



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

November 7, 2019

Sara Seltzer
Registration Specialist
Diversey, Inc.
8310 16th St., MS 707
Sturtevant, WI 5317

Subject: PRIA Label Amendment – Adding Efficacy Claims
Product Name: Oxivir 1
EPA Registration Number: 70627-74
Application Date: 02/05/2019
Decision Number: 556984

Dear Ms. Seltzer:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Page 2 of 2
EPA Reg. No. 70627-74
Decision No. 556984

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 Terria Northern by phone at 703-347-0265, or via email at northern.terria@epa.gov.

Sincerely,



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

Enclosure: Accepted label

(Note to Agency: Text appearing in parenthesis is done to show optional text which can be used partially or in its entirety. Commas may be added where needed.)

OXIVIR 1

(MULTI-SURFACE) (ONE-STEP) (HOSPITAL) DISINFECTANT
(SANITIZER) • (CLEANER) • (*VIRUCIDE) • (BACTERICIDE) • (TUBERCULOCIDE) • (FUNGICIDE) • (MILDEWCIDE)
• (DEODORANT) • (Fungicidal disinfectant against *C. auris*)

(Meets surface disinfection recommendations under OSHA Bloodborne Pathogen Standard for *HBV, *HCV & *HIV)

(READY TO USE)

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

Active Ingredient:

Hydrogen Peroxide0.5%

Other Ingredients:.....99.5%

Total:.....100.0%

KEEP OUT OF REACH OF CHILDREN

Net Contents: _____

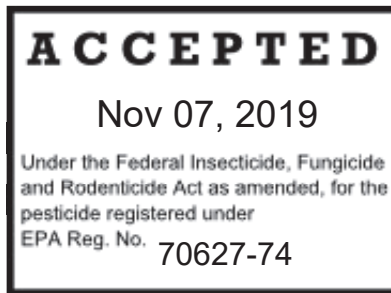
[Made in (Product of) _____]

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

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

(General)

- Acute Oral Toxicity (LD50>5,000 mg/kg) (Category IV)
- Acute Inhalation Toxicity (LC50>2.08 mg/L) (Category IV)
- Acute Dermal Toxicity (LD50>5,050 mg/kg) (Category IV)
- Compatible with most (virtually all) surfaces
- Contains no VOC-emitting ingredients
- Compatible with microfiber (cloths)
- Contains no phosphates
- Deodorizer (Odor Counteractant) (Odor Neutralizer)
- Easy to use
- Formulated with patented hydrogen peroxide technology
- For everyday use (in institutional (and) (industrial) facilities)
- Fragrance Free Formula (Unscented)



[Note to Reviewer: Footnotes for Symbols Mentioned in Label]

*Virucidal Claims

***Candida Auris* Claim

(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.)

Help make any hard, non-porous washable surface where disinfection is required. Oxivir Clean
Leaves a fresh, clean scent
Leaves no (dull) (sticky) residue.
Leaves *[insert use sites from lists below]* smelling clean (with a clean fresh scent)
Leaves surfaces virtually streak-free
No fragrance added
No harsh (chemical) fumes
No streaking (or) (filming) (sticky residue) (formula)
Non-tainting (leaves no unsightly residues)
No rinse required
Non-corrosive (to eyes) (and) (skin)
No mixing, measuring or rinsing required
Not a skin (dermal) sensitizer (non-sensitizer)
Powerful odor control (odor neutralizer) (deodorizer) (odor-counteractant) formula (on hard non-porous surfaces)
Phenol free (No phenols)
Primary Skin Irritation Category IV
Primary Eye Irritation Category IV
Quickly (eliminates 99.9%) (removes) odors
Step-saving, (Labor-saving,) (Time-saving,) (Cost-saving) formula
Suitable for everyday use
Versatile, Fast-acting, Convenient formula

(Allergens)

Breaks down (destroys (eliminates 99.9%) (removes) (the most common) allergens (found in dust)**

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

Reduces allergens**

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

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

(Cleaning)

Clean you expect.
Cleans, deodorizes and brightens in one step
Cleans fast
Cleans grout
Cleans hard, non-porous water washable surfaces!
Cleans (removes) (eliminates 99.9%) (destroys) stains
Cleans (tough) grease and grime (and) (institutional) (soils) (fast)
Cleans (tough) soap scum

Effective – Cleans soap scum

For a cleaner, fresher *[insert use sites/surfaces from lists below]* (or – any hard, non-porous washable surface where disinfection is required.)

For multiple cleaning tasks

For non-scratch cleaning of showers and tubs, shower doors and curtains[†], fixtures and toilet bowls

Good for most indoor cleaning tasks

Intense cleaning action

Keeps day care centers clean

[Note to Reviewer: Footnotes for Symbols Mentioned in Label]

*Virucidal Claims

***Candida Auris* Claim

(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.)

Powerful cleaning

Powers away tough stains (stuck on dirt)

Powerful bubbles blast away (dried) (stuck on) dirt (grime) (food) (spills) (grease) (greasy messes)

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

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

Uses (harnesses) the cleaning power of hydrogen peroxide

Will not leave grit or soap scum

(Antimicrobial-related statements)

An effective one-step sanitizer-cleaner for use on hard non-food contact surfaces

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

Broad-spectrum (Multi-Purpose) (Multi-Surface) (Bactericidal) (*Virucidal) (Tuberculocidal) (Fungicidal) (Sanitizer) (Disinfectant) (activity)

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

Controls (Eliminates 99.9%) odor-causing bacteria

Disinfects as it cleans when used according to disinfection directions for use

Deodorizes odor-causing bacteria

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

Effective against *Candida auris* (*C. auris*) in one minute

Eliminates 99.9% (Kills) (odor-causing) bacteria (from surfaces)

Eliminates 99.9% odors (caused by bacteria), (mold), (mildew)

Fast / Easy / Effective

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

For terminal cleaning

For any non-food contact hard, non-porous surface where germs are a concern.

Kills bacteria (in 1 minute)

Kills *viruses

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

Kills (99.9% of) [the] [cold and flu viruses] in 30 seconds

Kills (Effective against) cold (flu) virus (on hard, nonporous surfaces)

Kills bacteria and sanitizes

Kills odor-causing bacteria

Kills (Destroys) (Eliminates 99.9%) germs while it cleans

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

Kills (and) (or) (inactivates) *Candida auris* on hard, non-porous surfaces.

Kills a minimum of 99.999% or five logs of *Candida auris* on hard, non-porous surfaces.

One-step cleaner sanitizer on soft surfaces[†]

[†]plain cotton weave and 100% polyester fabric

*Canine and Murine parvocidal

Proven to kill *Candida auris* (*C. auris*) in one minute

Sanitizes

Surface cleaner with antibacterial formula

To be used in sanitizing and disinfecting of hard, non-porous non-food contact surfaces and non-critical equipment which may harbor or spread germs

Tough on germs.

Use only one product to get a streak-free shine plus antimicrobial action

[Note to Reviewer: Footnotes for Symbols Mentioned in Label]

*Virucidal Claims

***Candida Auris* Claim

(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.)

BACTERICIDAL: 1 MINUTE

VIRUCIDAL: 30 SECONDS

ANIMAL PREMISE *VIRUCIDAL and ENTEROVIRUS TYPE D68: 1 MINUTE

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

SOFT SURFACE SANITIZATION: 30 SECONDS

FUNGICIDAL: 30 SECONDS

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

(CLAIMS & USES:)

This product cleans, disinfects, and deodorizes hard, nonporous inanimate (environmental) surfaces *[insert use sites/surfaces from lists below]* ~~(and patient care equipment)~~ in one step with no rinsing required. This product is a (one-step,) (broad spectrum,) (hospital,) disinfectant (germicidal) cleaner and deodorizer (odor counteractant) designed for general cleaning, disinfection and deodorizing of hard, nonporous surfaces. (Designed for (non-critical) hard, nonporous surfaces in healthcare.) (It quickly) Removes (bathtub ring,) blood, body fluids, body oils, dirt, fungus, food residue, fecal matter, grime, laboratory stains, mold stains, soils, stains, urine and other organic matter commonly found *[insert use sites/surfaces from lists below]* (or – any hard, non-porous washable surface where disinfection is required.) (on hard, nonporous, inanimate (environmental) surfaces) (where housekeeping is of prime importance in reducing cross-contamination between treated surfaces). It (also) eliminates 99.9% odors leaving (restroom) surfaces smelling clean and fresh. Use where odors are a problem.

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

(This product can be used in the following areas:)

(Medical Facilities:)

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

[Note to Reviewer: Footnotes for Symbols Mentioned in Label]

*Virucidal Claims

***Candida Auris* Claim

(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.)

(General Institutional Facilities:)

(This product has been developed to aid in the reduction of cross-contamination between treated surfaces (not only in hospitals (and healthcare facilities), but also) in:)

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

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

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

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

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

[Note to Reviewer: Footnotes for Symbols Mentioned in Label]

*Virucidal Claims

***Candida Auris* Claim

EPA Reg. No. 70627-74
November 7, 2019
Page 5 of 20

(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.)

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

(Medical Surfaces/Items:)

[Note to Reviewer: When this product is manufactured and listed as an FDA Medical Device General Purpose Disinfectant, it can be used to disinfectant the following noncritical medical items:]

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

[Note to Reviewer: Footnotes for Symbols Mentioned in Label]

*Virucidal Claims

***Candida Auris* Claim

EPA Reg. No. 70627-74
November 7, 2019
Page 6 of 20

(Note to Agency: Text appearing in parenthesis is done to show optional text which can be used partially or in its entirety. Commas may be added where needed.)

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

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

(General Surfaces Items:)

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

(Animal/Veterinary Items:)

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

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

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

[Note to Reviewer: Footnotes for Symbols Mentioned in Label]

*Virucidal Claims

**Candida Auris Claim

EPA Reg. No. 70627-74
November 7, 2019
Page 7 of 20

(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.)

(Soft Surface Sanitization:)

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

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

[†]plain cotton weave and 100% polyester fabric

(This product) (Oxivir 1) [*insert 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*, Multi-Drug Resistant (MDRO)

(This product) (Oxivir 1) [*insert marketed product name*] kills hard-to-kill ESKAPE organisms with a 1 minute kill time.

(This product) (Oxivir 1) [*insert marketed product name*] cleans and disinfects, killing ESKAPE organisms with a 1-minute dwell time.

Kills ESKAPE bacteria (in 1 minute)

DIRECTIONS FOR USE:

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

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

(CLAIMS:)

When used as directed, this product is 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

[Note to Reviewer: Footnotes for Symbols Mentioned in Label]

*Virucidal Claims

***Candida Auris* Claim

(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.)

<i>Pseudomonas aeruginosa</i>	(ATCC 15442)	1 minute
<i>Salmonella enterica</i> , formerly known as <i>Salmonella choleraesuis</i>	(ATCC 10708)	1 minute
<i>Bordetella bronchiseptica</i> ,	(ATCC 10580)	1 minute
<i>Burkholderia cepacia</i> ,	(ATCC 25416)	1 minute
<i>Bordetella pertussis</i> ,	(ATCC 12743)	1 minute
<i>Enterobacter aerogenes</i>	(ATCC 13048)	1 minute
<i>Enterococcus faecium</i> ,	(ATCC 51559)	1 minute
<i>Escherichia coli</i> ,	(ATCC 11229)	1 minute
<i>Escherichia coli</i> O157:H7	(ATCC 35150)	1 minute
<i>Klebsiella pneumonia</i>	(ATCC 4352)	1 minute
<i>Legionella pneumophila</i> ,	(ATCC 33153)	1 minute
<i>Listeria monocytogenes</i> ,	(ATCC 19117)	1 minute
<i>Pasteurella multocida</i> ,	(ATCC 12947)	1 minute
<i>Staphylococcus pseudintermedius</i>	(ATCC 49444)	1 minute
<i>Stenotrophomonas (Pseudomonas) maltophilia</i>	(ATCC 25596)	1 minute
<i>Streptococcus pyogenes</i>	(ATCC19615)	1 minute
<i>Citrobacter freundii</i>	(ATCC 8090)	1 minute
<i>Vibrio cholerae</i>	(ATCC 39050)	1 minute
<i>Campylobacter jejuni</i>	(ATCC 29428)	1 minute
<i>Streptococcus pneumonia</i>	(ATCC 51936)	1 minute
<i>Haemophilus influenzae</i>	(ATCC 33930)	1 minute
<i>Klebsiella oxytoca</i>	(ATCC700324)	1 minute
† Antibiotic-Resistant (Strains of) Bacteria [list below]:		
<i>Acinetobacter baumannii</i> , (Multi-Drug Resistant (MDR)) Ampicillin, Cefazolin, Cefepime, Gentamicin, Ertapenem, and Trimethoprim/Sulfa)	(ATCC 19606)	1 minute
<i>Enterobacter cloacae</i> , (New Delhi metallo-β- lactamase 1 positive (producing) (NDM 1))	(CDC 1000654)	1 minute
<i>Enterococcus faecalis</i> (Resistant to Vancomycin (VRE))	(ATCC 51575)	1 minute
<i>Escherichia coli</i> with extended beta-lactamase resistance (ESBL), (ATCC BAA- 196)	(ATCC BAA-196)	1 minute
<i>Escherichia coli</i> , (New Delhi metallo-β- lactamase 1(NDM-1) producing (positive))	(CDC 1001728)	1 minute
<i>Klebsiella pneumoniae</i> , (Carbapenem Resistant (CRE))	(ATCC BAA 1705)	1 minute
<i>Klebsiella pneumoniae</i> , (Extended Spectrum beta-lactamase (ESBL) producing (positive))	(ATCC700603)	1 minute
<i>Klebsiella pneumoniae</i> , (New Delhi metallo-β- lactamase 1(NDM-1) producing (positive))	(CDC 1000527)	1 minute
<i>Staphylococcus aureus</i> (CA-MRSA), (Community Associated Methicillin Resistant)	(NARSA NRS 123)(Genotype USA400)	1 minute
<i>Staphylococcus aureus</i> , (Methicillin Resistant (MRSA))	(ATCC 33591)	1 minute
<i>Staphylococcus aureus</i> , (Methicillin Resistant (MRSA))	(ATCC 33592)	1 minute
<i>Staphylococcus aureus</i> , (Vancomycin Intermediate Resistant (VISA))	(HIP 5836)	1 minute
<i>Staphylococcus aureus</i> , (Vancomycin Resistant (VRSA))[VRS1]	(VRS1)	1 minute
<i>Staphylococcus epidermidis</i> , (Methicillin Resistant (MRSE))	(ATCC 51625)	1 minute
<i>Streptococcus pneumoniae</i> , (Penicillin Resistant (PRSP))	(ATCC 700677)	1 minute
Multidrug-resistant <i>Klebsiella aeogenes</i> , (formerly <i>Enterobacter aerogenes</i>)	(ATCC BAA-2356)	1 minute
Carbapenem-resistant <i>Escherichia coli</i>	(ATCC BAA-2469)	1 minute
Multidrug-resistant <i>Klebsiella pneumoniae</i>	(ATCC BAA-1705)	1 minute

[Note to Reviewer: Footnotes for Symbols Mentioned in Label]

*Virucidal Claims

***Candida Auris* Claim

(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.)

<i>Klebsiella pneumoniae</i> (NDM-1)	(ATCC BAA-2470)	1 minute
Multidrug-resistant <i>Pseudomonas aeruginosa</i> ,	(ATCC BAA-2108)	1 minute
Multidrug-resistant <i>Enterococcus faecium</i>	(ATCC 51559)	1 minute
VIRUCIDAL:		
<i>[Note to reviewer: Only one of the following statements will be on the product label]</i>		
(in the presence of 5% serum load and 30 second contact time at 20°C (68°F) on hard, non-porous environmental surfaces.)		
- or -		
(30 second contact time)		
- or -		
(30 seconds)		
(Viruses (Virucidal Activity)):		
(Organism)	(ATCC Number)	(Contact Time)
Adenovirus Type 2, (strain: Adenoid 6)	(ATCC VR-846)	30 second
Adenovirus Type 7, (strain: Gomen)	(ATCC VR-7)	30 second
Adenovirus type 8	(ATCC VR-1368)	30 second
Cytomegalovirus,	(ATCC VR-538)	30 second
Hepatitis B Virus (HBV), Duck Hepatitis B Virus as surrogate (Acquired from Hepadnavirus Testing)		30 second
Hepatitis C Virus (HCV), Bovine Viral Diarrhea Virus as surrogate (Acquired from National Veterinary Services Laboratories)		30 second
Herpes Simplex Virus, Type 1 (HSV-1)	(ATCC VR-733)	30 second
Herpes Simplex Virus, Type 2 (HSV-2)	(ATCC VR-734)	30 second
HIV-1 (AIDS Virus), Strain HTLV-III _B (HIV-1)	(Acquired from Adv. Biotechnologies, Inc.)	30 second
Human Coronavirus, (ATCC VR-740)	(ATCC VR-740)	30 second
Influenza A/Hong Kong, (ATCC VR-544)	(ATCC VR-544)	30 second
Influenza B Virus, (ATCC VR-823)		30 second
Measles Virus, (strain: Edmonston, source)	(ATCC VR-24)	30 second
Middle East Respiratory Syndrome Coronavirus (MERS-CoV), (strain: EMC/2012)	BEI Resources	30 second
Norovirus, (Feline Calicivirus as the surrogate)	(Feline Calicivirus, ATCC VR-782 as the surrogate)	30 second
Pandemic Influenza A Virus H1N1		30 second
Parainfluenza Virus Type 3,	(ATCC VR-93)	30 second
Poliovirus Type 1, Strain Brunhilde	(ATCC VR-1000)	30 second
Respiratory Syncytial Virus, (RSV)	(ATCC VR-26)	30 second
Rhinovirus Type 37, Strain 151-1,	(ATCC VR-1147)	30 second
Rotavirus WA	(Acquired from University of Ottawa)	30 second
Vaccinia Virus,	(ATCC VR-119)	30 second
(Viruses with 1 minute contact time:)		
Enterovirus type D68, (Strain US/KY/14-18953)	(ATCC VR-1825)	1 minute
(Animal Viruses:)		
Avian Influenza A Virus (H7N9)		30 second
Avian Influenza A Virus (H3N2)	(ATCC VR-2072)	30 second
Avian Influenza A Virus (H5N1)		30 second
Bovine Viral Diarrhea Virus (BVDV)		30 second
Duck Hepatitis B Virus		30 second
Equine Influenza A Virus (H3N8) (EIV)		30 second
Feline Calicivirus, Strain F9	(ATCC VR-782)	30 second
Murine Norovirus		30 second
(Animal Viruses with a 1 minute contact time:)		

[Note to Reviewer: Footnotes for Symbols Mentioned in Label]

*Virucidal Claims

***Candida Auris* Claim

EPA Reg. No. 70627-74

November 7, 2019

Page 10 of 20

(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.)

Canine Parvovirus,	(ATCC VR-2017)	1 minute
Feline Infectious Peritonitis Virus, (FIPV)	(ATCC VR-2022)	1 minute
Feline Herpes Virus, (Feline Rhinotracheitis)	(ATCC VR-636)	1 minute
Murine Hepatitis Virus,	(ATCC VR-765)	1 minute
Minute Virus of Mouse, (Murine Parvovirus)	(ATCC VR-1346)	1 minute

TUBERCULOCIDAL:

[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 minutes)

(Organism)	(ATCC Number)	(Contact Time)
<i>Mycobacterium bovis</i> (Tb) (OT 451C150)	<i>Mycobacterium bovis</i> (Tb) (OT 451C150)	1 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 interdigitale* (formerly *Trichophyton mentagrophytes*) (ATCC 9533) (the fungus which causes Athlete’s Foot) when used as directed on hard, non-porous surfaces.)

- or -

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

- or -

(30 second contact time)

- or -

(30 second)

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

FUNGICIDAL:

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

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

- or -

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

- or -

(1 minute contact time)

- or -

(1 minute)

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

**** (Fungicidal):**

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

(Using Standard Quantitative Disk Carrier Test Method

[Note to Reviewer: Footnotes for Symbols Mentioned in Label]

*Virucidal Claims

***Candida Auris* Claim

(Note to Agency: Text appearing in parenthesis is done to show optional text which can be used partially or in its entirety. Commas may be added where needed.)

(under Good Laboratory Practices, [GLPs]), in the presence of soil and 1 minute contact time, against <i>Candida auris</i> (CDC AR-0381) and <i>Candida glabrata</i>(ATCC 26512))		
(Organism)	(ATCC Number)	(Contact Time)
<i>Candida glabrata</i>	(ATCC 26512)	1 minute
<i>Candida auris</i>	(CDC AR-0381)	1 minute
Non-Food Contact Surface Sanitizer for hard non-porous surfaces: <i>[Note to reviewer: Only one of the following statements will be on the product label]</i>		
(in the presence of 5% serum load and 10 second contact time at 20°C (68°F) on hard, non-porous environmental surfaces.) - or - (in the presence of a 5% serum load and 10 second contact time (at 20°C (68°F)) on hard, non-porous environmental surfaces.) - or - (10 second contact time) - or - (10 seconds)		
(Organism)	(ATCC Number)	(Contact Time)
<i>Acinetobacter baumannii,</i>	(ATCC 19606)	10 seconds
<i>Campylobacter jejuni,</i>	(ATCC 29428)	10 seconds
<i>Enterobacter aerogenes,</i>	(ATCC 13048)	10 seconds
<i>Enterococcus faecalis, (Resistant to Vancomycin [VRE])</i>	(ATCC 51575)	10 seconds
<i>Escherichia coli O157:H7</i>	(ATCC 35150)	10 seconds
<i>Klebsiella pneumonia</i>	(ATCC 4352)	10 seconds
<i>Listeria monocytogenes</i>	(ATCC 19111)	10 seconds
<i>Pseudomonas aeruginosa</i>	(ATCC 15442)	10 seconds
<i>Salmonella enterica, (formerly known as Salmonella choleraesuis)</i>	(ATCC 10708)	10 seconds
<i>Staphylococcus aureus</i>	(ATCC 6538)	10 seconds
<i>Staphylococcus aureus, (Resistant to Methicillin [MRSA])</i>	<i>Staphylococcus aureus,</i> (ATCC 33592)	10 seconds
Soft Surface Spot Sanitizer <i>[Note to reviewer: Only one of the following statements will be on the product label]</i>		
- (in the presence of 5% serum load and 30 second contact time on cotton or polyester fabrics (surfaces) - or - (30 second contact time) - or - (30 seconds)		
(Organism)	(ATCC Number)	(Contact Time)
<i>Staphylococcus aureus,</i>	(ATCC 6538)	30 seconds
<i>Enterobacter aerogenes</i>	(ATCC 13048)	30 seconds
<i>Enterococcus faecalis, (Resistant to Vancomycin [VRE])</i>	(ATCC 51575)	30 seconds
<i>Staphylococcus aureus, , (Resistant to Methicillin [MRSA])</i>	(ATCC 33592)	30 seconds

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

Mold/Mildew (Mildewstatic Activity): Controls and prevents the growth of mold and mildew: *Aspergillus brasiliensis* (formerly known as *Aspergillus niger*) (and the odors caused by them) when applied to hard, non-porous environmental surfaces.

[Note to Reviewer: Footnotes for Symbols Mentioned in Label]

*Virucidal Claims

***Candida Auris* Claim

(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.)

Malodor(s) (Activity) (Counteractancy) – eliminates 99.9% (destroys) odors and odor-causing bacteria on hard, nonporous surfaces in restroom areas, behind and under sinks and counters, and storage areas (and other places where bacterial growth can cause malodors).

(Optional Pandemic Influenza Statements)

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

(Emerging Pathogens Claims)

(Oxivir 1) (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 virus	Enterovirus type D68 (Strain US/KY/14-18953)
Large, non-enveloped virus	Enterovirus type D68 (Strain US/KY/14-18953)
Small, non-enveloped virus	Canine Parvovirus Enterovirus type D68 (Strain US/KY/14-18953)

(Oxivir 1) (This product) has demonstrated effectiveness against viruses similar to *[insert name of emerging virus]* on hard, non-porous surfaces. Therefore, Oxivir 1 (this product) 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.

[Name of illness / outbreak] is caused by *[insert name of emerging virus]*. Oxivir 1 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.

(Packaging Related Statements) *(Note to Reviewer: Appropriate language can be selected from this section, depending on packaging, but is not required.)*

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

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

(For containers with top pump dispensing mechanism:)

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

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

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

Refill only with this product.

To Refill (Spray Bottles): Remove trigger sprayer from empty bottle.

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

(Note to Agency: Text appearing in parenthesis is done to show optional text which can be used partially or in its entirety. Commas may be added where needed.)

(Note 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.)

To Use as a One-Step Cleaner/Disinfectant:

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

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

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

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

(The below sentence is optional language:)

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

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

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

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

[Note to Reviewer: Footnotes for Symbols Mentioned in Label]

*Virucidal Claims

***Candida Auris* Claim

(Note to Agency: Text appearing in parenthesis is done to show optional text which can be used partially or in its entirety. Commas may be added where needed.)

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

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

To Disinfect Non-Critical, Pre-cleaned Instruments:

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

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

To Clean and Disinfect Manikins Used in CPR Training:

Manikins should be cleaned as soon as possible at the end of each class to avoid drying of contaminants on surfaces. Disassemble the manikin as directed by manufacturer's instructions. Spray surface with this product until thoroughly wet. Let stand for 1 minute and rinse with potable water.

[Note to Reviewer: Footnotes for Symbols Mentioned in Label]

*Virucidal Claims

***Candida Auris* Claim

EPA Reg. No. 70627-74
November 7, 2019
Page 15 of 20

(Note to Agency: Text appearing in parenthesis is done to show optional text which can be used partially or in its entirety. Commas may be added where needed.)

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

1. Pre-clean heavily soiled areas.
2. Spray 6-8 inches from surface until surface is thoroughly wet.
3. Allow surfaces to remain wet for 1 minute.
4. Rinse with sterile water.
5. Wipe with a dry, clean cloth and let air dry.

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

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

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

1. Drain: Drain the water (from) (the) (unit) (basin) (bowl) and remove any visible debris.
2. Clean: Thoroughly clean all surfaces with (this product) (soap) (detergent), then rinse with water and drain.
3. Apply: Spray this product 6 – 8 inches from hard, non-porous surfaces.
4. Scrub: Brush or swab thoroughly and allow solution to stand for 1 minute.
5. Rinse (cleaned) (treated) (surfaces) with fresh water and drain.

For Use as a Cleaner/Disinfectant on External Surfaces of Toilet Bowls:

1. Pre-clean heavily soiled areas.
2. Empty toilet bowls by forcing water through the trap. Spray 6 – 8 inches from exposed surfaces in toilet bowls.
3. Swab entire surface area especially under the rim.
4. Allow entire surface to remain wet for 1 minute.
5. Flush toilet and rinse swab applicator thoroughly.

***KILLS HIV, HCV and HBV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in health care settings (Hospitals, Nursing Homes) and other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood/body fluids, and in which the surfaces/objects likely to be soiled with blood/body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS), Hepatitis C Virus (HCV) or Hepatitis B Virus (HBV).

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

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

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

Contact Time: Allow surface to remain wet for 30 seconds to kill HIV-1, HCV and HBV, 4 minutes for mold, and 1 minute to kill all other organisms cited on label.

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

[Note to Reviewer: Footnotes for Symbols Mentioned in Label]

*Virucidal Claims

***Candida Auris* Claim

EPA Reg. No. 70627-74
November 7, 2019
Page 16 of 20

(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.)

Animal Housing Facilities (Including Veterinary Clinics, (Equine) Farms, Livestock, Swine and Poultry Houses):

For cleaning and disinfecting the following hard, non-porous surfaces: feeding and watering equipment, utensils, instruments, cages, kennels, stables, catteries, etc.

1. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc.
2. Remove all litter, droppings and manure from floors, walls and surfaces of facilities (including barns, pens, stalls, chutes, and barns) occupied or traversed by animals.
3. Empty (or cover) all troughs, racks, and other feeding and watering appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with potable water.
5. Saturate all hard, non-porous surfaces by spraying with product until thoroughly wet. To disinfect, all surfaces must remain wet for 1 minute.
6. Immerse or spray all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.
7. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.
8. Thoroughly scrub treated feed racks, troughs, mangers, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

To Kill Fungi:

For *Candida auris*, please see special instructions. Pre-clean heavily soiled areas. Spray 6 – 8 inches from hard, nonporous surface until completely wet. Allow to remain wet for 30 seconds. Wipe surfaces and let air dry.

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

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

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

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

Disinfection Procedure: Pre-clean heavily soiled areas. Spray 6 – 8 inches from hard, nonporous surface until completely wet. Allow to remain wet for 30 seconds. Wipe surfaces and let air dry.

To Use as a Non-Food Contact Sanitizer:

1. Pre-clean heavily soiled areas.
2. Apply product with trigger sprayer, cloth, (microfiber cloth,) (sponge,) (disposable wipe) (or) (mop) to hard, non-porous environmental surfaces.
3. Allow the surface to remain wet for 10 seconds.
4. Wipe surfaces dry (or rinse) (or allow to air dry).

To Sanitize Soft Surfaces[†]:

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

[†]plain cotton weave and 100% polyester fabric

To Kill Mold and Mildew:

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

To Control Mold and Mildew:

[Note to Reviewer: Footnotes for Symbols Mentioned in Label]

*Virucidal Claims

***Candida Auris* Claim

EPA Reg. No. 70627-74

November 7, 2019

Page 17 of 20

(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.)

Spray 6 – 8 inches from hard, nonporous surfaces until completely wet. Let air dry (or wipe surface dry) (or rinse). Repeat application weekly or when growth reappears.

To Clean (and/or Deodorize):

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

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

To Clean/Remove Soap Scum:

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

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

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

(Allergen Destruction)

To Clean and Destroy Specified Allergens: Spray, 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

(Note to Agency: Text appearing in parenthesis is done to show optional text which can be used partially or in its entirety. Commas may be added where needed.)

STORAGE AND DISPOSAL

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

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

Store in a dry, well-ventilated area away from chemicals, direct light, heat or open flame.

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

(For containers smaller than 5 gallons:)

CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill empty container. Offer empty container for recycling, if available, or discard in trash.

(For containers 5 gallons and larger:)

CONTAINER HANDLING: Non-refillable container. Do not reuse or refill this container. Offer for recycling or reconditioning, or (puncture and) dispose of in a sanitary landfill; or incinerate, or, if allowed by state and local authorities, burn. If burned, stay out of smoke.

(For bottles intended to be refilled by the end-user i.e. not for resale:)

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Store this product in areas inaccessible to small children. Keep securely closed. 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.

CONTAINER HANDLING: Do not reuse or refill this container except as described in the directions for use. Refill only with this product. Offer empty container for recycling, if available, or discard in trash.

(For labels with animal housing/veterinary use patterns:)

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

EPA Reg. No. 70627-74

EPA Est. No.

(Lot code letters indicate establishment number.)

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

© 2019 Diversey, Inc., P.O. Box 19747, Charlotte, NC 28219-0747 U.S.A. All Rights Reserved

[Graphics:]



Hydrogen Peroxide (logo) patent pending



[Note to Reviewer: Footnotes for Symbols Mentioned in Label]

*Virucidal Claims

***Candida Auris* Claim

EPA Reg. No. 70627-74

November 7, 2019

Page 19 of 20

(Note to Agency: Text appearing in parenthesis is done to show optional text which can be used partially or in its entirety. Commas may be added where needed.)

REFERENCE SHEET

OXIVIR 1

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

DIRECTIONS FOR USE:

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

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

See the container label for use directions and additional required information for use, storage and disposal.

EPA Reg. No. 70627-74

[Manufactured for:] © 2019 Diversey, Inc., P.O. Box 19747, Charlotte, NC 28219-0747 U.S.A. All Rights Reserved.

[Note to Reviewer: Footnotes for Symbols Mentioned in Label]

*Virucidal Claims

***Candida Auris* Claim

EPA Reg. No. 70627-74
November 7, 2019
Page 20 of 20