



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 30, 2021

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

Subject: PRIA Label Amendment – Add Efficacy Claims against SARS-CoV-2
Product Name: Oxivir Wipes
EPA Registration Number: 70627-60
Application Date: April 1, 2021
Action Code Case: 00296038

Dear Sara 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.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf, you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens 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.

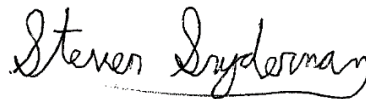
2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
 - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
 - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
 - A. CDC Current Outbreak List for “U.S. Based Outbreaks” (www.cdc.gov/outbreaks),
 - B. CDC Current Outbreak List for “Outbreaks Affecting International Travelers” with an “Alert” or “Advisory” classification (www.cdc.gov/outbreaks) (also released through the CDC’s Health Alert Network (HAN) notification process)
 - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
 - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page (www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI).
 - A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup is small non-enveloped, large non-enveloped, enveloped.
 - B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE’s publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against SARS-CoV-2 is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

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) lists 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 Assurance.

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 Zebora Johnson by phone at (703) 308-7080, or via email at johnson.zebora@epa.gov

Sincerely,



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

Enclosure: Accepted Label

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OXIVIR[®] Wipes

• [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

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. 70627-60

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*)].]

ACCEPTED

08/30/2021

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 70627-60

{Features, Claims and Uses}

{Product Descriptors}

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- | | |
|---|---|
| <ul style="list-style-type: none"> • 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! • Cleaner spot sanitizer on soft surfaces[†] • Deodorizer • Disinfectant • Easy to Use • For (Industrial), (Institutional) & (Residential) Use • Fungicide • Fungicidal disinfectant against <i>C. auris</i> • Hospital Disinfectant Cleaner • Hydrogen Peroxide • Meets Surface Recommendations from OSHA's Bloodborne Pathogens Standard for *HBV, *HCV & *HIV-1 • Mildewcide | <ul style="list-style-type: none"> • Multi-Surface • Multi-surface Disinfectant Cleaner • Multi-surface [One-Step¹] Disinfectant • Non-Dulling • No Gloves Required, unless directed • Odor Counteractant • Odor Neutralizer • One-step¹ when used according to disinfection directions • One-step¹ Disinfectant (Cleaner) (& Deodorizer) (Wipes) • Oxidizer • Ready to Use • Sanitizer • Sanitizes • Tuberculocide • Towelette • (Restroom) (&) (Bathroom) (Disinfectant Cleaner) • Use Daily to Prevent the Buildup of Dirt and Grime. • *Virucide • Wipe |
|---|---|

(Marketing Statements)

1 Minute bactericidal, virucidal, (and 3 minute fungicidal)

A proven spot sanitizer on soft surfaces[†]

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

Alcohol Free

All-in-one Disinfecting Wipe¹

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

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

An effective soft surfaces[†] spot sanitizer

Approved for Use in Home

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

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

Cleaning and disinfection in 1 minute

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

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

Cleans grout

Cleans hard, non-porous water washable surfaces!

Cleans, deodorizes and brightens in one step¹

Cleans (tough) soap scum

Cleans while it kills germs¹

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

Compatible with microfiber (cloths)

Compatible with (most) (virtually all) surfaces

Contains no phosphates

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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)
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.
Formulated with patented hydrogen peroxide technology
Fragrance Free Formula (Unscented)
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) (household²) germs while it cleans
(Kills) (Effective against) (the) cold (and) (flu) virus(es) (on hard, nonporous surfaces)
Kills germs including: SARS-CoV-2, Salmonella, E. coli, MRSA, Rhinovirus, Strep and Norovirus on hard non-porous 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
Kills bacteria and *viruses on (common household²) 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)

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Leaves a fresh, clean scent
Leaves no (dull) (sticky) residue.
Leaves surfaces virtually streak-free
Lift the Cap, Pull Wipe, Wipe Surface
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
Odor control (odor neutralizer) (deodorizer) (odor-counteractant) formula (on hard non-porous surfaces)
One-step¹ cleaner sanitizer on soft surfaces[†]
One-step¹ Cleaning and Disinfection with 1 wipe, in 1 minute
Oxivir[®] Clean
Patented (Technology)
(Phenol free) (No phenols)
Remove (dried) (stuck on) dirt (grime) (food) (spills) (grease) (greasy messes)
Proven "one-step¹" disinfectant/cleaner/fungicide/mildewcide/virucide that is effective for hard, non-porous surfaces
Category IV Tox(icity) Rating (in all 6 toxicity categories)
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 (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

(FUNGICIDAL: 3 MIN(UTES).)
(FUNGICIDAL AGAINST C. AURIS: 5 MIN(UTES).)**
(*VIRUCIDAL: 1 MIN(UTES))
(BACTERICIDAL: 1 MIN(UTES))
(TUBERCULOCIDAL: 5 MIN(UTES))

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(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 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.

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

(Oxivir Tb 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 – any hard, non-porous washable surface where disinfection is required.)

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

(Oxivir Tb 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 step¹ (with no rinsing required).

(Oxivir Tb Wipes) (This product) cleans, disinfects and deodorizes surfaces by killing odor-causing microorganisms. Its (non-dulling) (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 Tb 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 – any hard, non-porous washable surface where disinfection is required.

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(CLAIMS & USES:)

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

(This product) (Oxivir Tb 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 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.]

[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 Tb Wipes) (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}*]

(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.]

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{Hard Non-Porous Surfaces of the following (Areas)/ (Use Sites)}

-
- | | | |
|--|---|---|
| <ul style="list-style-type: none"> • 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 | <ul style="list-style-type: none"> • 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 | <ul style="list-style-type: none"> • 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 • Nurseries • Offices • Office Buildings • O[perating] R[oom]s • Orthopedics • Patient Rooms • Pediatric Intensive Care Units [PICU] • Pet Animal Quarters • Pet Shops • Pharmacies • Physical Therapy Rooms |
|--|---|---|

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- | | | |
|----------------------------------|---------------------------------|--|
| • Physicians' Offices | • Respiratory Therapy Rooms | • Tattoo Parlors |
| • Play [Areas] (and) [Rooms] | • Rest Stops | • Toilet Areas |
| • [Police] (and) [Fire] Vehicles | • Restaurants | • Transportation Terminals |
| • Psychiatric Facilities | • Restroom Areas | • Trains |
| • Public [Areas] (and) [Places] | • Retail Businesses | • Trolleys |
| • Public Facilities | • School Buses | • Universities |
| • [Public] Restrooms | • Schools | • Urgent Care [Centers] [Facilities] |
| • Public [Tele]phone [Booths] | • Shelters | • Veterinary [Offices] [Waiting Rooms] |
| • Radiology | • Shops | • Waiting [Rooms] (and) [Areas] |
| • Reception areas | • Shower Rooms | • Work Stations |
| • Recovery Rooms | • Sports Stadiums | • X-Ray Rooms |
| • Recreational Facilities | • Storage [Rooms] (and) [Areas] | • Zoos |
| • Rehabilitation Centers | • Subways | |
| • Rental Cars | • Surgery Rooms [Centers] | |

{Surface Materials} (Surfaces)

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

- | | | |
|--|---|--|
| • Amalgamators | • Burner trays | • Cribs |
| • Anesthesia machines | • Cabinets | • Dental countertops |
| • Animal equipment | • Cages | • Dental operatory surfaces |
| • Apex locators | • Call boxes | • Dental surfaces |
| • Apheresis machines | • Car interiors | • [Dentists'] [Dental] chairs |
| • Appliance exterior(s) [surfaces] | • Chairs | • Dental unit instrument trays |
| • Appliance -or- cabinet knobs | • Changing tables | • Desk [tops] |
| • Autoclaves | • Charging stations | • Diagnostic equipment |
| • Automatic feeders | • Chemotherapy hoods | • Dialysis machines |
| • Bathroom doorknobs | • Furniture | • Dictating equipment [surfaces] |
| • Baked enamel surfaces | • Closets | • Docking stations |
| • Bassinets | • Coated mattresses | • Door [handles] (and) [frames] |
| • [Bathroom] fixtures | • Coated pillows | • Doorknobs |
| • [Bathroom] (and) [Kitchen] faucets (and) [handles] | • [Common] hard, nonporous [household] surfaces | • Drainboards |
| • Bathrooms sinks and faucets | • Compactors | • Drawers |
| • Bathroom surfaces | • Computers | • Dryers |
| • [Bath]tubs | • [Computer] keyboards | • Dressing carts |
| • Bed frames | • [Computer] monitors | • Elevator buttons |
| • Bedpans | • Computer mouse | • Endodontic equipment |
| • Bedrails | • Computer screens | • [Exam] [Examination] tables |
| • Commodes | • Cooler exteriors | • Exercise] (and) [athletic] equipment |
| • Bedside tables | • Cords | • Exercise mats |
| • Blood pressure cuffs and monitors | • Counter[top]s | • Exhaust fans |
| • Booster chairs | • [Crash] (and) [emergency] carts | • Exterior surfaces of air vents |
| • Bottoms of pots and pans | • Cupboards | • External surfaces of [medical] equipment |

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- [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
- Germ-prone [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)
- [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 exteriors at room temperature
- 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 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

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- | | | |
|-----------------------------------|------------------------------|-----------------------------|
| • Stainless steel surfaces | • Telephones | • Walkers |
| • Stall doors | • Tiled walls | • Walls |
| • Staplers | • T[omography] equipment | • Wash basins |
| • Stereo consoles | • Tools | • Washable kitchen surfaces |
| • Stethoscopes | • Towel dispensers | • Washable walls |
| • Stools | • Toys | • Wastebaskets |
| • Storage bins | • Traction devices | • Wheelchairs |
| • Stove[top]s at room temperature | • Trash cans | • Window blinds |
| • Stretchers | • Tray tables | • Windows |
| • Support bars | • Troughs | • Windshields |
| • Strollers | • Vanity tops | • Work benches |
| • Table[top]s | • Vending machine surfaces | • X-ray equipment |
| • Tablet PCs | • Veterinary [care] surfaces | |
| | • Vinyl tile | |

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, | • glazed tile, | • sealed fiberglass, |
| • baked enamel surfaces, | • laminated surfaces, | • sealed granite, |
| • Corian®, | • linoleum, | • sealed marble, |
| • Chrome, | • metal (except copper and brass), | • sealed mirror stone, |
| • non-food contact crystal, | • painted surfaces, | • stainless steel, |
| • finished terrazzo, | • plastic (surfaces), | • synthetic marble, |
| • glass, | • glazed quarry tiles, | • vinyl, |
| • glazed ceramic (tile), | • rubber, | |
| • glazed porcelain, | | |

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

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

(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

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<i>Acinetobacter baumannii</i>	(ATCC 19606)	1 minute
<i>Enterococcus faecium</i>	(ATCC 51559)	1 minute
<i>Escherichia coli</i> O157:H7	(ATCC 35150)	1 minute
<i>Klebsiella aerogenes</i> , (formerly <i>Enterobacter aerogenes</i>)	(ATCC 13048)	1 minute
<i>Klebsiella pneumonia</i>	(ATCC 4352)	1 minute
<i>Legionella pneumophila</i>	(ATCC 33153)	1 minute
<i>Listeria monocytogenes</i>	(ATCC 19111)	1 minute
<i>Shigella dysenteriae</i>	(ATCC 11835)	1 minute
(Antibiotic-Resistant (Strains of) Bacteria):		
<i>Enterococcus faecalis</i> (Resistant to Vancomycin (VRE))	(ATCC 51575)	1 minute
<i>Escherichia coli</i> , carbapenem resistant (CRE)	(ATCC BAA-2469)	1 minute
<i>Escherichia coli</i> with extended beta-lactamase resistance (ESBL)	(ATCC BAA-196)	1 minute
<i>Klebsiella aerogenes</i> , (formerly <i>Enterobacter aerogenes</i>), Multi-Drug Resistant (BEI UCI15)	(ATCC BAA-2356)	1 minute
<i>Klebsiella pneumoniae</i> , carbapenem resistant (CRKP)	(ATCC BAA-1705)	1 minute
Extended spectrum beta-lactamase <i>Klebsiella pneumoniae</i> (NDM-1)	(ATCC 700603)	1 minute
<i>Streptococcus pneumoniae</i> , Penicillin-resistant (PRSP)	(ATCC 700677)	1 minute
Multidrug-resistant (MDR) <i>Pseudomonas aeruginosa</i>	(ATCC BAA-2108)	1 minute
<i>Staphylococcus aureus</i> (Resistant to Methicillin (MRSA))	(ATCC 33592)	1 minute
<i>Staphylococcus aureus</i> (CA-MRSA), (Community Associated Methicillin Resistant) (NARSA NRS 384)(Genotype USA300)		1 minute
<i>Staphylococcus aureus</i> (CA-MRSA), (Community Associated Methicillin Resistant) (NARSA NRS 123)(Genotype USA400)		1 minute
*VIRUCIDAL: {Note to reviewer: Only one of the following statements will be on the product label}		
(in the presence of 5% serum load and 1 minute contact time at 20°C (68°F) on hard, non-porous environmental surfaces.)		
{or}		
(1 minute contact time)		
{or}		
(1 minute)		
(*Viruses (*Virucidal Activity)):		
(Organism)	(ATCC Number)	(Contact Time)
Adenovirus type 8	(ATCC VR-1368)	1 minute
Hepatitis B Virus (HBV) (Acquired from Hepadnavirus Testing)		1 minute
Hepatitis C Virus (HCV) (Acquired from National Veterinary Services Laboratories)		1 minute
Herpes Simplex Virus, Type 1 (HSV-1)	(ATCC VR-733)	1 minute
Herpes Simplex Virus, Type 2 (HSV-2)	(ATCC VR-734)	1 minute
HIV-1 (AIDS Virus), Strain HTLV-III _B (HIV-1) (Acquired from Adv. Biotechnologies, Inc.)		1 minute
Human Coronavirus	(ATCC VR-740)	1 minute
Influenza A/Hong Kong	(ATCC VR-544)	1 minute
Middle Eastern Respiratory Syndrome Coronavirus (MERS-CoV) (Strain EMC/2012)		1 minute
Norovirus, (Feline Calicivirus as the surrogate)	(ATCC VR-782)	1 minute
Poliovirus Type 1, Strain Brunhilde	(ATCC VR-1000)	1 minute
Respiratory Syncytial virus (RSV)	(ATCC VR-26)	1 minute
Rhinovirus Type 14	(ATCC VR-284)	1 minute
Rotavirus WA (Acquired from University of Ottawa)		1 minute
SARS-Related Coronavirus 2 [SARS-CoV-2] [cause of COVID-19] [USA-WA1/2020]		1 minute
Vaccinia Virus	(ATCC VR-156)	1 minute
(*Veterinary Viruses:)		
Avian Influenza A (H3N2)	(ATCC VR-2072)	1 minute
Feline Calicivirus, Strain F9	(ATCC VR-782)	1 minute

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

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

{or}

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

{or}

(30 second contact time)

{or}

(30 seconds)

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

TUBERCULOCIDAL:

(in the presence of 5% serum load and 5 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)		5 minutes

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

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

{or}

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

{or}

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

{or}

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

{or}

(3 minute contact time)

{or}

(3 minutes)

(Organism)	(ATCC Number)	(Contact Time)
<i>Trichophyton interdigitale</i> (formerly <i>Trichophyton mentagrophytes</i>)	(ATCC 9533)	3 minutes
<i>Candida albicans</i>	(ATCC 10321)	3 minutes

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

(This product is fungicidal against *Candida auris* (CDC AR-0381) with a 5 minute contact time.)

{or}

(5 minute contact time)

{or}

(5 minutes)

(Organism)	(ATCC Number)	(Contact Time)
<i>Candida auris</i>	(CDC AR-0381)	5 minutes

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).

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{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*

<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>	• Poliovirus type 1 (ATCC VR-1000), (Strain Brunhilde)
<i>Large, Non-Enveloped Viruses</i>	• Feline Calicivirus (ATCC VR-782) / Norovirus • Poliovirus type 1 (ATCC VR-1000), Strain Brunhilde
<i>Small, Non-Enveloped Viruses</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 [Poliovirus type 1] [Feline Calicivirus] on hard, non-porous surfaces. Refer to the [CDC or OIE] website at {website address} for additional information.

For Use as a (One-Step¹) (Cleaner)/(Disinfectant):

1. Pre-clean visibly soiled areas.
2. Pull towelette from dispenser (canister) (bucket) and wipe hard, non-porous environmental surfaces.
3. All surfaces must remain visibly wet for 1 minute. Use a 5 minute contact time for Tuberculosis. Use a 3 minute contact time for fungi and 5 minute contact time for *Candida auris*.
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.

For Use as (Daily) (Bathroom) (Restroom) (Shower Rooms) (Locker Rooms) (Athletic Equipment) (One-Step¹) Cleaner/Disinfectant:

1. Pre-clean visibly soiled areas.
2. Pull towelette from dispenser (canister) (bucket) and wipe hard, non-porous environmental surfaces.
3. To disinfect, all surfaces must remain wet for one (1) minute. Use a 5 minute contact time for Tuberculosis. Use a 3 minute contact time for fungi and 5 minute contact time for *Candida auris*.
4. Wipe surfaces dry (or rinse) (or allow to air dry).

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***KILLS HIV AND 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 B Virus (HBV), or Hepatitis C Virus (HCV).

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

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

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

Contact Time: Allow surface to remain wet for 1 minute to kill HIV-1, HBV and HCV. Use a 5 minute contact time for Tuberculosis and a 3 minute contact for fungi and 5 minute contact time for *Candida auris*.

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

For Use as a Tuberculocide at 20°C (68°F):

1. Pre-clean visibly soiled areas.
2. Pull towelette from dispenser (canister) and wipe hard, non-porous environmental surfaces.
3. Allow the surface to remain wet for 5 minutes. Use additional towelettes if needed to ensure the correct wet contact time.
4. Wipe surfaces dry (or rinse) (or allow to air dry).
5. Change towelette after each use (application).

To Kill Fungi:

For Candida auris, please see special instructions.

1. Pre-clean visibly soiled areas.
2. Pull towelette from dispenser (canister) and wipe hard, non-porous environmental surfaces.
3. All surfaces must remain visibly wet for 3 minutes. Use additional towelettes if needed to ensure the correct wet contact time.
4. Wipe surfaces dry (or rinse) (or allow to 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. Wipe hard, non-porous environmental surfaces with towelette. Allow to remain wet for 5 minutes. Use additional towelettes if needed to ensure the correct wet contact time. Wipe surfaces or let air dry.

For use as a Non-Food Contact Sanitizer:

1. Pre-clean visibly soiled areas.
2. Pull towelette from dispenser (canister) and wipe hard, non-porous environmental surfaces.
3. Allow the surface to remain wet for 30 seconds.
4. Wipe surfaces dry (or rinse) (or allow to air dry).
5. Change towelette after each use (application).

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For Use as a Cleaner and/or Deodorizer:

Pull towelette from dispenser (canister) and wipe hard, non-porous environmental surfaces. Allow to air dry (or rinse (with potable water if necessary)).

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

1. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc.
2. Remove all litter, droppings and manure from floors, walls and surfaces of facilities (including pens, chutes, and barns) occupied or traversed by animals.
3. Empty all troughs, racks, and other feeding or watering appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with potable water. Pull towelette from dispenser (canister) and wipe hard, non-porous environmental surfaces.
5. All surfaces must remain visibly wet for 1 minute.
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 set or dried.

NOTE: Not for use on handling and restraining equipment such as leashes, muzzles, halters or ropes, as well as forks, shovels, and scrapers used for removing litter and manure.

(Allergen Destruction)

To Clean and Destroy Specified Allergens: Spray [Spray/Apply], wait 1 minute, and wipe 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.

{Note to Agency: Text appearing in [brackets] or (parenthesis) is done to show interchangeable or optional text. Commas may be added where needed. Any language which appears between {braces} and is italicized is for administrative purposes only and will NOT appear on final printed label. Listed uses and use sites can be used partially or in their entirety. }

(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).

{Note to Agency: Text appearing in [brackets] or (parenthesis) is done to show interchangeable or optional text. Commas may be added where needed. Any language which appears between {braces} and is italicized is for administrative purposes only and will NOT appear on final printed label. Listed uses and use sites can be used partially or in their entirety. }

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 Tb 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.

{Note to Agency: Text appearing in [brackets] or (parenthesis) is done to show interchangeable or optional text. Commas may be added where needed. Any language which appears between {braces} and is italicized is for administrative purposes only and will NOT appear on final printed label. Listed uses and use sites can be used partially or in their entirety. }

{Graphics - May be placed anywhere on the label}



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Not a baby wipe
Not for personal use



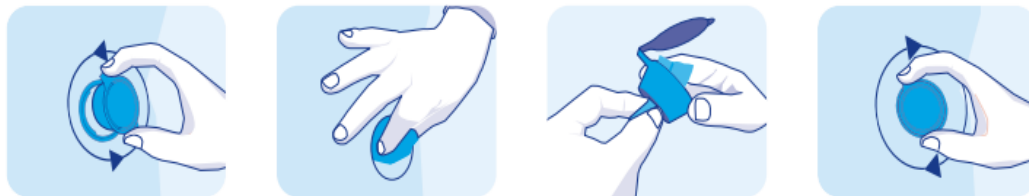
One-step cleaning
and disinfection



For hard, non-porous
surfaces



{Note to Agency: Text appearing in [brackets] or (parenthesis) is done to show interchangeable or optional text. Commas may be added where needed. Any language which appears between {braces} and is italicized is for administrative purposes only and will NOT appear on final printed label. Listed uses and use sites can be used partially or in their entirety. }



{Footnotes for Symbols Mentioned in Label}

++ Claims against non-living allergens

** *Candida auris* Use Directions

* Viruses

¹ when used according to disinfection directions

² *Staphylococcus aureus*, *Pseudomonas aeruginosa*

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REFERENCE SHEET

OXIVIR[®] TB 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).

EPA Reg. No. 70627-60

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