

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

November 28, 2022

Rebecca Mannion Agent for Scientific & Regulatory Consultants, Inc. Representing Midlab Electronic Transmittal: <u>rmannion@srcconsultants.com</u>

Subject: PRIA Label Amendment – Adding Efficacy Claims Product Name: HP202 EPA Registration Number: 45745-11 Received Date: June 13, 2022 Action Case Number: 00370252

Dear Rebecca Mannion:

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. Pursuant to 40 CFR 156.10(a)(6), 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 FIFRA and is subject to review by the Agency. See FIFRA section 2(p)(2). If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process, FIFRA section 12(a)(1)(B). Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Assurance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

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with FIFRA section 6. If you have any questions, please contact Zebora Johnson by phone at (202) 566-0730, or via email at johnson.zebora@epa.gov.

Sincerely,

Steven Ingdorman

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

Enclosure: Accepted Label

HP202

ACTIVE INGREDIENT:	
Hydrogen Peroxide	4.25%
OTHER [INERT] INGREDIENTS:	<u></u>
TOTAL:	

KEEP OUT OF REACH OF CHILDREN CAUTION

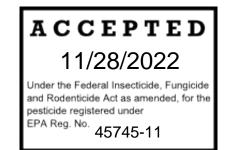
See additional precautionary statements on [back] [below][side] [left] [right] (panel) (of) (label)

(See reference sheet (enclosed in each case) for (a complete list of *pathogenic organisms) (additional features, claims, direction for use) (claimed for this product) (eliminated by this product).)

A reference sheet may be included with the phrase 'Reference Sheet' added to the top, listing claims and uses that appear on this label.

Net Contents: EPA Reg No. 45745-11 EPA Est No.

[Distributed by:][Manufactured by:] Midlab 140 Private Brand Way Athens, TN 37303



OPTIONAL CLAIMS – May appear on any panel of the label in any order. "This product" may be replaced with the specific product brand name.

FEATURES, CLAIMS & USES:

ONE-STEP DISINFECTANT[§] CLEANER AND DEODORANT

(MULTI-SURFACE[§])(DISINFECTANT[§]) • (ONE-STEP DISINFECTANT[§]) • (CLEANER) • (*VIRUCIDAL) • (BACTERICIDAL) • (DEODORIZER) (ODOR COUNTERACTANT) (ODOR NEUTRALIZER) • (NON-DULLING TO [FLOORS] [FLOOR FINISHES]) (CONCENTRATE) (CLEANS, DISINFECTS[§] & DEODORIZES)

(Restroom) (&) (Bathroom) (Disinfectant[§] Cleaner)

Hospital Disinfectant[§] Cleaner

Multi-Surface Disinfectant[§] Cleaner

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

This product is a one-step (hospital-use) germicidal[‡] disinfectant[§] cleaner and ([deodorant] [odor-counteractant] [odor neutralizer]) designed for general cleaning, (and) disinfecting, (deodorizing) (and controlling mold and mildew odors) (on) (of) hard, non-porous surfaces when used according to disinfection directions.

This product cleans, disinfects[§] and deodorizes hard, non-porous surfaces in one step when used according to disinfection directions.

[This product][Is a disinfectant[§] cleaner that] cleans, disinfects[§] and deodorizes in one labor saving step.

[This product] [It] cleans quickly by removing dirt, grime, mold & mildew, (odors,) (stains, food residue, body oils, dead skin, blood and other common soils (organic matter) (commonly) found in *insert sites from Locations List or Medical Locations and Surfaces List* only on hard, non-porous non-food contact (medical) surfaces.

[It is designed for use on] [Use daily on] (the following) hard, non-porous (inanimate) surfaces: *insert from Surfaces List or Medical Locations and Surfaces List* (- any hard, non-porous washable non-food contact surface where disinfection is required.)

Use where odors are a problem.

[This product] [It] cleans, disinfects[§] and deodorizes hard, non-porous surfaces by killing odor-causing microorganisms.

Cross-contamination is of major housekeeping concern. This product has been formulated to aid in the reduction of cross-contamination between treated surfaces not only in hospitals, but in schools, institutions, and industry.

[Bathroom] [Restroom] [Bowl] Disinfectant[§] Cleaner [for] [use on] (hard nonporous surfaces): *insert from Surfaces List.*

This product is a (concentrated) (bowl and) (bathroom) (restroom) cleaner that cleans, disinfects[§] and deodorizes in one easy step when used according to disinfection directions.

Its non-abrasive formula is designed for use on hard, non-porous (restroom) surfaces: *insert from Surfaces List or Medical Locations and Surfaces List.*

[Its non-abrasive formula is designed for use] [Use it daily] on hard, non-porous [bathroom] [restroom] surfaces: *insert from Surfaces List or Medical Locations and Surfaces List.*

It cleans, disinfects[§] and deodorizes *insert from Surfaces List* and all hard nonporous, washable surfaces found in the bathroom (restroom) (in the presence of 5% organic soil).

Removes and/or cleans Bathtub ring, Blood, Body oils, Dirt, Fecal matter, Grime, Laboratory stains, Common soils and/or stains, Organic matter, Urine.

[This product] [It] (also) reduces odor-causing bacteria leaving [bathrooms] [restrooms] [surfaces] smelling clean and fresh.

This product cleans, disinfects[§] and deodorizes hard, non-porous [hospital] [medical] surfaces in one step (with no rinsing required) when used according to disinfection directions (for the following use sites): *insert from Medical Locations and Surfaces List*.

(Animal Housing Facilities:) This product cleans by removing dirt, grime, (mold & mildew) (odors) (stains), blood, urine, fecal matter and other common soils found in *insert from Locations list.*

[Its non-abrasive formula is designed for use on] [Use daily on] [Use daily to clean and disinfect[§]] hard, non-porous surfaces: *insert from Surfaces List* found in [barns, pens and stalls] [animal housing facilities].

It can also be used to pre-clean and disinfect[§] hospital items: wheelchairs, [hospital] [patient] bed rails and linings, wash basins, bed pans, medical equipment surfaces (- any washable non-food contact surface where disinfection[§] is required.)

Locations List – commas may be added as well as "and" "to" make a complete sentence:

- hospitals
- nursing homes
- (acute) (and) (long-term) care facilities
- office buildings
- schools
- colleges [universities]
- day care centers
- Medical (and) (dental) offices
- funeral homes
- transportation facilities

- train [depots] [stations]
- bus [depots] [stations]
- airports
- cruise ships
- casinos
- correctional facilities
- athletic facilities
- playgrounds
- locker rooms
- health clubs
- barber/beauty [salons] [shops]

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- veterinary clinics
- pet [shops] [stores]
- equine farms
- animal life science laboratories
- hotels
- motels
- public areas and restrooms
- foodservice establishments
- restaurants
- commercial kitchens
- federally inspected meat and poultry establishments
- food (and) (beverage)
 [processing] [brewing] plants

- [dairies] [dairy farms]
- warehouses
- industrial (and) (commercial) buildings
- animal housing facilities
- livestock, swine or poultry facilities
- grooming facilities
- farms
- kennels
- laboratories or other small animal facilities
- cages
- animal equipment

Surfaces List - commas may be added as well as "and" and "to" make a complete sentence

- vinyl
- painted surfaces
- plastic (surfaces)
- glass
- mirrors
- glazed ceramic
- glazed porcelain
- chrome
- stainless steel
- plated steel
- aluminum
- Plexiglas

- laminated surfaces and baked enamel surfaces associated with
 - floors, walls,
 - and non-food
 - contact countertops
 - walls
- wallsceilings
- tables
- tables
- chairs
- countertops
- telephones
- fixtures

- athletic equipment
- exercise equipment
- glazed tile
- toilet(s)
- (bowls)(rims)
- urinals
- sinks
- sink basins
- faucets
- tubs
- shower rooms and locker room areas
- sealed concrete

Medical Locations and Surfaces List - commas may be added as well as "and" and "to" make a complete sentence

- ambulances or [emergency medical] transport vehicles
- ambulatory care centers
- ambulatory surgical centers (ASC)
- anesthesia rooms or areas
- anesthesia machines

- apheresis machines
- [assisted living]
 [full care]
 nursing homes
- autoclaves[¶]
- bathroom doorknobs

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- bedpans
- bed rails
- [bedside] commodes
- bedside tables
- blood pressure cuffs
- blood pressure (BP) monitors
- cabinet handles
- call boxes
- [CAT]
 [Computerized Axial Tomography]
 equipment
- CAT Laboratories
- carts
- cellular phones
- central service areas
- central supply [rooms] [areas]
- chairs
- charging stations
- closet handles
- coated mattresses
- coated pillows
- computer mouse
- computer peripherals
- computer tables
- cords
- counters
- [crash]
 [emergency]
 carts
- [Critical Care Units] [CCUs]
- desktops
- diagnostic equipment

- dialysis [clinics] [facilities]
- external surfaces of dialysis machines
- docking stations
- doctor's offices
- [blood] [plasma] [semen] [milk] [apheresis] donation centers
- examination rooms or areas
- [emergency rooms] [ERs] surfaces
- [exam] [examination] tables
- exterior surfaces of air vents or air vent exteriors
- external surfaces of (medical) equipment or (medical) equipment surfaces
- external surfaces of ultrasound transducers (and/or probes)
- exterior of pipes
- eye surgical centers
- footboards
- gurneys
- handheld (electronic) devices
- hard, nonporous edges of privacy curtains
- hard, nonporous hospital

or medical surfaces headboards

- healthcare settings or facilities
- high touch surfaces
- home health care (settings)
- (hospital) headboards
- External surfaces of ultrasound transducers (and/or probes)
- hospices
- [hospital]
 [patient] bed(s)
 (springs)
 (railings)
 (frames)
- [linings] [inner] [inside of] drawers
- isolettes
- IV [stands] [pumps] Jpoles]
- Intensive Care Units or ICU[s] [areas]
- isolation areas
- keyboards
- laboratories
- laptops
- laundry rooms
- long term care facilities
- loupes
- mammography equipment
- [Mayo]
 [instrument]
 stands
- medication carts
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- (medical) clinics
- Medical facilities
- [medical]
 [physician's]
 [doctor's] offices
- Mobile devices
- mobile electronic equipment
- mobile workstations
- mouse pads
- [MRI] [Magnetic Resonance Imaging equipment]
- nonporous hospital mattresses
- nurse-call [devices]
 [buttons] (and cords)
- nursing homes, nursing or nurses' stations
- operating room tables and lights
- operatory light switches
- overbed tables
- operating rooms
- ophthalmic offices
- Out-Patient [Surgical Centers (OPSC)] [Clinics] [Facilities]
- Pagers

- patent chairs
- patient monitoring equipment
- patient support and delivery equipment
- phlebotomy trays
- pharmacies
- phone cradle
- physical therapy rooms
- patient areas
- physician's offices
- [physical therapy] [PT] equipment
- plastic mattress covers
- psychiatric facilities
- power cords
- public [care] areas
- pulse oximeters
- PVC tubing
- [Radiology] [X-Ray] [rooms] [areas]
- reception
 [counter]
 [desks] [areas]
- recovery rooms
- rehabilitation
- centers
- remote controls

- respirators
- respiratory therapy equipment
- respiratory centers
- respiratory therapy [rooms] [areas]
- restrooms
- scales
- sequential compression devices
- shower fixtures
- side rails
- slit lamps
- spine
- backboards
- stethoscopes
- stools
- stretchers
- support bars
- Surgery Rooms
- Operating Rooms
- tablet PCs
- toilet handholds
- traction devices
- waiting [rooms] [areas]
- walls [around toilet] [in patient rooms]
- wash basins
- wheelchairs
- x-ray equipment paddles

Cleans.

Cleans and disinfects[§] without dulling gloss.

Cleans, Deodorizes and Brightens in One Step.

Cleans everyday messes.

Cleans Grout.

Cleans hard, non-porous water washable surfaces!

Cleans to a shine.

Cleans (floors) (glass) (carpets) (countertops) (bathrooms) (kitchens) (hard, nonporous surfaces).

Clear drying formula.

[Concentrate] [Concentrated], [Disinfects[§]] [Disinfectant[§]] [Cleans] [Cleaner].

Contains hydrogen peroxide.

Counteracts [common] [hospital] malodors.

Cuts cleaning time.

Daily cleaning.

Daily defense against [*germs] [*pathogenic microorganisms].

Deodorizes by killing microorganisms that causes offensive odors.

Designed for daily use on common materials found in hospitals.

Degradable active ingredients.

Degreaser

Designed for healthcare (non-critical hard nonporous surfaces).

Do not use on marble or un-sealed/un-coated terrazzo floors.

Do not use on glasses, dishes, and utensils.

Economical concentrate.

Is effective yet economical.

Effective against antibiotic resistant bacteria**

Fast strong cleaning.

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

For use in [dilution systems[^]] [dilution systems[^]] [Dilution System trade name[^]].

Fragrance free.

Fragrance Free Formula

Good for use with microfiber cloths.

Hydrogen Peroxide Disinfectant[§] Cleaner

Incidental or accidental splash, spray or spills can happen. These will not [stain] [discolor] [bleach] uniforms, furnishings, equipment, clothing or color safe fabrics.

Is a complete disinfectant[§] that provides clear use solutions even in the presence of hard water.

Is an economical concentrate (that can be diluted for use) (with a mop and bucket, cloth, microfiber cloth, sponge, low pressure mechanical spray device, coarse spray device or by soaking).

Kills odor causing bacteria.

Kills 99.9% of *insert organism name from Organism Claim list* in *insert corresponding contact time for listed organism*§

Kills *viruses on hard, nonporous surfaces

Leaves no visible residue.

Makes cleaning easier.

May be used to clean and disinfect[§] finished floors.

May be used to clean and disinfect[§] floor areas, sinks, faucets, bathrooms and tubs.

Meets Surface Disinfection Recommendations From OSHA Bloodborne Pathogen Standard For HBV & HIV

Multi surface cleaner disinfectant[§] for hard, non-porous surfaces.

No added (perfumes) (fragrances) (and) (or) (dyes).

No alcohol smell cleaner.

Non-abrasive.

SARS-CoV-2 claims

Effective against SARS-Related Coronavirus 2 (SARS-CoV-2) (the virus that causes COVID-19) (and variant hCoV-19/Delta/PHC658/2021) (and Delta variant) \pm

[Kills 99.9%] [Eliminates 99.9%] of SARS-CoV-2 (the virus that causes COVID-19) (and variant hCoV-19/Delta/PHC658/2021) (and Delta variant)[±]

[Kills] [Effective against] the virus that causes COVID-19[±] (and variant hCoV-19/Delta/PHC658/2021) (and Delta variant) [in 30 seconds].

One-step disinfectant[§] for killing SARS-CoV-2[±] (and variant hCoV-19/Delta/PHC658/2021) (and Delta variant) [in 30 seconds] [in the presence of soil].

Tested [proven effective] against SARS-CoV-2[±] (and variant hCoV-19/Delta/PHC658/2021) (and Delta variant) [in 30 seconds]

The smell of clean.

This product deodorizes areas that are hard to keep fresh smelling.

(This product) [kills,] [eliminates] 99.9%, removes and destroys germs‡, bacteria and viruses* on hard, non-porous surfaces.

This (product's) formula will not dull surfaces, eliminating time and labor normally required for rinsing.

This product will deodorize hard, nonporous surfaces (where (obnoxious) (nasty) (disagreeable) odors may develop).

This product will deodorize surfaces and other places bacteria growth can cause malodors.

Unscented

Use Daily to Prevent the Buildup of Dirt and Grime.

Will disinfect[§], clean and deodorize hard, nonporous surfaces in rest rooms and toilet areas, behind and under sinks and counters, garbage cans and garbage storage areas, and other places where bacterial growth can cause malodors.

Will not leave grit or soap scum.

Electrostatic Sprayer Claims

Positively charged antimicrobial droplets are attracted to negatively charged environmental surfaces allowing for improved coverage on hard, non-porous environmental surfaces.

May be applied with an electrostatic sprayer.

For use with electrostatic sprayers.

Microorganism Claims

When used as directed, this product is effective against a wide variety (broadspectrum) of ‡pathogenic microorganisms (including bacteria, **antibiotic-resistant bacteria, and *viruses). At a 1:64 dilution (2 fl. oz. of product per gallon of water), in the presence of 200 ppm hard water, 5% serum load and 10 minute contact time, unless otherwise noted, this product kills the following on hard, non-porous inanimate surfaces:

[Bacteria] [Bactericidal Activity]:

Pseudomonas aeruginosa (ATCC 15442) Staphylococcus aureus (ATCC 6538) Salmonella enterica (formerly known as Salmonella choleraesuis) (ATCC 10708) Escherichia coli (0157:H7) (ATCC 35150) ^BListeria monocytogenes (ATCC 19117) **Staphylococcus aureus, Methicillin resistant (MRSA) (ATCC 33592) **Staphylococcus aureus, [Community Acquired Methicillin-resistant] [(CA-MRSA)] USA300 (NRS 384) **Staphylococcus aureus, [Community Acquired Methicillin-resistant] [(CA-MRSA)] USA400 (NRS 123) **Staphylococcus epidermidis, [Methicillin-resistant] [(MRSE)] (ATCC 51625) Streptococcus pneumoniae (ATCC 6305)

**Streptococcus pneumoniae, [Penicillin-resistant] [PRSP] (ATCC 700677)

^{*∞*}***Enterococcus faecalis,* [Vancomycin Resistant] [VRE] (ATCC 51575)

***Viruses (Virucidal Activity):** At a 1:64 dilution (2 fl. oz. of product per gallon of water), in the presence of 200 ppm hard water, 5% serum load and 5 minute contact time, unless otherwise noted, this product kills the following on hard, non-porous inanimate surfaces:

*Adenovirus type 8 (ATCC VR-1368)

*Enterovirus type D68 (ATCC VR-1825, Strain US/KY/14-18953)††

*Hepatitis B Virus (HBV) (Duck Hepatitis B Virus as the surrogate) on pre-cleaned surfaces

*Hepatitis C Virus (HCV) (Bovine Viral Diarrhea Virus as the surrogate)

*Herpes Simplex Virus Type 1 (ATCC VR-733)

*Herpes Simplex Virus Type 2 (ATCC VR-734)

*HIV-1 (Human Immunodeficiency Virus Type 1) (AIDS virus) (1 minute contact time) *The full virus name will appear at least once when used on the label.*

*Human Coronavirus (ATCC VR-740, Strain 229E) ††

*Influenza Virus Type A (H1N1) (ATCC VR-1469) (1 minute contact time)

*Influenza B Virus (ATCC VR-823) (Strain B/5/72) (1 minute contact time)††

*Norovirus (Feline Calicivirus as the surrogate)

*Respiratory syncytial virus (ATCC VR-26, Strain Long) ++

*Rhinovirus Type 37 (ATCC VR-1147)

*Rotavirus (ATCC VR-2018)

*SARS-Related Coronavirus 2 (SARS-CoV-2), BEI Resources NR-52281, Strain Isolate USA-WA1/2020 (the virus that causes COVID-19) (ATCC CRL-1586) (30-second contact time)††

^α*SARS-Related Coronavirus 2 (SARS-CoV-2) Delta Variant (B.1.617.2), BEI Resources NR-55611, Strain hCoV-19/PHC658/2021 (the virus that causes COVID-19) (ATCC CRL-1586) (30 second contact time)††

Animal Premise Virucidal* Performance: This product kills the following viruses in 5% soil on hard, non-porous surfaces: *Parenthetical dilute rate and contact times are required to appear on the label*

*Canine Parvovirus (CPV) (ATCC VR-2017) (8 fl. oz. per gallon, 10 minute contact time)

*Murine Norovirus (MNV-1) (4 fl. oz. per gallon, 10 minute contact time)
 *Avian Influenza A (H7N9) virus[≠] (2 fl. oz. per gallon, 1 minute contact time)

Fungicidal Performance: This product kills the following fungi in 10 minutes at 1:16 (8 fl. oz. per gallon of water), (in the presence of 200 ppm hard water, 5% serum load,) on hard, non-porous surfaces: *Trichophyton interdigitale* (Athlete's foot fungus) (a cause of ringworm) (ATCC 9533).

Bactericidal Stability of Use Solution: When diluted at 2 fl. oz. of product per gallon of water, in the presence of 400 ppm hard water, and a 10 minute contact time, this product remains effective against *Staphylococcus aureus* and *Pseudomonas aeruginosa* for up to 6 days when stored at room temperature in a sealed trigger spray bottle. If the solution becomes visibly dirty or contaminated, prepare fresh product.

Sanitizing: When used as a non-food contact sanitizer at a 1:16 dilution (8 fl. oz. of product per gallon of water), in the presence of 200 ppm hard water, 5% serum load, this product reduces the following bacteria by 99.9% with a 1 minute contact time on hard non-porous inanimate surfaces: *Staphylococcus aureus* (ATCC 6538) *Klebsiella aerogenes* (ATCC 13048)

Sanitizing: When used as a non-food contact sanitizer at a 1:128 dilution (1 fl. oz. of product per gallon of water), in the presence of 200 ppm hard water, 5% serum load, this product reduces the following bacteria by 99.9% with a 5 minute contact time on hard non-porous inanimate surfaces: *Klebsiella aerogenes* (ATCC 13048) *Salmonella enterica* (ATCC 6539)

Emerging Viral Pathogen Claims

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

[Product Name] [this product] meets the criteria to make claims against emerging pathogen claims from the following viral categories:

- Enveloped viruses
- Large non-enveloped viruses
- Small non-enveloped viruses

For an emerging viral pathogen that is a/an	<i>follow the directions for use for the following organisms on the label</i>
Enveloped virus	Norovirus (Feline Calicivirus as the
	surrogate)
	Rhinovirus Type 37
Large, non-enveloped virus	Norovirus (Feline Calicivirus as the
	surrogate)
	Rhinovirus Type 37
Small, non-enveloped virus	Norovirus (Feline Calicivirus as the
	surrogate)
	Rhinovirus Type 37

[Product Name] (this product) has demonstrated effectiveness against viruses similar **to insert name of emerging virus** on hard, nonporous surfaces. Therefore, product name (this product) can be used against **insert name of emerging virus** when used in accordance with the directions for use against **Norovirus -or-Rhinovirus Type 37** on hard, nonporous surfaces. Refer to the CDC -or- OIE website at **insert pathogen-specific website address** for additional information.

Insert name of illness/outbreak is caused by **insert name of emerging virus**. **Product name** (this product) kills similar viruses and therefore can be used against insert name of emerging virus when used in accordance with the directions for use against **Norovirus -or- Rhinovirus Type 37** on hard, nonporous surfaces. Refer to the CDC -or- OIE website at **insert pathogen-specific website address** for additional information.

(Modes of Application:)

This product, unless otherwise noted, can be applied by mop, sponge, cloth, (low pressure mechanical spray device,) (coarse) (trigger sprayer), (or auto-scrubber). Change cloth, sponges or towels frequently to avoid redeposition of soil.

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

Reviewer note: Bulleted use directions may be written in paragraph form. If the label includes a SARS-CoV-2 Delta variant claim the " α " that appears in the below use directions must be included, however, if the claim is not used then it may be omitted.

This statement will only be included on labels listing metal surfaces in hospitals and/or medical devices when the product is made according to FDA Medical Device GMPs

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

-or-

This product is not for use on medical device surfaces.

Not recommended for use on copper, brass, granite, marble, or zinc.

To Prepare Use Solution:

Add the product at 2 fl. oz. of product per gallon of water (1:64).

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

- Dilute at 2 fl. oz. of product per gallon of water (1:64)[†].
- Pre-clean visibly soiled surfaces.
- Apply Use Solution with a (sponge), (brush), (cloth), (mop,) (low pressure mechanical spray device,) (or) (hand pump)(coarse) (trigger sprayer)^α to hard, non-porous surfaces. Spray 6 8 inches from surface, making sure to wet surfaces thoroughly.
- All surfaces must remain visibly wet for ten (10) minutes.
- Wipe surfaces (or let air dry).

[†]Use 4 fl. oz. of product per gallon of water to kill *Enterococcus faecalis* (Vancomycin Resistant) (VRE). *(Must include if VRE is listed as a claim.)* Use 2.5 fl. oz of product per gallon of water to kill *Listeria monocytogenes* (ATCC 19117) *(Must include if Listeria monocytogenes is listed as a claim.)*

Use 8 fl. oz. of product per gallon of water to kill *Trichophyton interdigitale* (Athlete's foot fungus). *(Must include if Trichophyton interdigitale is listed as a claim.)*

NOTE: Rinsing is not necessary unless floors are to be coated with finish or restorer. When cleaning floors position "wet floor" signs around area to be cleaned. Floors will be slippery when wet or contaminated with foreign materials.

When disinfecting food contact surfaces used for food preparation, rinse surfaces thoroughly with potable water. Do not use on glassware, utensils, or dishes.

The following directions are considered optional language and will only appear as supplemental language when the directions above appear on the label.

For Use as One-Step Cleaner/Disinfectant:

- 1. Wear chemical splash-proof googles or face shield.
- 2. Dilute at 2 fl. oz. of product per gallon of water (1:64)[†].
- 3. Spray surface until thoroughly wet.
- 4. Allow surface to remain visibly wet. Read label for contact times.
- 5. Wipe surface or let air dry.

 \bigcirc

Read label for entire directions for use.]

GENERAL DIRECTIONS FOR USE WITH [ELECTROSTATIC SPRAYER APPLICATION] [APPLICATOR/SPRAYER NAME]:

Note: Consider material compatibility and potential for damage prior to application.

- Place signs or warning indicators outside the treatment area to indicate that treatment is in progress.
- Ensure that bystanders and pets are not present in the area to be treated.
- Put on appropriate PPE. At a minimum, this must include safety glasses, gloves and N95 mask.
- Follow manufacturer's instructions for sprayer use. Spray droplet particle size should be set to limit volume median diameter of $\geq 110 \ \mu m$.
- Place the electrostatic spray function in the ON position for electrostatic spray models that have the functionality to toggle ON/OFF.
- Wiping is not required to ensure surface disinfection; however, you may choose to wipe specific surfaces to polish them (e.g., glass, mirrors) or to remove visible residue after the contact time is achieved.
- Individuals may enter area 30 minutes after treatment.

For Use as a One-Step Cleaner/Disinfectant by Electrostatic Spraying: Dilute at 2 fl. oz. of product per gallon of water (1:64). Pre-clean visibly soiled surfaces. Apply Use Solution with electrostatic sprayer to hard, non-porous surfaces. Spray from 5 inches for 5 seconds or 18 inches for 15 seconds, making sure to wet surfaces thoroughly. All surfaces must remain visibly wet for ten (10) minutes for listed bacteria. Let air dry or wipe surfaces to polish.

For Use as a *Virucide by Electrostatic Spraying: Dilute at 2 fl. oz. of product per gallon of water (1:64). Pre-clean visibly soiled surfaces. Apply Use Solution with electrostatic sprayer to hard, non-porous surfaces. Spray –from 5 inches for 5 seconds or 18 inches for 15 seconds, making sure to wet surfaces thoroughly. All surfaces must remain visibly wet for five (5) minutes for listed viruses. A one (1) minute contact time is required for *HIV-1 (AIDS virus), *Influenza Virus Type A (H1N1), *Avian Influenza A (H7N9) virus[≠] and *SARS-Related Coronavirus 2 (the virus that causes COVID-19)††. For *Canine Parvovirus (CPV) (ATCC VR-2017) use an 8 fl. oz. of product per gallon of water dilution and a 10 minute contact time. *(Virus to be listed if used as a kill claim.)* Let air dry or wipe surfaces to polish.

For Use as (Daily) Bathroom (Restroom) (One-Step) Cleaner/Disinfectant:

- Dilute at 2 fl. oz. of product per gallon of water (1:64)[†]
- Pre-clean visibly soiled surfaces.
- Apply Use Solution with a (sponge), (brush), (cloth,) (mop,) (low pressure mechanical spray device,) (or) (hand pump) (coarse) (trigger sprayer) to hard, non-porous surfaces^α. Spray 6 8 inches from surface, making sure to wet surfaces thoroughly.
- All surfaces must remain visibly wet for ten (10) minutes.
- Wipe surfaces (or let air dry).

For Use To Clean and Disinfect Shower Rooms, Locker Rooms and Other Large, Open Areas with Floor Drains:

- Dilute at 2 fl. oz. of product per gallon of water (1:64)[†]
- Pre-clean visibly soiled surfaces.
- Apply Use Solution to hard, non-porous surfaces of floors, walls and ceilings making sure not to over spray ^α. To disinfect, all surfaces must remain visibly wet for ten (10) minutes.
- Scrub using a deck brush.
- Rinse surfaces thoroughly and let air dry.

For Use as a *Virucide:

- Dilute at 2 fl. oz. of product per gallon of water (1:64)[€] (Qualifier required if related organisms are listed on label.)
- Pre-clean visibly soiled surfaces.

- Apply Use Solution until thoroughly wet to hard, non-porous surfaces^α.
- All surfaces must remain visibly wet for five (5) minutes. A one (1) minute contact time is required for *HIV-1 (AIDS virus), *Influenza Virus Type A (H1N1), and *Avian Influenza A (H7N9) virus[≠]. A 30 second contact time is required for *SARS-Related Coronavirus 2 (the virus that causes COVID-19)†† (Virus to be listed if used as a kill claim.)
- Wipe surfaces (or let air dry).

***Kills HIV-1, HBV and HCV on pre-cleaned surfaces/object previously soiled with blood and body fluids** in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or 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 DECONTAMINATION AGAINST HIV-1, HBV, and HCV ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

Personal Protection: Disposable latex or vinyl gloves, gowns, face masks, and eye coverings, must be worn during all cleaning of body fluids, blood, and decontamination procedures. **Cleaning Procedures:** Blood and body fluids must be thoroughly cleaned from surfaces and objects before application of this product. **Contact Time:** Allow surface to remain visibly wet for 1 minute to kill HIV-1, 5 minutes to kill HBV & HCV. **Disposal of Infectious Material**: Blood and other body fluids must be autoclaved and disposed of according to Federal, State, and local regulations for infectious waste disposal.

To Kill Fungi:

- Pre-clean visibly soiled areas.
- Prepare use solution by adding 8 fl. oz. of this product per gallon of water (1:16).
- Apply use solution to hard, non-porous surfaces.
- Allow surface to remain visibly wet for ten (10) minutes. Wipe surfaces (or let air dry).

To control Mold Odors and Mildew Odors:

- Dilute at 1-2 fl. oz. of product per gallon of water (1:128-1:64).
- Pre-clean visibly soiled surfaces.
- Apply Use Solution to hard, non-porous surfaces until thoroughly wet.
- Let air dry.
- Repeat application as necessary.

Toilet Bowl and Urinal Disinfectant Directions

Remove visible soil prior to disinfection.

From a Concentrate: Add 2 fl. oz.[†] of this product directly into the water in the toilet bowl. Brush thoroughly over exposed surfaces and under the rim with a toilet [brush][mop], cloth or sponge^{α}. Allow solution to stand for ten (10) minutes.

For Use as a Cleaner/Disinfectant in Food Processing Plants:

- Dilute at 2 fl. oz. of product per gallon of water (1:64)⁺
- Before using this product in food processing areas, food products and packaging materials must be removed from the room or carefully protected.
- Apply Use Solution evenly over hard, nonporous surfaces. Be sure to wet all surfaces thoroughly.
- Allow product to remain visibly wet on surface for ten (10) minutes^α.
- Wipe with clean cloth, sponge or paper towel.
- For visibly soiled areas, thoroughly clean surface prior to disinfecting.
- When disinfecting food contact surfaces used for food preparation, rinse surfaces thoroughly with potable water. This product must not be used to clean the following surfaces: utensils, glassware, and dishes.

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

- Dilute at 2 fl. oz. of product per gallon of water (1:64)[†]
- Pre-clean visibly soiled items.
- Completely immerse pre-cleaned combs, brushes, scissors, clipper blades, razors, manicure implements and other non-porous instruments in the Use Solution so that surfaces remain visibly wet for ten (10) minutes^α.
- Rinse surfaces thoroughly and let air dry before reuse.
- Change solution daily or when visibly dirty.

NOTE: Remove instruments after ten (10) minutes. Then rinse, dry and keep in a clean, non-contaminated receptacle until use. Prolonged soaking may cause damage to instruments.

For Treatment of Animal Housing Facilities (including Poultry barns):

- Dilute at 2 fl. oz. of product per gallon of water (1:64)€.
- Remove all animals and feeds from areas being treated.
- Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes, and other facilities occupied or traversed by animals.
- Empty or cover all troughs, racks and other feeding and watering appliances.
- Thoroughly clean all surfaces with soap or detergent and rinse with water.
- Apply fresh Use Solution to floors, walls, cages and other washable hard, nonporous surfaces^α. For smaller surfaces, use a trigger spray bottle to spray all hard, nonporous surfaces with solution until wet. To disinfect, all surfaces must remain visibly wet for ten (10) minutes.

- Immerse 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.^{α}
- Ventilate buildings and other closed spaces. Do not house animals or reemploy equipment until product has dried.
- For disinfection of feed racks, troughs, automatic feeders, fountains and watering appliances scrub with use-solution^α, surfaces must remain visibly wet for ten (10) minutes. Then thoroughly scrub all treated surfaces with soap or detergent and rinse with potable water before reuse.

[€]Prepare a Use Solution of 8 fl. oz. of product per gallon of water for effectiveness against *(designated animal viruses on the label)* (1:16). Prepare a Use Solution of 4 fl. oz. of product per gallon of water for effectiveness against *(designated animal viruses on the label)* (1:32).

To Sanitize Non-Food Contact Surfaces:

- Dilute at 8 fl. oz. of product per gallon of water (1:16).
- Pre-clean visibly soiled hard non-porous surfaces.
- Apply Use Solution until thoroughly wet.
- All surfaces must remain visibly wet for one (1) minute.
- Wipe surfaces (or let air dry).
- Not for use on food contact surfaces or on food preparation areas.

NOTE: Do not use on glassware, utensils, or dishes.

To Sanitize Non-Food Contact Surfaces:

- Dilute at 1 fl. oz. of product per gallon of water (1:128).
- Pre-clean visibly soiled hard non-porous surfaces.
- Apply Use Solution until thoroughly wet.
- All surfaces must remain visibly wet for five (5) minutes.
- Wipe surfaces (or let air dry).
- Not for use on food contact surfaces or on food preparation areas.

NOTE: Do not use on glassware, utensils, or dishes.

For Use as a Cleaner/Degreaser:

- Dilute product at 0.5 1 fl. oz. of product per gallon of water (1:256-1:128).
- Apply to hard, non-porous surfaces.
- Wipe surfaces (or let air dry).

For Use as a Deodorizer:

- Dilute product at 0.5-1 fl. oz. of product per gallon of water (1:256-1:128).
- Apply to hard, non-porous surfaces.
- Let stand for ten (10) minutes.
- Wipe surfaces or let air dry.

For Use as a Carpet Cleaner (Spotter):

- Use full strength.
- Apply a small amount to stain.
- Agitate with bone scraper and let stand for 3-5 minutes.
- Blot dry and rinse with clean water.
- Repeat as needed until the stain is completely removed.

Always test first in an inconspicuous area. To test: Apply a small amount, press with an absorbent white cloth for 10 seconds and see if there is any dye transfer.

For Use in Carpet Cleaning (Pre-Spray):

- Dilute product at 2 fl. oz. of product per gallon of water (1:64).
- Apply evenly to carpet surfaces through a coarse hand pump or trigger spray device. Do not breathe spray.
- Let stand for 5-10 minutes.
- Extract carpeting per manufacturer's instructions.
- Allow to dry thoroughly before resuming foot traffic.

Always test first in an inconspicuous area. To test: Apply a small amount, press with an absorbent white cloth for 10 seconds and see if there is any dye transfer.

For Use as a Glass Cleaner:

- Dilute product at 1 fl. oz. of product per gallon of water (1:128).
- Apply evenly to glass surfaces through a coarse trigger spray device. Do not breathe spray.
- Wipe dry with an absorbent cloth or towel.

Toilet Bowl and Urinal Cleaning Directions

Empty water out of toilet bowl urinal and apply a use solution prepared by adding 2 fl. oz. of this product per gal of water (or equivalent use dilution) to exposed surfaces, including under the rim with a toilet (brush) (mop), (cloth) or (sponge), (low pressure mechanical spray device,) (hand pump) (coarse) (trigger spray device). Brush or swab thoroughly, then flush.

DIRECTIONS FOR ALTERNATE CONTAINERS DELIVERY SYSTEMS

[DILUTION SYSTEM] [DILUTION SYSTEMS TRADE NAME] INSTRUCTIONS^:

Remove cap/spray nozzle from empty container. Fill empty container with a newly prepared use-solution. Replace cap/spray nozzle. Place correct use-dilution label on newly filled container.

ELECTROSTATIC SPRAYER: NOTE: Always read and carefully follow manufacturer's safety and technical instructions.

BAG-IN BOX CONTAINERS

How to use this package: This package is designed to be used with dilution control systems only. Open package and connect to dispense according to directions on the box.

TRIGGER SPRAYERS: Fill bottle from dispenser. Apply to surfaces according to directions above.

MOP BUCKETS: Fill bucket from dispenser. Set up "Wet Floor" signs. Mop floor surfaces as specified in directions above.

PACKETS (For pre-measured tear open packets)

(Simply) (Tear) open and pour contents into (X) gallon(s) of water. Keep packets in box until ready to use.

OR

Pour contents of (X fl. oz) packet into (X) gallon(s) of water. Keep packets in box until ready to use.

PRECAUTIONARY STATEMENTS HAZARD TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wear chemical splash-proof goggles or face shield. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses if present, after the first 5 minutes, then continue rinsing eye. **IF ON SKIN OR CLOTHING:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. **IF SWALLOWED**: Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IN CASE OF EMERGENCY, CALL A POISON CONTROL CENTER OR DOCTOR FOR TREATMENT ADVICE. (Call 1-XXX-XXX) Have the product container or label with you when calling a Poison Control Center or doctor or going in for treatment. **Note to Physician**: Probable mucosal damage may contraindicate gastric lavage.

The following language will only appear on containers of 5 gallons or more ENVIRONMENTAL HAZARDS

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

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STORAGE AND DISPOSAL

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

PESTICIDE STORAGE

Do not reuse empty container.

PESTICIDE DISPOSAL Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

One or more of the following paragraphs for Container Disposal will be selected, depending on packaging type:

Non-refillable sealed container is designed to reduce worker exposure to the concentrate. This container cannot be triple rinsed because it is a closed container. The following text will be used on this container.

CONTAINER DISPOSAL: Non-refillable sealed container. Do not reuse or refill this container. Offer for recycling or wrap empty container and put in trash.

For containers 5 gallons or less.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse this container to hold materials other than pesticides or diluted pesticide rinsate. Triple rinse as follows: Fill container ¼ full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times. Then offer for recycling or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by incineration.

For containers greater than 5 gallons

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat procedure two more times. Then offer for recycling or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by incineration.

For 2.5 gallon bladder in box

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. Remove empty bladder from outer corrugated box. Triple rinse as follows: Fill container ¼ full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times. Then offer box and bladder for recycling or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by incineration.

For 275 gallon, 300 gallon or 330 gallon tote

CONTAINER DISPOSAL: Refillable container. Refill this container with (this product) 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. To clean the container before final disposal, empty the remaining contents from this container into application equipment or a mix tank. Fill container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times.

Claims Qualifiers

- ^ must be manually diluted
- [±] in 30 seconds on hard, nonporous surfaces.
- * The words "pathogens", "Pathogenic microorganism" and "germicidal" will be qualified with bacteria and viruses from the Microorganisms Claims section.
- ** will be followed by a list of antibiotic resistant bacteria from the Microorganisms Claims section.
- α for SARS-CoV-2 Delta variant, apply via spray only
- $^{\infty}$ 4 fl. oz. of product per gallon of water is required
- β 2.5 fl. oz. of product per gallon of water is required
- †† Indicates testing in the presence of 400 ppm hard water
- Prepare a Use Solution of 8 fl. oz. of product per gallon of water for effectiveness against *(designated animal viruses on the label)* (1:16). Prepare a Use Solution of 4 fl. oz. of product per gallon of water for effectiveness against *(designated animal viruses on the label)* (1:32).
- allow to come to room temperature first
- (Not for Use in California) {required text if a brand name is marketed in California}
- § This leads to the disinfection directions for use.

Note to Reviewer: These are representative icons for use sites/application methods that may appear on the label with the appropriate directions for use or package type.

Rug icon Disinfectant icon Floor/mopping icon Glass icon Bathroom icon Floor icon Safety glasses icon Recycle icon Clean wall icon Child drowning warning icon



(above graphic must be accompanied by Carpet Cleaning/Spotter directions)















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BATHROOMS







X OZ TO X GAL. WATER DISINFECTS





Optional Kosher certification logo



Note to reviewer: Sealed containers are designed to reduce worker exposure to the concentrate. It is an industry standard to number each product in a dilution control system to further prevent misidentification. For labels using numbering for a sealed, dilution control system, the below represents any number from 1-*9999.*



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(Represents Alternate Dilution Control System logos)

This product may be patented.

Subregistrant Specific Claims

(Note to reviewer: the following statements should only be used for Waxie's Enterprises, LLC, an Envoy Solutions Company)



(Note to reviewer: this logo may appear next to numerical identifiers for the dilution system)

Optional Marketing Logos





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