WA1/2020] [in 1 minute] on hard nonporous surfaces
[Effective against] [Disinfects] [Kills] [99.9%] SARS-CoV-2 [virus] on hard nonporous surfaces
[Effective against] [Disinfects] [Kills] [99.9%] SARS-CoV-2 virus, the cause of COVID-19 on hard nonporous surfaces
(Eliminates) (Kills) 99.9% of (odor-causing) bacteria (from surfaces)
Eliminates 99.9% of odors (caused by bacteria), (mold), (and) (mildew)
Easy / Effective
For (a) cleaner, fresher *{insert use sites/surfaces from lists below}* (or any hard, non-porous washable surface where disinfection is required.)
For any 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 multi-purpose disinfectant cleaner)
For terminal cleaning
Formula powered by AHP to clean.
Formulated with patented hydrogen peroxide technology
Fragrance Free Formula (Unscented)
Good for most indoor cleaning tasks
High (Frequently) touch[ed] surface(s) [disinfectant] [and] [cleaner]
(Highly) compatible formula for most surfaces
Intense cleaning action
Keeps day care centers clean
Kills (99.9% of) germs in 1 minute when following disinfectant directions
Kills (99.9%) SARS-CoV-2, which causes COVID-19 on hard nonporous surfaces
Kills (99.9% of) the cold and flu viruses (Rhinovirus Type 37 and Norovirus) when following disinfectant directions
Kills 99.999% or five logs of Candida auris on hard, non-porous surfaces.
Kills (and) (or) (inactivates) Candida auris on hard, non-porous surfaces when following disinfectant directions.
Kills bacteria and sanitizes
Kills bacteria and *viruses on hard, non-porous surfaces in 1 minute when following disinfectant directions
Kills bacteria (in 1 minute) when following disinfectant directions
Kills coronavirus that causes COVID-19 on hard nonporous surfaces
(Kills) (Destroys) (Eliminates 99.9% of) germs while it cleans
(Kills) (Effective against) (the) cold (and) (flu) virus(es) (Rhinovirus Type 37 and Norovirus) (on hard, nonporous surfaces)
[Kills] [Effective against] SARS-CoV-2, the virus that causes COVID-19, on hard nonporous 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 nonporous surfaces
Kills odor-causing bacteria
Kills the SARS-CoV-2 Virus that causes COVID-19 on hard nonporous surfaces
Kills *viruses when following disinfectant directions
Leaves *{insert use sites/surfaces from lists below}* smelling clean (with a clean fresh scent)

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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
Not for use on skin
Odor Neutralizer
One-step cleaner sanitizer on soft surfaces[†] when used according to sanitization directions
Oxivir[®] Clean
**Parvocidal against canine parvovirus and murine parvovirus
Patented (Technology)
(Phenol free) (No phenols)
Powerful to remove (dried) (stuck on) dirt (grime) (food) (spills) (grease) (greasy messes)
Powerful cleaning
Powerful odor control (odor neutralizer) (deodorizer) (odor-counteractant) formula (on hard non-porous surfaces)
Powers away tough stains (stuck on dirt)
Proven "one-step" disinfectant/cleaner/fungicide/mildewcide/*virucide that is effective for hard, non-porous surfaces when used according to disinfection directions
Proven to kill *Candida auris* (*C. auris*) in one minute
Quickly (eliminates 99.9% of) (removes) odors
Reduces allergens++
Sanitizes
Soft surface[†] sanitizing (in 30 seconds).
Specially designed to dissolve (penetrate) the toughest (stubborn) soils
Spot sanitizes soft surfaces[†] in 30 seconds
(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.
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 virucidal and sanitizer, Convenient formula
Will not leave grit or soap scum

[*VIRUCIDAL DISINFECTION: 30 SEC(ONDS) (EXCEPT FOR ENTEROVIRUS TYPE D68 and SARS-CoV-2: 1 MIN(UTE)]

[ANIMAL PREMISE VIRUCIDAL DISINFECTION: 1 MIN(UTE)]**

[*FUNGICIDAL DISINFECTION AGAINST *C. AURIS*: 1 MIN(UTE)]**

[BACTERICIDAL DISINFECTION: 1 MIN(UTE)]

[(BROAD-SPECTRUM) NON-FOOD CONTACT SANITIZER: 10 SEC(ONDS)]

[FUNGICIDAL DISINFECTION AGAINST *TRICHOPHYTON INTERDIGITALE*: 30 SEC(ONDS)]

[SOFT SURFACE[†] SANITIZER: 30 SEC(ONDS)]

[SOFT SURFACE[†] SANITIZATION: 30 SEC(ONDS)]

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(General Uses:)

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

This product is a one-step (hospital-use) germicidal disinfectant (and) (deodorant) (odor-counteractant) (odor neutralizer) designed for general cleaning, (and) disinfecting (deodorizing) (of) hard, non-porous inanimate surfaces when used according to disinfection and sanitizing directions. It cleans by removing dirt, grime, and other common soils found (in) (on) *{insert use sites/surfaces from lists below}* (or any 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.

This product is a one-step (hospital-use) germicidal disinfectant and deodorant (odor-counteractant) (odor neutralizer) designed for cleaning, (and) disinfecting (deodorizing) (of) hard, non-porous inanimate surfaces when used according to disinfection and sanitizing directions. It cleans by removing dirt, grime, and other common soils found in *{insert use sites/surfaces from lists below}* (or any hard, non-porous washable surface where disinfection is required.)

[It is designed for use on] [Use daily on] (the following) (hard, non-porous inanimate surfaces): *{insert use sites/surfaces from lists below}* – (where disinfection is required). A potable water rinse is required for food contact surfaces. Do not use on glasses, dishes and utensils.

{Note to reviewer: Only one of the following statements will be on the product label}

[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) (This product) can be used (in) (on) hard non-porous surfaces (of the following items) (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}*]

(CLAIMS & USES:)

(This product) (Oxivir 1) (*{Product name}*) cleans and disinfects *{insert organism name(s) from list in Efficacy Claims section}* including ESKAPE pathogens - Enterococcus faecium, Staphylococcus aureus, Klebsiella pneumoniae, Acinetobacter baumannii, Pseudomonas aeruginosa, and Multidrug-resistant Klebsiella aerogenes (Formerly MDR – Enterobacter aerogenes).

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

(This product) (Oxivir 1) (*{Product name}*) cleans and disinfects, killing ESKAPE organisms with a 1-minute dwell time.

Kills ESKAPE bacteria (in 1 minute)

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

This product is a one-step (hospital-use) (laboratory-use) germicidal disinfectant and deodorant (odor-counteractant) (odor neutralizer) designed for cleaning, (and) disinfecting, (deodorizing) (of) hard, non-porous inanimate surfaces when used according to disinfection and sanitizing directions. This product cleans by removing dirt, grime, food residue; dead skin, blood and other organic matter commonly found in *{insert use sites/surfaces from lists below}*. It also eliminates odors, leaving (restroom) surfaces smelling clean and fresh. Use where odors are a problem.

This product cleans, disinfects and deodorizes hard, non-porous inanimate (hospital) (medical) (dental) (laboratory) surfaces in one step (with no rinsing required). [Its non-abrasive formula is designed for use on] [Use daily on] [(the following) (hard, non-porous inanimate surfaces :)] *{insert use sites/surfaces from lists below}*] (or any hard, non-porous washable surface where disinfection is required.) (found in) *{insert use sites/surfaces from lists below}* (It can be used to pre-clean and disinfect hospital items: *{insert use sites/surfaces from lists below}*) (where disinfection is required). A potable water rinse is required when disinfecting food contact surfaces. Do not use on glasses, dishes and utensils.

(Animal Housing Facilities :)

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

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

(Residential (Household) Use:)

[This product] [*{Product name}*] is an effective [cleaner] [disinfectant] [sanitizer] on non-food contact surfaces in [around] [Residential], [Household], [Homecare], [Daycare centers], [Nursing homes] [settings].] [

[This product] [*{Product name}*] is a[n] [Antibacterial] [Multi-Purpose] [Bathroom] [Floor] [Glass & Surface] [Kitchen] [Restroom] [Cleaner] [Cleaning] [Disinfectant] [Disinfecting] [Sanitizer]. This product is for use [in] [on] [the] *{insert use sites/surfaces from lists below}* [common hard non-porous household surfaces].]

[For everyday cleaning [and disinfecting] [use daily to clean [and disinfect]] [on] hard, non-porous surfaces [where germs are a concern], [high] [hand] touch surfaces, and other hard [non-food contact] surfaces around the house [hold] [home].

{Use Sites}

- Airplanes
- Airports
- 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

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- Dining Halls
- Dialysis Clinics
- Doctors' Offices
- Dorm[itorie]s
- 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[oratorie]s
- 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
- Nurseries
- Offices
- Office Buildings
- O[perating] R[oom]s
- Orthopedics
- Patient Rooms
- P[ediatric] I[ntensive] C[are] U[nit]s
- Pet Animal Quarters
- Pet Shops
- Pharmacies
- Physical Therapy Rooms
- Physicians' Offices
- Play [Areas] (and) [Rooms]
- [Police] (and) [Fire] Vehicles
- Psychiatric Facilities
- Public [Areas] (and) [Places]
- Public Facilities
- [Public] Restrooms
- Public [Tele]phone [Booths]
- Radiology
- Reception areas
- Recovery Rooms
- Recreational Facilities
- Rehabilitation Centers
- Rental Cars
- 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
- Tattoo Parlors
- Toilet Areas
- Transportation Terminals
- Trains
- Trolleys
- Universities
- Veterinary [Offices] [Waiting Rooms]
- Waiting [Rooms] (and) [Areas]
- Work Stations
- X-Ray Rooms
- Zoos

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{Surface Materials}

(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
- Autoclaves at room temperature
- 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
- Endodontic equipment
- [Exam] [Examination] tables
- Exercise] (and) [athletic] equipment
- Exercise mats
- Exhaust fans
- Exterior surfaces of air vents
- External surfaces of [medical] equipment
- [External surfaces of] [Ultrasound transducers] (and) [probes]
- Exterior (of) [toilet] (and) [urinal] surfaces
- External surfaces of [veterinary] equipment
- Exterior surfaces of watering appliances
- Faucets
- Fax machine [handles]
- Feed racks
- [Filing] (and) [medicine] cabinets
- Finished hardwood
- [Finished] (and) [painted] walls
- Finished windowsills
- Fixtures
- Flower buckets
- Food cases
- Food trays
- Footboards
- Freezer exteriors
- Furniture
- Garage surfaces
- [Garbage] disposals
- Garbage -or- trash cans
- High-touch [hard, nonporous] surfaces
- 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)

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- [Hospital] [Patient] [plastic] [vinyl] bed linings
- 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 tables and lights
- Operatory light switches
- Outside of appliances
- Oxygen hoods
- Oven exteriors
- 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
- Portable toilets
- Power cords
- Pulse oximeters
- PVC tubing
- Range hoods
- Reception [counters] [desks]
- Recycling bins
- Refrigerator exteriors
- Respirators
- Respiratory therapy equipment
- Restroom fixtures
- Scales
- Seats
- Sequential compression devices
- Shelves
- Shower(s) [curtains] [doors] [stalls] [walls]
- Shower fixtures
- Side rails
- Signs
- Sink [basins]
- Spine backboards
- Sports equipment
- Stainless steel surfaces
- Stall doors
- Staplers
- Stereo consoles
- Stethoscopes
- Stools
- Storage bins
- Stove[top]s at room temperature
- Stretchers
- Support bars
- Strollers
- Table[top]s
- Tablet PCs
- Telephones
- Tiled walls
- T[omography] equipment
- Tools
- Towel dispensers
- Toys
- Traction devices
- Trash cans
- Tray tables
- Troughs
- Vanity tops
- Vending machine surfaces at room temperature
- 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).

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(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
- Coffee [stains]
- Cosmetics
- Dead skin
- Dirt
- Fecal matter
- Fingerprints
- Food spills
- Food residues
- Food stains
- Fruit [stains]
- Grease
- Grime
- Heel [marks] [scuffs]
- Juice stains
- Laboratory stains
- Mold (and) [mildew] stains
- Mud
- Common [soils] [stains]
- Organic matter
- Ink [marks]
- Pet stains
- Rust
- Smudges
- Soap Scum
- Tea [stains]
- Tough soils
- Urine [stains]
- Wine stains

(Soft Surface[†] Sanitization:)

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

(Great) For use as a spot treatment sanitizer on soft surfaces[†] (composed of cotton or polyester) found in (hospitals), (medical offices) (nursing homes), (healthcare facilities), (and) (dental offices). (This product) Kills (removes) (sanitizes) microorganisms on (hospital) soft surfaces[†] or fabric[†] including: blinds, bedding, blankets, chairs, couches, curtains, drapes, exercise mats, gym bags, headrests, linens, mats, mattresses, seat (soft) cushions, shades, sheets, sofas, sports equipment (lining), towels, upholstered furniture, upholstery, washcloths, and window treatments. Removes (and) (or) (eliminates 99.9% of) odors by killing odor-causing bacteria on soft surfaces[†] or fabrics[†]. A cost effective solution compared to laundering or dry cleaning (hospital) curtains.

[†]plain cotton weave and 100% polyester fabric

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{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] [formula] [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.

{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.)

(CLAIMS AND ORGANISMS:)

When used as directed, this product is effective against a wide variety (broad-spectrum) of pathogenic microorganisms (including bacteria, antibiotic resistant bacteria, *{list of antibiotic resistant organisms found 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)

(Bactericidal Activity):

| (Organism) | (ATCC Number) | (Contact Time) |
|--|----------------------|-----------------------|
| <i>Staphylococcus aureus,</i> | (ATCC 6538) | 1 minute |
| <i>Pseudomonas aeruginosa,</i> | (ATCC 15442) | 1 minute |
| <i>Salmonella enterica,</i> formerly known as <i>Salmonella choleraesuis</i> | (ATCC 10708) | 1 minute |
| <i>Bordetella bronchiseptica,</i> | (ATCC 10580) | 1 minute |
| <i>Burkholderia cepacia,</i> | (ATCC 25416) | 1 minute |
| <i>Bordetella pertussis,</i> | (ATCC 12743) | 1 minute |
| <i>Enterobacter aerogenes</i> | (ATCC 13048) | 1 minute |
| <i>Enterococcus faecium,</i> | (ATCC 51559) | 1 minute |
| <i>Escherichia coli,</i> | (ATCC 11229) | 1 minute |
| <i>Escherichia coli</i> O157:H7 | (ATCC 35150) | 1 minute |
| <i>Klebsiella pneumonia</i> | (ATCC 4352) | 1 minute |
| <i>Legionella pneumophila,</i> | (ATCC 33153) | 1 minute |
| <i>Listeria monocytogenes,</i> | (ATCC 19117) | 1 minute |

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| | | |
|---|--------------|----------|
| <i>Pasteurella multocida</i> , | (ATCC 12947) | 1 minute |
| <i>Staphylococcus pseudintermedius</i> | (ATCC 49444) | 1 minute |
| <i>Stenotrophomonas (Pseudomonas) maltophilia</i> | (ATCC 25596) | 1 minute |
| <i>Streptococcus pyogenes</i> | (ATCC19615) | 1 minute |
| <i>Citrobacter freundii</i> | (ATCC 8090) | 1 minute |
| <i>Vibrio cholera</i> | (ATCC 39050) | 1 minute |
| <i>Campylobacter jejuni</i> | (ATCC 29428) | 1 minute |
| <i>Streptococcus pneumonia</i> | (ATCC 51936) | 1 minute |
| <i>Haemophilus influenza</i> | (ATCC 33930) | 1 minute |
| <i>Klebsiella oxytoca</i> | (ATCC700324) | 1 minute |

(*Antibiotic-Resistant (Strains of) Bacteria):

| | | |
|---|-----------------|----------|
| <i>Acinetobacter baumannii</i> , (Multi-Drug Resistant (MDR)) Ampicillin, Cefazolin, Cefepime, Gentamicin, Ertapenem, and Trimethoprim/Sulfa) | (ATCC 19606) | 1 minute |
| <i>Enterobacter cloacae</i> , (New Delhi metallo-β-lactamase 1 positive (producing) (NDM 1)) | (CDC 1000654) | 1 minute |
| <i>Enterococcus faecalis</i> , (Resistant to Vancomycin (VRE)) | (ATCC 51575) | 1 minute |
| Multidrug-resistant <i>Enterococcus faecium</i> , | (ATCC 51559) | 1 minute |
| Carbapenem-resistant <i>Escherichia coli</i> , | (ATCC BAA-2469) | 1 minute |
| <i>Escherichia coli</i> with extended beta-lactamase resistance, (ESBL) | (ATCC BAA-196) | 1 minute |
| <i>Escherichia coli</i> , (New Delhi metallo-β-lactamase 1(NDM-1) producing (positive)) | (CDC 1001728) | 1 minute |
| Multidrug-resistant <i>Klebsiella aerogenes</i> , (formerly MDR - <i>Enterobacter aerogenes</i>) | (ATCC BAA-2356) | 1 minute |
| <i>Klebsiella pneumoniae</i> , (Carbapenem Resistant (CRE)) | (ATCC BAA 1705) | 1 minute |
| <i>Klebsiella pneumoniae</i> , (Extended Spectrum beta-lactamase (ESBL) producing (positive)) | (ATCC700603) | 1 minute |
| <i>Klebsiella pneumoniae</i> (NDM-1) | (ATCC BAA-2470) | 1 minute |
| <i>Klebsiella pneumoniae</i> , (New Delhi metallo-β-lactamase 1 (NDM-1) producing (positive)) | (CDC 1000527) | 1 minute |
| Multidrug-resistant <i>Klebsiella pneumoniae</i> , | (ATCC BAA-1705) | 1 minute |
| Multidrug-resistant <i>Pseudomonas aeruginosa</i> , | (ATCC BAA-2108) | 1 minute |
| <i>Staphylococcus aureus</i> , (CA-MRSA), (Community Associated Methicillin Resistant) (NARSA NRS 123) (Genotype USA400) | | 1 minute |
| <i>Staphylococcus aureus</i> , (Methicillin Resistant (MRSA)) | (ATCC 33591) | 1 minute |
| <i>Staphylococcus aureus</i> , (Methicillin Resistant (MRSA)) | (ATCC 33592) | 1 minute |
| <i>Staphylococcus aureus</i> , (Vancomycin Intermediate Resistant (VISA)) (HIP 5836) | | 1 minute |
| <i>Staphylococcus aureus</i> , (Vancomycin Resistant (VRSA)) [VRS1] | | 1 minute |
| <i>Staphylococcus epidermidis</i> , (Methicillin Resistant (MRSE)) | (ATCC 51625) | 1 minute |
| <i>Streptococcus pneumoniae</i> , (Penicillin Resistant (PRSP)) | (ATCC 700677) | 1 minute |

***VIRUCIDAL:** {Note to reviewer: Only one of the following statements will be on the product label}

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

{or}
(30 second contact time)

{or}
(30 seconds)

(*Viruses (*Virucidal Activity)):

| (Organism) | (ATCC Number) | (Contact Time) |
|--|----------------|----------------|
| Adenovirus Type 2, (strain: Adenoid 6) | (ATCC VR-846) | 30 second |
| Adenovirus Type 7, (strain: Gomen) | (ATCC VR-7) | 30 second |
| Adenovirus type 8, | (ATCC VR-1368) | 30 second |
| Cytomegalovirus, | (ATCC VR-538) | 30 second |
| Hepatitis B Virus, (HBV), Duck Hepatitis B Virus as surrogate (Acquired from Hepadnavirus Testing) | | 30 second |
| Hepatitis C Virus, (HCV), Bovine Viral Diarrhea Virus as surrogate (Acquired from National Veterinary Services Laboratories) | | 30 second |
| Herpes Simplex Virus, Type 1 (HSV-1) | (ATCC VR-733) | 30 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 Strain) | (ATCC VR-544) | 30 second |
| Influenza B Virus, | | 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) | (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-1562) | 30 second |

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| | | |
|--|----------------|-----------|
| Respiratory Syncytial Virus, (RSV) | (ATCC VR-26) | 30 second |
| Rhinovirus Type 37, Strain 151-1 | (ATCC VR-1147) | 30 second |
| Rotavirus, (WA strain) (Acquired from University of Ottawa) | | 30 second |
| Vaccinia Virus, | (ATCC VR-119) | 30 second |
| ** (Viruses with 1 minute contact time:) | | |
| 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:) | | |
| 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 |
| ** (Animal Viruses with a 1 minute contact time:) | | |
| Canine Parvovirus, | (ATCC VR-2017) | 1 minute |
| 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 |

Non-Food Contact Surface Sanitizer for hard non-porous surfaces: {Note to reviewer: Only one of the following statements will be on the product label}

(in the presence of 5% serum load and 10 second contact time at 20°C (68°F) on hard, non-porous environmental surfaces.)

{or}
(in the presence of a 5% serum load and 10 second contact time (at 20°C (68°F)) on hard, non-porous environmental surfaces.)

{or}
(10 second contact time)

{or}
(10 seconds)

| (Organism) | (ATCC Number) | (Contact Time) |
|--|----------------------|-----------------------|
| <i>Acinetobacter baumannii</i> , | (ATCC 19606) | 10 seconds |
| <i>Campylobacter jejuni</i> , | (ATCC 29428) | 10 seconds |
| <i>Enterobacter aerogenes</i> , | (ATCC 13048) | 10 seconds |
| <i>Enterococcus faecalis</i> , (Resistant to Vancomycin [VRE]) | (ATCC 51575) | 10 seconds |
| <i>Escherichia coli</i> O157:H7, | (ATCC 35150) | 10 seconds |
| <i>Klebsiella pneumoniae</i> , | (ATCC 4352) | 10 seconds |
| <i>Listeria monocytogenes</i> , | (ATCC 19111) | 10 seconds |
| <i>Pseudomonas aeruginosa</i> , | (ATCC 15442) | 10 seconds |
| <i>Salmonella enterica</i> , (formerly known as <i>Salmonella choleraesuis</i>) | (ATCC 10708) | 10 seconds |
| <i>Staphylococcus aureus</i> , | (ATCC 6538) | 10 seconds |
| <i>Staphylococcus aureus</i> , (Resistant to Methicillin [MRSA]) | (ATCC 33592) | 10 seconds |

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

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

{or}
(30 second contact time)

{or}
(30 seconds)

| (Organism) | (ATCC Number) | (Contact Time) |
|--|----------------------|-----------------------|
| <i>Staphylococcus aureus</i> , | (ATCC 6538) | 30 seconds |
| <i>Enterobacter aerogenes</i> , | (ATCC 13048) | 30 seconds |
| <i>Enterococcus faecalis</i> , (Resistant to Vancomycin [VRE]) | (ATCC 51575) | 30 seconds |
| <i>Staphylococcus aureus</i> , (Resistant to Methicillin [MRSA]) | (ATCC 33592) | 30 seconds |

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TUBERCULOCIDAL:

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

| (Organism) | (ATCC Number) | (Contact Time) |
|--|---------------|----------------|
| <i>Mycobacterium bovis</i> (Tb) (OT 451C150) | | 1 minute |

FUNGICIDAL: {Note to reviewer: Only one of the following statements will be on the product label}

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

{or}
(in the presence of 5% serum load and 30 second contact time on hard, non-porous environmental surfaces.)

{or}
(30 second contact time)

{or}
(30 second)

| (Organism) | (ATCC Number) | (Contact Time) |
|--|---------------|----------------|
| <i>Trichophyton interdigitale</i> (formerly <i>Trichophyton mentagrophytes</i>) | (ATCC 9533) | 30 second |

FUNGICIDAL: {Note to reviewer: Only one of the following statements will be on the product label}

(This product is fungicidal against the pathogenic fungi, *Candida albicans* (ATCC 10231) and *Microsporum canis* (ATCC 10214) when used as directed on hard, non-porous surfaces.)

{or}
(in the presence of 5% serum load and 1 minute contact time on hard, non-porous environmental surfaces.)

{or}
(1 minute contact time)

{or}
(1 minute)

| (Organism) | (ATCC Number) | (Contact Time) |
|----------------------------|---------------|----------------|
| <i>Candida albicans</i> , | (ATCC 10231) | 1 minute |
| <i>Microsporum canis</i> , | (ATCC 10214) | 1 minute |

*****(FUNGICIDAL):** {Note to reviewer: Only one of the following statements will be on the product label}

(1 minute contact time) (1 minute)

{or}
(in the presence of soil and 1 minute contact time on hard, non-porous environmental surfaces.)

{or}
(Using Standard Quantitative Disk Carrier Test Method (under Good Laboratory Practices, [GLPs]), in the presence of soil and 1 minute contact time, against *Candida auris* (CDC AR-0381) and *Candida glabrata* (ATCC 26512))

| (Organism) | (ATCC Number) | (Contact Time) |
|---------------------------|---------------|----------------|
| <i>Candida glabrata</i> , | (ATCC 26512) | 1 minute |
| <i>Candida auris</i> , | (CDC AR-0381) | 1 minute |

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

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surfaces.

Malodor(s) (Activity) (Counteractancy) – eliminates 99.9% (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).

To Use as a One-Step Cleaner/Disinfectant:

1. Pre-clean visibly soiled areas.
2. Spray 6 – 8 inches from hard, non-porous inanimate surfaces, making sure surface is visibly wet.
3. Allow surface to remain visibly for 1 minute.
4. Wipe surfaces dry (or rinse). (If streaking is observed, wipe with a clean, damp (microfiber) (cloth) (or) (paper towel)). (Allow to air dry.)

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

To Clean and Disinfect Bathtubs, Shower Stalls and Other Large, Open Areas with Floor Drains:

1. Pre-clean visibly soiled areas.
2. Spray 6 – 8 inches from surfaces of sealed floors, walls and ceilings making sure not to over spray. Allow surfaces to remain visibly for 1 minute.
3. (Scrub using a deck brush or other coarse material as necessary. After contact time has elapsed)
4. Rinse surfaces thoroughly and let air dry.

{The following 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 pre-clean critical and semi-critical medical items:}

To Pre-clean Instruments Prior to Terminal Sterilization/High Level Disinfection (as a pre-cleaning spray):

1. Place instruments into a suitable container.
2. Spray this product onto hard, nonporous instruments to visibly wet all surfaces.
3. Allow the surface to remain visibly wet for 1 minute.
4. Rinse instruments.
5. Follow with an appropriate disinfection process.

Note: Cleaning of critical and semi-critical devices must be followed by an appropriate terminal sterilization/high-level disinfection process.

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{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 spraying with this product).
2. Spray all hard, nonporous surfaces of instruments with this product until thoroughly wet.
3. Allow the surface 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. Spray surface with this product until thoroughly wet. Allow the surface to remain visibly wet for 1 minute and rinse with potable water.

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

1. Pre-clean visibly soiled areas.
2. Spray 6-8 inches from surface until surface is thoroughly wet.
3. Allow surfaces to remain visibly for 1 minute.
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 visibly soiled items.
2. Spray 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 the surface 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) (soap) (detergent), then rinse with water and drain.
3. Apply: Spray this product 6 – 8 inches from hard, non-porous surfaces.
4. Scrub: Brush or swab thoroughly and allow solution to stand for 1 minute.
5. Rinse (cleaned) (treated) (surfaces) with fresh water and drain.

To Clean and Disinfect External Surfaces of Toilet Bowls:

1. Pre-clean visibly soiled areas.
2. Spray 6 – 8 inches from external surfaces on toilet bowl.
3. Swab entire surface area.
4. Allow entire surface to remain visibly for 1 minute.
5. Wipe with a clean, damp cloth or paper towel and allow to air dry

For Use as a Bactericide, Fungicide and *Virucide with (a) (an) [Mechanical Sprayer] [Pressure Sprayer]:

1. Pre-clean visibly soiled areas.
2. Spray hard, non-porous environmental surfaces, making sure to wet surfaces thoroughly.
3. All surfaces must remain visibly for 1 minutes for bactericidal and *virucidal efficacy. Allow 5 minutes for Tuberculocidal efficacy and 3 minute contact time for fungi.
4. Let air dry.

***KILLS HIV, HCV and HBV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED**

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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 visibly for 30 seconds to kill HIV-1, HCV and HBV, 4 minutes for mold, and 1 minute to kill all 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. Saturate all hard, non-porous surfaces by spraying with product until thoroughly wet. To disinfect, all surfaces must remain visibly for 1 minute.
6. Immerse or spray all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.
7. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.
8. 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 visibly soiled areas. Spray 6 – 8 inches from hard, nonporous surface until visibly wet. Allow to remain visibly for 1 minute. For *Trichophyton interdigitale*, allow to remain visibly for 30 seconds. Wipe surfaces and 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 visibly soiled areas. Spray 6 – 8 inches from hard, nonporous surface until completely wet. Allow to remain visibly for 1 minute. Wipe surfaces and let air dry.

To Use as a Non-Food Contact Sanitizer:

1. Pre-clean visibly soiled areas.
2. Apply product (with) (trigger sprayer), (cloth), (microfiber cloth,) (sponge,) (disposable wipe) (or) (mop) to hard, non-porous environmental surfaces.

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3. Allow the surface to remain visibly for 10 seconds.
4. Wipe surfaces dry (or rinse) (or allow to air dry).

To Sanitize Soft Surfaces[†]:

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

[†]plain cotton weave and 100% polyester fabric

To Kill Mold and Mildew:

Pre-clean surfaces. Spray 6 – 8 inches from hard, nonporous surfaces until completely wet. Allow to remain visibly for 4 minutes. Let air dry (or) (wipe surface dry) (or) (rinse).

To Control Mold and Mildew:

Apply product on to hard, nonporous surfaces until completely wet. Let air dry (or wipe surface dry) (or rinse). Repeat application weekly or when growth reappears.

To Clean (and/or Deodorize):

Apply product by (coarse trigger sprayer,) (wipe,) (sponge,) (paper towel,) (by pumping (pushing) (down on) top of the unit once (twice) (three) (a few times)) to hard, non-porous inanimate surfaces. Wipe surfaces dry (or rinse) (or allow to air dry). Repeat for visibly soiled areas. For stubborn stains or visibly soiled areas or tougher jobs, allow product to penetrate (dirt) before wiping.

To Spot Clean: Spray and wipe clean with damp sponge(, mop) or cloth.

To Clean/Remove Soap Scum:

(Just) spray on (soils) and wipe off (with a dry paper towel or lint-free cloth or microfiber cloth or sponge). No rinsing necessary. (For best results, use a dry paper towel or lint-free cloth or microfiber cloth or sponge.) Repeat for visibly soiled areas. (For stubborn stains or visibly soiled areas or tougher jobs, allow product to penetrate (dirt -and/or- soap scum) before wiping.) (For best results, use regularly to prevent dirt and soap scum build up).

To Clean (Non-Porous) Surfaces (and/or) (Small Areas of Floors): Apply to soiled area, then wipe clean.

To Spot Clean Carpet: Spray a light even coating (from 6 – 8 inches above) on soiled area of the carpet until damp. Gently blot area with a clean, damp, color-safe cloth. Repeat as needed (for stubborn stains). Let air dry. Vacuum.

(Allergen Destruction)

To Clean and Destroy Specified Allergens: Apply, wait 1 minute, and wipe excess. (Allow to air dry) (or) (rinse).

Allergens:

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

{Packaging Related Instructions}

{Appropriate language will be selected from this list, depending on packaging and is optional}

(For bottles with induction seal :) Unscrew cap, remove seal and place the (trigger) (sprayer) on the bottle.

(For bottles with sprayer :) To Operate: Open hinged cover of sprayer and snap into opening on top. -or- Turn nozzle (counterclockwise) to "spray" -or- "stream" (setting). -or- Adjust (nozzle) to desired pattern.

(For containers with top pump dispensing mechanism :)

To Open: (To Operate :) (To Unlock :) Twist (rotate) (top) (pump) (head) (counter) (clockwise).

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To Close: (To Lock :) (Twist) (rotate) (pump) (head) (counter) (clockwise).

(Optional Directions for Product Supplied in Refill and Refillable Bottles :)

Refill only with this product.

To Refill (Spray Bottles): Remove trigger sprayer from empty bottle. (Pour :) Unscrew cap (and remove seal) on refill container and pour contents directly into empty bottle. Use a funnel to minimize product spills –or- waste. Pour product into spray bottle over sink or tub basin.

(Refill)

(To Transfer This Product Into Smaller Containers:)

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

(Recommended to dispense with plastic trigger)

[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.

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. Do not allow to freeze.

PESTICIDE DISPOSAL

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

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

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

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

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

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

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

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

{or}

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

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

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

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

{or}

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

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

[Storage and Disposal for Residential Use Only Products]

Storage and Disposal

{Note to reviewer: Sizes for Residential use will be 1 gallon or less}

PESTICIDE [PRODUCT] STORAGE:

Store in original container in areas inaccessible to small children. Keep securely closed. Do not allow to freeze.

CONTAINER HANDLING:

Non-refillable container. Do not reuse or refill this container. Wrap [container] and put in trash or offer for recycling [if available].

{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*

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- *Large, non-enveloped viruses*
- *Small, non-enveloped viruses*

| | |
|---|---|
| <i>For an emerging viral pathogen that is a/an...</i> | <i>...follow the directions for use for the following organisms on the label:</i> |
| <i>Enveloped virus</i> | <i>Enterovirus type D68 (Strain US/KY/14-18953)</i> |
| <i>Large, non-enveloped virus</i> | <i>Enterovirus type D68 (Strain US/KY/14-18953)</i> |
| <i>Small, non-enveloped virus</i> | <i>Canine Parvovirus Enterovirus type D68 (Strain US/KY/14-18953)</i> |

{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] [Canine Parvovirus] on hard, non-porous surfaces. Refer to the [CDC or OIE] website at *{website address}* for additional information.

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

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

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

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

{Graphics - May be placed anywhere on the label}



{Footnotes for Symbols Mentioned in Label}

++ Claims against non-living allergens

* Virucidal Claim

† Soft Surface Sanitizer for use on plain cotton weave and 100% polyester fabric

**1 minute Virucidal Claims

*** Candida Auris Claim

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REFERENCE SHEET

OXIVIR 1

{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).

EPA Reg. No. 70627-74

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