



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 19, 2019

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

Subject: Notification per PRN 98-10 – Updating Marketing Claims
Product Name: Oxivir Wipes
EPA Registration Number: 70627-60
Application Date: 04/09/2019
Decision Number: 549951

Dear Ms. Seltzer:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped “Notification” and will be placed in our records.

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.

If you have any questions, you may contact Aline Heffernan at 703-347-8602 or via email at heffernan.aline@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Aline Heffernan".

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

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

NOTIFICATION

70627-60

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

04/19/2019

OXIVIR™ WIPES

(Ready to Use) (Easy to Use) (Towelette) (Wipe)
(One-Step Disinfectant and Deodorizing Wipes)

•(Sanitizer) •(Sanitizing Wipes) •(Cleaner) •(Disinfectant) •(Deodorizer)

(*Virucidal) •(Bactericidal) •(Fungicidal) •(Tuberculocidal)

(Meets OSHA Bloodborne Pathogen Standards)

• (Kills Norovirus)

(Use on hard non-porous non-food contact surfaces, including: (Grocery Cart Handles) (Cash Registers)
(Telephones) (Doorknobs))

•(Just pull, wipe, let wet surfaces sit for 1 minute & toss!) •(Eliminates Buckets) •(No need to Spray!)

•(Pre-moistened) •(Pre-measured) • (Always Ready-to-Use)

(No measuring or mixing required)

(Hydrogen Peroxide)

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

ACTIVE INGREDIENT:

Hydrogen Peroxide..... 0.5%

OTHER INGREDIENTS: 99.5%

TOTAL:..... 100.0%

KEEP OUT OF REACH OF CHILDREN

Emergency Number: XXX-XXX-XXXX

Net Contents: xxxxxxxxxxxxxxx

EPA Reg. No. 70627-60

EPA Est. No. xxxxxxxxxxxxxxx

(Lot code letters indicate establishment number.)

[Made in (Product of) xxxxxxxxxxxxxxx]

[Manufactured][Distributed][by][for]: © 2019 Diversey, Inc., P.O. Box 19747, Charlotte, NC 28219-0747 USA

(See reference sheet (enclosed in each case) for (a completed list of organisms) (additional (features) (claims) (directions for use)) (for this product)).

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

(MARKETING CLAIMS):

(General)

A disinfectant cloth for use on telephone surfaces and other telecommunications equipment surfaces

A Hydrogen Peroxide solution impregnated in a wiping cloth

Aids in reducing (or in the reduction of) cross contamination between treated surfaces

Always ready to use

An effective way to clean, deodorize against odor-causing organisms and disinfect hard, non-porous surfaces

An effective way to disinfect hard, non-porous environmental surfaces

Built-in Scrubbing Fibers

Clean & disinfect any room, any time

Clean & disinfect hard non-porous surfaces

Clean & disinfect hard non-porous surfaces easily

Cleaner and disinfectant towel (or cloth)

Cleans and disinfects

Cleans and disinfects (cell phone surfaces) (telephone equipment) (telephone equipment surfaces) (dictating equipment surfaces) (telecommunications equipment surfaces) (devices)

Cleans and disinfects common hard, non-porous surfaces

Cleans, deodorizes and disinfects

Cleans, deodorizes and brightens in one step

A (cleaner) (and) (disinfectant (and) cleaner (that (cleans), (disinfects) and (deodorizes) in one labor saving step)

Cloth

Chlorine free (No (chlorine) (bleach))

Compatible with most hard, nonporous surfaces

Contains no (abrasives) (bleach) (or) (harsh acids)

Contains no phosphates

Compatible with (Suitable for) (Will not harm) most hard non-porous surfaces. (No bleach (or chlorine) stains)

Deodorizer (Odor Counteractant) (Odor Neutralizer)

Convenient

Convenient & easy cleaning all around (the office) (business) (workplace)

Cuts grease

Cuts the toughest grime and grease without scratching surfaces

Disposable

Pre-moistened towelettes (disposable wipes) clean, deodorize and kill listed bacteria all around your (office) (business) (workplace)

~~Easy to use — just wipe, (and) let wet surfaces sit for 1 minute (and) (walk away).~~

Easy / Effective

For everyday use (in (institutional) (and) (industrial) facilities)

For hard, non-porous surfaces

For use in critical care areas (where control of the hazards of cross-contamination between treated surfaces is of prime importance)

For use (in) (Hospitals), (Health Care) (settings) (as a multi-purpose disinfectant cleaner)

For your toughest bathroom messes

Formulated with patented hydrogen peroxide technology

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Formulated with patented AHP technology
(Fragrance Free) (Unscented) Formula
Great on-the-go disinfectant (cloth)
Hard non-porous surface (cleaning &) disinfecting made easy Heavy-duty cleaner (or cleaning) (cloth)
Help make your (the) [*insert any use site from use site section*] Oxivir Clean
~~Just pull, wipe, let wet surfaces sit for 1 minute and toss!~~
No fragrance added (No added fragrance)
No rinse required
Non-corrosive (to eyes) (and) (skin)
Non-tainting (leaves no unsightly residues)
Non-woven disposable cloth
Not a skin (dermal) sensitizer (non-sensitizer)
Pre-measured (towelette) (towelettes) (wipe) (wipes)
Pre-moistened (towelette) (towelettes) (wipe) (wipes)
Pre-soaked (cloth or towelette or wipe)
Efficiently (eliminates) (removes) (bad) (mal)odors
Quaternary ammonium compound-free (No quaternary ammonium compounds)
Restroom Wipes for hard, non-porous surfaces
Stay-moist package
(Step-saving), (Labor-saving), (Time-saving), (Cost-saving) formula
Strong towelettes (or wipes)
Suitable for everyday use
Towel
Use on hard, non-porous surfaces only. (Test wipe on a small inconspicuous area first)
Use to disinfect shopping (or grocery) cart handles
Wipe down grocery (or shopping) cart handles

(Cleaning)

An effective counter cleaner
Built-in scrubbing fibers
Cleans without scratching surface(s)
Cleaner
Clean(s) and deodorize(s)
Cleans effectively
Cleans hard-to-remove stains
Clean you expect
Cleans fast
Cleans sealed grout
Cleans hard, non-porous water washable surfaces!
Cleans (removes) (eliminates) (destroys) stains
Cleans (tough) grease and grime (and) (institutional) (soils) (~~fast~~)
Cleans (tough) soap scum
Cleans without bleaching
Compatible with (equipment) and (hard) (non-porous) surfaces
Convenient, (effective) (efficient) (&) easy cleaning
Effective daily cleaner
Effective against soap scum
For a cleaner, fresher [*insert any use site from use site section*]
For multiple cleaning tasks

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For non-scratch cleaning of showers and tubs, shower doors and (nonporous) curtains, fixtures and toilet bowls

Good for most indoor cleaning tasks

Grease Cutting Formula

Great for grease cutting

Great for on-the-go cleaning

Intense cleaning action

Keeps day care centers clean

Leaves no (dull) (sticky) residue

Leaves (office) (washroom) (restroom) (bathroom) smelling clean

Leaves surfaces virtually streak-free

No mixing

No streaking

Powerful clean

Powers away tough stains (stuck on dirt)

(Efficient) (effective) (and) easy cleaning everywhere

Removes tough stains

Scrubbing surface cleaner

(Specially) (Specifically) designed to dissolve (penetrate) the toughest (stubborn) soils

Use daily to prevent the build-up of dirt and grime

Uses (Harnesses) the cleaning power of hydrogen peroxide

Will not leave grit or soap scum

(Antimicrobial-related statements)

Antimicrobial

Antimicrobial (hard non-porous surface) Cleaner (cloth)

Antimicrobial Cell phone Wipe

Anti-microbial cleaner (cloth)

Bactericidal Cleaner

Bactericidal

Bactericidal (hard non-porous surface) Cleaner (cloth)

Bactericidal Cell phone Wipe

*Virucidal

*Virucidal (Surface) Cleaner (cloth)

*Virucidal Cell phone Wipe

Broad-Spectrum (Multi-Purpose) (Multi-Surface) (Bactericidal) (*Virucidal) (Tuberculocidal) (Fungicidal)
(Sanitizer) (Disinfectant) (Activity) (Cleaner)

Controls the spread of listed bacteria on treated hard, non-porous environmental surfaces

Controls (Eliminates) odor-causing bacteria

Cleans as it disinfects

(Disinfects) (Kills germs) for a deep-down clean

Disinfectant (disinfecting) hard non-porous surface cleaner (cloth) (wipe)

Disinfects against *Staphylococcus aureus*, *Salmonella enterica*, and *Pseudomonas aeruginosa*

Disinfects environmental hard non-porous surfaces

Disinfects hard, non-porous environmental surfaces

Disinfects headsets and telephones

Dual action formulation providing broad spectrum activity against; fungi, mycobacteria, *viruses, and bacteria

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Each pre-moistened towelette (disposable) (wipe) cleans and deodorizes all around the [*insert any use site from use site section*].

~~Pre-moistened towelette (disposable) (wipe) cleans, deodorizes and kills listed bacteria all around the [*insert any use site from use site section*]. Just wipe and let surface remain wet for 1 minute.~~

Effective against flu *virus (*Influenza A Virus/Hong Kong)

Effective in 1 minute against *Staphylococcus aureus*, *Salmonella enterica*, and *Pseudomonas aeruginosa*

Effectively disinfects hard, non-porous surfaces

Effectively disinfects in the presence of organic soil (5% blood serum)

Every day, every room disinfectant

Exhibits effective *virucidal activity: kills *Influenza A Virus/Hong Kong and *Herpes Simplex Type 2

Kills antibiotic resistant organisms† [*list of antibiotic resistant organisms is below, in Efficacy Claims section, under subheading Antibiotic-Resistant (Strains of) Bacteria*]

Kills bacteria (and sanitizes)

Kills bacteria (and *viruses) (on hard, non-porous surfaces) in 1 minute

Cleans while it kills (destroys) (eliminates) germs

Kills (Effective against) cold *virus on hard, non-porous surfaces

Kills (Effective against) flu *virus on hard, non-porous surfaces

Kills (Effective against) cold and flu *virus on hard, non-porous surfaces

Kills odor-causing bacteria

Kills *viruses (in 30 seconds (in 1 minute))

Kills (99.9% of) germs (in 1 minute)

Kills (99.9% of) (cold) (and) (flu) (*viruses) in 30 seconds (in 1 minute)

Kills *Avian Influenza A Virus on pre-cleaned environmental hard non-porous surfaces

Kills: *Staphylococcus aureus*, *Salmonella enterica*, and *Pseudomonas aeruginosa*

Kills the flu virus *Influenza A

Kills *Norovirus (Norwalk virus)

Kills *Human Coronavirus

Kills *HIV-1 (AIDS virus) (HTLV-III_B)

Kills *HCV

Kills *HBV

On-the-go disinfectant

Oxivir™ (Tb) Wipes control the spread of listed bacteria on treated hard, non-porous environmental surfaces

Oxivir™ (Tb) Wipes help control listed bacteria on treated surfaces while keeping your office (or workstation or workplace or business) clean and dust-free

Restroom Disinfectant Wipes

Telephone (cleaner [and] disinfectant) wipes

These wipes are a convenient way to disinfect hard non-porous surfaces all around your (business) (office) (workplace)

Versatile (convenient) (disinfectant) (or disinfecting) cleaner

*Virucidal (or) Kills *viruses *Influenza A Virus/Hong Kong (Hong Kong flu), *Herpes Simplex Type 2, *HCV, *HBV, *HIV-1

*Virus killing cleaner

(New & Improved Claims)

{*Note to reviewer: New and approved claims only to be used for maximum 6 months, and in accordance with New and Approved claims guidance*}

New (packaging) (!)

New & Improved (Packaging) (!)

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Improved (Cleaning) (Scrubbing)

(Packaging Claims)

Assures proper dilution strength for product effectiveness

Easy flip-top lid

(Eliminates buckets)

Dispenses exactly what you need

Take (1) (one) or Many Wipes

Easy to Dispense

Hassle Free Lid

Never fight the lid again

Unique lid design

No need to remove lid to get to wipes

No more pinched fingers

No more broken lids

Stronger Wipes!

One handed dispensing

Great for on the go

Mounts to (on) virtually anything (any surface)

Portable & Accessible Design

Wipes where and when you need them

Less packaging than traditional bucket

Uses (10 or 15 or 20 or 25)% less (packaging) (plastic) [than (traditional) (standard) (canister) (wipes)

(packaging)] [*Note to reviewer: only one number will be used on final label, depending on which package is used*]

Helps to support your (sustainability) (Corporate Social Responsibility) (CSR) (reduced packaging) (reduced packaging waste) initiatives

Takes up less space

Portable

Easy to dispense

Made with less plastic

Reduced packaging material

Made with the environment in mind

One handed dispensing

Ideal for daily cleaning and disinfecting

Dispensing Simplified

Wipes Simplified

Easy carry handles

Secure bracket

Just insert in dispenser (bracket) for one handed dispensing

Now (10 or 15 or 20 or 30 or 40)% stronger package [*Note to reviewer: only one number will be used on final label, depending on which substrate and/or package is used*]

Now (10 or 15 or 20 or 30 or 40)% stronger wipe [*Note to reviewer: only one number will be used on final label, depending on which substrate and/or package is used*]

Now (10 or 15 or 20 or 30 or 40)% stronger towelette [*Note to reviewer: only one number will be used on final label, depending on which substrate and/or package is used*]

No more wasted wipes

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Portable or can be attached to brackets
Point of care dispensing or access or availability
No threading
Our (best or easiest or fastest) dispensing ever(!)
Just pull and go
Pull up for many pull forward for one wipe(s)
Wipes on demand
Easy to use (dispenser) (package)
Easy (to store) (to start dispensing) (to use lid)
Stackable packs
(Stays) (keeps) wipes wet
Convenient
Versatile packaging for every need
Ready to dispense
(Regular or Clinical or Large or EVS) Wipe size
Snap and seal closure
Same great product, (easier or better or improved) package
Wipes that clean better
Wipes are stronger
Wipes can do more
Clean Better
Clean and disinfect more easily
Travel size
Great for on the go disinfection
Convenient package size great for on the go
Puts wipes where you need them
Puts wipes always within reach
Clean and disinfect when the moment strikes
Clean and disinfect when the occasion strikes
Clean and disinfect key moments
Increase moments of disinfection
Just pop the top and grab a wipe
Place container where you need it
Wipes always when and where you need them
Quick lock wipe dispenser
First time use, lift here
First time use, do not remove lid
First time use, lift here to expose seal
Not a baby wipe
Wipe dispensing simplified
Stronger Wipes
Wipes when and where you need them
Large wipes perfect for everyday disinfection
Powered by AHP
Just flip the lid and grab a wipe
Stand-up pouch takes up less space than bulky buckets
Easy dispensing, happy (nurses, staff, employees, users)
Do Not Remove Lid

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Open Lid Here

Tear/Break/Puncture film to expose wipe roll

Remove seal for first wipe

Remove seal for wipe access

Tear Here

Remove seal here

Pull Seal Here

Remove to access wipe roll

(Additional Claims)

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

(Oxivir Tb Wipes) (This product) is a one-step (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.

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

(Oxivir Tb Wipes') (This product's) (Its) (non-dulling) (advanced) (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 step (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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Do not use on glasses, dishes and utensils.

Not recommended for use on brass, copper or marble.

(Oxivir Tb Wipes) (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/surfaces from lists below*]

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

(USE SITES:)

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

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

- alternative care facilities,
- ambulances or (emergency medical) transport vehicles,
- ambulatory care centers (ASCs); ambulatory surgery centers,
- anesthesia rooms,
- assisted living facilities,
- (acute) (and) (long-term) care facilities,
- backboards,
- (hospital) (patient) bedrails and linings (patient bed linings), (vinyl mattress covers),
- bedpans,
- (hospital) (patient) bedrails, bedframes, bed springs, side rails,
- bedside (overbed) table,
- (bedside) commodes,
- blood pressure cuffs (for use on hard, non-porous surfaces)
- blood pressure monitors,
- CAT laboratories,
- (crash) (medication) carts,
- cabinets,
- (nurse) call buttons (boxes) (devices),
- (central service areas,
- central supply rooms,
- clinics,
- critical care units,
- dental chairs,
- dental clinics,
- dental curing lights,
- dental offices,
- dental operatory surfaces,
- diagnostic equipment,
- dialysis clinics (facilities),
- (blood) (plasma) donation centers,
- examination (exam) rooms (areas),
- exam tables
- emergency rooms (ERs) (areas),
- eye surgical centers,
- footboards,
- gurneys,
- health care facilities,
- high-touch surfaces,
- home health care (settings),
- hospices,
- hospitals,
- infant incubators,
- instrument trays,
- IV stands (poles) and exterior surfaces of pumps,
- (medical) (neonatal) (pediatric) (surgical) intensive care units (ICUs) (MICUs) (NICUs) (PICUs) (SICUs) (areas),
- isolation rooms (areas),
- laboratories,
- laboratory settings
- laundry rooms,
- long-term care facilities (homes),
- (medical assistance services),
- medical facilities,
- (medical) (physicians') (doctors') offices,
- (neonatal) (newborn) nurseries,
- non-critical medical equipment surfaces,
- nursing homes,
- nurses stations,
- operating rooms (theaters),
- ophthalmic offices,
- outpatient (surgical) centers (clinics) (OPSCs) (facilities),
- paddles,
- patient rooms (areas),
- patient care (monitoring) equipment,
- pharmacies,
- phlebotomy trays,
- (physical) (patient) therapy rooms,
- physical therapy equipment,
- procedure rooms,
- psychiatric facilities,
- radiology (X-Ray) rooms (areas),
- reception areas,
- recovery rooms,
- rehabilitation centers,
- respiratory therapy rooms,
- skilled nursing facilities,
- stethoscopes,

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- stretchers,
- surgery rooms,
- traction bars, devices and patient slings,
- waiting rooms (areas)
- wash basins,
- wheelchairs,
- x-ray equipment,

(USE SITES, continued)

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

(Animal/Veterinary Facilities/Animal Housing Facilities:)

- airports,
- animal equipment,
- animal crates,
- animal hospitals,
- animal housing facilities,
- animal treatment facilities,
- animal life science laboratories,
- automatic feeders (not for food contact),
- barns, pens, and stalls,
- bathrooms,
- brushes,
- buckets,
- bus (depots) (stations),
- cages,
- carts,
- non food contact counters,
- crates,
- dog runs,
- examination tables
- exercise facilities,
- exercise equipment,
- farm vehicles (trucks),
- fencing,
- fume hoods and animal cages (found in laboratory settings),
- farms,
- gates,
- gathering (guiding) equipment,
- general merchandise stores,
- grooming equipment,
- grooming facilities,
- health clubs,
- handling equipment,
- harnesses & leashes,
- kennels,
- kennel runs,
- laboratories or other small animal facilities,
- office buildings,
- pens,
- pet shops (equine farms),
- shower rooms (areas),
- troughs,
- veterinary clinics
- veterinary equipment,
- veterinary care surfaces,
- (wash) stalls,

(General Areas:)

- airports,
- aluminum
- athletic equipment,
- athletic facilities,
- baked enamel surfaces associated with floors,
- barber/beauty (salons) (shops),
- exterior surfaces of air vents covers,
- cabinets,
- cages,
- carts,
- casinos,
- ceilings
- chairs,
- changing tables,
- chrome
- closets,
- coated (removable) (plastic) covers for mattresses and pillows,
- computer mouse, keyboards, peripherals, screens, tables,
- convenience stores,
- convention centers,
- correctional facilities,
- counters (not for food contact),
- cruise ships,
- day care centers,
- desks,
- desktops,
- docking stations,
- doors,
- drawers,
- elevators,
- exercise equipment,
- exercise facilities,
- faucets,
- fixtures,
- floors (flooring),
- funeral homes,
- glass,
- glazed ceramic,
- glazed ceramic (restroom) tile,
- glazed porcelain,
- glazed tile,
- handheld electronic devices,
- handles,
- hand rails (railings),
- high touch non-food contact surfaces,
- homes cleaned by (home cleaning services) (professional cleaning services),
- hotels (motels),
- institutions,
- laminated surfaces
- laptops,
- laundromats,
- libraries,
- light fixtures, switches,
- lockers,
- locker rooms (areas),
- lounges,

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- mirrors,
- military installations,
- mobile devices (electronic equipment),
- mobile workstations,
- Naugahyde,
- non-food contact countertops,
- non-food contact surfaces,
- office buildings
- pagers,
- painted surfaces,
- phones, phone cradles and accessories,
- plastic (surfaces),
- plated steel
- playgrounds,
- public areas,
- public buildings,
- public restrooms,
- recreational facilities,
- restrooms,
- rest stops (public restrooms),
- retail businesses,
- schools (colleges, and universities),
- shelves,
- shopping centers,
- showers,
- shower fixtures,
- shower rooms (areas)
- sinks,
- sink basins,
- sinks found in (health care facilities),
- (hospitals), (dental offices), (patient rooms), (operating rooms), (ICU areas), (shower rooms), and (locker rooms)
- stainless steel,
- stools,
- spas,
- sports arenas (stadiums)
- train (depots) (stations),
- transportation terminals (facilities),
- tables,
- tablet PCs,
- telephones,
- tubs,
- exterior surfaces of toilets,
- toilet exteriors,
- toilets
- exterior surfaces of urinals,
- urinal exteriors,
- urinals,
- walls,
- wash basins,
- vinyl,

(EFFICACY CLAIMS:)

(When used as directed, (Oxivir Tb Wipes) (This product) is effective against a wide variety (broad-spectrum) of pathogenic microorganisms (including bacteria, tuberculosis, 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
<i>Acinetobacter baumannii</i>	(ATCC 19606)	1 minute
<i>Escherichia coli</i> O157:H7	(ATCC 35150)	1 minute
<i>Klebsiella pneumonia</i>	(ATCC 4352)	1 minute
<i>Shigella dysenteriae</i>	(ATCC 11835)	1 minute

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

<i>Enterococcus faecalis</i> (Resistant to Vancomycin (VRE))	(ATCC 51575)	1 minute
<i>Escherichia coli</i> with extended beta-lactamase resistance (ESBL), (ATCC BAA-196)	(ATCC BAA-196)	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

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

***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)	(ATCC VR-740)	1 minute
*Influenza A Virus/Hong Kong, (ATCC VR-544)	(ATCC VR-544)	1 minute
*Norovirus, (Feline Calicivirus as the surrogate)	(Feline Calicivirus , ATCC VR-782 as the surrogate)	1 minute
*Poliovirus Type 1, Strain Brunhilde (Strain Chat)	(ATCC VR- 1000-1562)	1 minute
*Rhinovirus Type 14	(ATCC VR-284)	1 minute
*Rotavirus WA	(Acquired from University of Ottawa)	1 minute

(*Veterinary Viruses:)

*Avian Influenza A Virus (H3N2)	(ATCC VR-2072)	1 minute
*Feline Calicivirus, Strain F9	(ATCC VR-782)	1 minute

TUBERCULOCIDAL:

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

- or -

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

- or -

(5 minutes)

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

FUNGICIDAL:

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

(This product is fungicidal against the pathogenic fungi, *Trichophyton mentagrophytes interdigitale* (ATCC 9533) (the fungus which causes Athlete's Foot) in the presence of a 5% serum load and 10 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 mentagrophytes* (ATCC 9533) (the fungus which causes Athlete's Foot) 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.)~~

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

~~- or -~~
 (This product is fungicidal against the pathogenic fungi, *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 10 minute contact time at 20°C (68°F) on hard, non-porous environmental surfaces.)
 - or -
 (10 minute contact time)
 - or -
 (10 minutes)

(Organism)	(ATCC Number)	(Contact Time)
<i>Trichophyton mentagrophytes interdigitale</i> (ATCC 9533)	<i>Trichophyton mentagrophytes</i> (ATCC 9533)	10 minutes

Non-Food Contact Surface Sanitizer for hard non-porous surfaces:
 [Note to reviewer: ~~Only One~~ of the following statements will be on the product label]

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

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

ALL SURFACES MUST REMAIN WET FOR:
1 minute – Bacteria & *Viruses
5 minutes – Tuberculosis
10 minutes – Fungi

Malodor(s) (Activity) – eliminates (destroys) odors and odor-causing bacteria on hard non-porous surfaces in restroom areas, behind and under sinks and counters, and storage areas (where bacterial growth can cause malodors).

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

{Note to reviewer: We will choose one or more of these statements depending on available space on the product label.}

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

(Emerging **Viral Pathogens Claims)**

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

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

<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>
Enveloped Viruses	One of the following: Feline Calicivirus (ATCC VR-782) / Norovirus Poliovirus type 1 (ATCC VR-1562, Strain Chat) Rhinovirus Type 14 (ATCC VR-284) Rhinovirus Type 37 (ATCC VR-1147) Adenovirus Type 8 (ATCC VR-1368) Rotavirus, Strain WA
Large, Non-Enveloped Viruses	One of the following: Feline Calicivirus (ATCC VR-782) / Norovirus Poliovirus type 1 (ATCC VR-1562, Strain Chat) Rhinovirus Type 14 (ATCC VR-284) Rhinovirus Type 37 (ATCC VR-1147)
Small, Non-Enveloped Viruses	Two of the following: Feline Calicivirus (ATCC VR-782) / Norovirus Poliovirus type 1 (ATCC VR-1562, Strain Chat) Rhinovirus Type 14 (ATCC VR-284) Rhinovirus Type 37 (ATCC VR-1147)

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

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

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

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: For labels that list semi-critical devices as defined by FDA.}

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the blood stream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

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

1. Pre-clean heavily soiled areas.
2. Pull towelette from dispenser (canister) 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 10 minute contact time for fungi.
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) (OneStep) Cleaner/Disinfectant:

1. Pre-clean heavily soiled areas.
2. Pull towelette from dispenser (canister) 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 10 minute contact time for fungi.
4. Wipe surfaces dry (or rinse) (or allow to air dry).

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 10 minute contact for fungi.

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

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

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

1. Pre-clean heavily 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:

1. Pre-clean heavily soiled areas.
2. Pull towelette from dispenser (canister) and wipe hard, non-porous environmental surfaces.
3. All surfaces must remain visibly wet for 10 minutes. Use additional towelettes if needed to ensure the correct wet contact time.
4. Wipe surfaces dry (or rinse) (or allow to air dry).

For use as a Non-Food Contact Sanitizer:

1. Pre-clean heavily soiled areas.
2. 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).

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.

(Package 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

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multiple wipes, pull wipe away from you, out of single wipe dispenser and pull up. Separate wipe at perforation. When finished, close lid to retain moisture.

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

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

(Rigid Can with Traditional-Open Lid)

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

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

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

(Stand Up Pouch)

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

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

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

(FlatPack)

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

[To Open Package:]

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

(Re-sealable soft pack:)

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

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STORAGE AND DISPOSAL:

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

Pesticide Disposal:

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

Container Disposal:

NONREFILLABLE READY-TO-USE FORMULATIONS: *Note to reviewer: The following text will be used on nonrefillable RTU container labels:*

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

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

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

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.

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

Optional Graphics:



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Not a baby wipe
Not for personal use



One-step cleaning
and disinfection



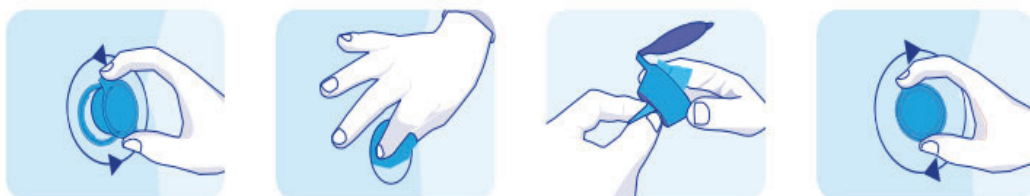
For hard, non-porous
surfaces

(Do not flush symbol from INDA)

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



(Package opening icons)



OXIVIR™ WIPES REFERENCE SHEET

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

DIRECTIONS FOR USE:

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

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

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

EPA Reg. No. 70627-60

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