

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

October 26, 2020

Juli Mann Senior Regulatory Specialist Noth American Infection Control, Ltd. c/o Steptoe & Johnson, LLC 1330 Connecticut Avenue, NW Washington, DC 20036-1795

Subject: PRIA Label and CSF Amendment –Change from a re-pack formulation to A stand-alone formulation. Adding marketing language container sizes, copy approved pathogens for use on the label and other label changes, Plus revising the Basic and Alternate #1 CSFs.
Product Name: Peak Disinfectant Wipes EPA Registration Number: 88494-4 Application Date May 29, 2020 Decision Numbers: 563425

Dear Ms. Mann:

The amended label and CSF(s) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, are 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.

Please note that the record for this product currently contains the following CSF(s):

- Basic CSF dated 10/08/2020
- Alternate Formulation #1 dated 10/08/2020

In addition; guidelines 830.6317 Storage and Stability and 830.6320 Corrosions Characteristics studies are not acceptable. New study is to be submitted.

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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.

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 Lorena Rivas by phone at 703-305-5027, or via email at <u>rivas.lorena@epa.gov</u>

Sincerely,

Jacque Hardy

Jacqueline Hardy Product Manager 34 Regulatory Management Branch II Antimicrobials Division 7510P

Enclose: Stamp label Product Chemistry Review Dated 10/15/2020

# **Peak Disinfectant Wipes** [Refill Pack]

ACTIVE INGREDIENTS:	
Ethyl Alcohol	72.50%
Didecyl Dimethyl Ammonium Chloride	0.33%
OTHER INGREDIENTS*	27.17%
Total	100.00%

\*Does not include the weight of the dry wipes.

# Keep Out of Reach of Children CAUTION

See [back] [side] panel for additional precautionary statements

ACCEPTED 10/26/2020 Under the Federal Insecticide, Fungicide

and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 88494-4

EPA Reg. No. 88494-4 EPA Est. No. XXXXX-XX-X

[Made] [Manufactured] for: North American Infection Control Ltd. 209 Strathearn Road Toronto, Ontario M6C1S5 Canada

[Manufactured] [Made] [Distributed] [in the] [United States] [US] [USA] [by:] 

NET CONTENTS: X lbs. X ozs.

XX [Medium] [Large] [Extra Large] [Pre-Moistened] [Pre-Saturated] Wipes (X in. by X in.)

- [EFFECTIVE] [WORKS] [KILLS BACTERIA/FUNGI/VIRUSES\*] [IN ONE MINUTE/60 SECONDS]
- [ONE MINUTE] [CLEAN AND DISINFECT] [ONE STEP] [ONE PRODUCT] [ONE SOLUTION] WHEN USED ACCORDING TO DISINFECTION INSTRUCTIONS
- [NEW] [EASY][EFFECTIVE] [CONVENIENT]
- [CLEANS, DISINFECTS & DEODORIZES]
- [ALL PURPOSE] [CLEANER] [DEODORIZER] [DETERGENT] [DISINFECTANT]
- [DETERGENT] FORMULA CLEANS [and] DISINFECTS and DEODORIZES]
- [UNSCENTED] [FRAGRANCE FREE]
- [BLEACH-FREE]
- [BACTERICIDAL] [TUBERCULOCIDAL] [FUNGICIDAL] [VIRUCIDAL\*]
- [BACTERICIDE] [TUBERCULOCIDE] [FUNGICIDE] [VIRUCIDE\*]
- [Kills Viruses\* [Responsible for] [Associated with] the Common Cold]
- [Kills Antibiotic Resistant Bacteria CRE, MRSA, VISA, VRSA, and VRE]
- [Effective Against] [Kills] [the] [ESKAPE Pathogens] [Enterococcus faecium, Staphylococcus aureus, Klebsiella pneumoniae, Acinetobacter baumannii, Pseudomonas aeruginosa, and Enterobacter species] [which are responsible for a substantial proportion of nosocomial infections in hospitals, and represent the vast majority of isolates whose resistance to antimicrobial agents presents serious therapeutic concerns for the medical community.]
- [Kills Flu Virus\*]
- [Kills Pandemic 2009 H1N1 Influenza A virus\*] [formerly called swine flu]
- [Kills] [Effective against] Human Coronavirus\*
- 1-Minute Disinfection
- [Disinfecting] and scrubbing power all in one
- 99.99% effective in killing [household] bacteria
- [detergent] formula cleans and disinfects in one step when used according to disinfection instructions
- [Antimicrobial] Wipe
- [Clean] and [Disinfect] hard, non-porous surfaces
- [Clean] and [Disinfect] [patient and] public areas in [hospitals] [medical offices] [dental offices] [ambulatory care facilities] [veterinary offices] [nursing homes] [long term care facilities] [ambulances] [residential sick rooms] [mortuaries] [pet shops] [animal holding areas] [pet grooming facilities]
- Cleaning made easy for all your hard, non-porous surfaces
- Cleans and cuts grease
- Cleans tough stains
- Cleans, [disinfects] and deodorizes
- Cuts through tough grime
- Easy Cleaning
- Easy to use
- Effective against odor-causing bacteria
- Effective daily use
- Effective in [disinfecting] [your] [the] [bathroom] [Medical] [Dental] [Veterinary] [Ambulance] [Emergency Vehicle] [Institutional] [pet care] [surfaces]
- Eliminates odors

- For all non-porous [environmental] surfaces
- For all your [heavy] [light] duty jobs
- Ideal for cleaning and [disinfecting] hard, non-porous surfaces
- Kills [institutional] [bathroom] bacteria
- Fragrance Free
- Leaves [your] [the] [bathroom] [institution] [facility] fresh and clean
- One-step [clean] [cleaning] and [disinfect] [disinfection] when used according to disinfection instructions
- Saves time
- Use every day in every room [throughout the facility] [throughout the institution] [throughout the office] on hard non-porous surfaces
- Use in [Laundromats] [pet areas] [hotels] [motels] [lodging establishments] [manufacturing facilities] [factories] [offices] [office buildings] on hard non-porous surfaces
- Use on hard, non-porous surfaces: [stainless steel] [Formica®] [glass] [glass tables] [glazed porcelain] [plastic] [sealed quartz] [sealed stone] [other hard and soft metals] [most painted surfaces] [most plastics] [see elsewhere on label for further guidance]
- [This product or product name] cleans and/or disinfects and/or deodorizes
- [Disinfectant] [Detergent] [formula] [Cleans and] Disinfects in [just] 1 minute.
- Leaves hard, non-porous surfaces disinfected.
- One step [cleaning] and /or [disinfecting] and/or [deodorizing] when used according to disinfection instructions
- Disinfecting wipe for hard, non-porous surfaces, [patient care equipment] [and] [pointof- care-equipment]
- True One Minute [Disinfectant] [Disinfection] [Formula] [Kill Time] [Contact Time] [In One Step]
- One Minute Contact Time = One Minute Kill Time for ALL Pathogens listed on this label
- Germicidal [Wipe]
- Do Not Flush
- Not a Skin or Baby Wipe

# [Optional text for Use Sites]:

[May be used on hard non-porous surfaces of] *{surfaces will be selected from the following}* autoclaves, bed railings, blood glucose monitors, Biological Safety Cabinets (BSCs), Biosafety Cabinets (BSCs), Restricted Access Barrier Systems (RABS), Closed Restricted Access Barrier Systems (C-RABS), Open Restricted Access Barrier Systems (O-RABS), Mobile Cleanrooms, Half Suit Isolators, cabinets, (cleanroom) carts, chairs, closets, controlled environments, counters, countertops, desks, exam tables, exteriors of (refrigerators)(freezers), furniture, garbage cans, glove boxes, gurneys, Isolator Hood surfaces, isolates, infant incubators and care cribs, IV poles, operation tables, pass through doors, door handles, doorknobs, patient room beds, phlebotomy trays, Primary Engineering Controls (PECs), PVC tubing, recycling bins, Secondary Engineering Controls (SECs), sterile compounding hoods, stethoscopes, stretchers, tables, bathrooms, sinks, faucets, toilet seats [and rims], towel dispensers, hand railings, lamps, light switch panels, stall doors, bath tubs, showers, hampers, tiled walls, telephones, door knobs, vanities, non-porous shelves, display cases, walls, [and] work surfaces.

[This product or product name] is intended for use on hard non-porous surfaces in:

- <u>[Hospitals and healthcare settings]</u> [including]: Ambulances, Anesthesia, Blood Banks, Cardiac Catheterization, CAT Labs, Central Supply, Clinics, Dental Offices, Dialysis Clinics, Doctor's Office[s], Electrocardiography [EKG], Emergency Rooms, [E.R.], Electroencephalography, Home Health Care, Hospices, Inhalation Therapy, IV Therapy, Labor and Delivery, Laboratories, Laundry Rooms, Long Term Care Facilities, Medical Records, MRI Lab, Newborn Nursery, Nursing Homes, Offices, Operating Rooms, Occupational Therapy, Ophthalmic Offices, Patient Transportation, Pediatrics, Physical Therapy, Physician's Office[s], Psychiatry, Psychology, Radiology, Recovery Rooms, Rehabilitation, Respiratory Therapy, Skilled Nursing Facilities, Social Services, Transport Vehicles, Ultrasound, Waiting Areas, X-Ray.
- [Critical Care Areas] [including]: Burn Intensive Care Units, [CCU] Cardiac Care Units, [ICU] Intensive Care Units, [NICU] Neonatal Intensive Care Units, [PICU] Pediatric Intensive care Units, Surgery, Surgical Prep, Surgical Recovery Units, Surgical Intensive Care Units.
- Barber Shops, Beauty Salons, Nail Salons, Spas, Tattoo Parlors.
- Funeral Homes, Mortuaries
- Airports, Athletic Facilities, [Gyms] Gymnasiums, Health Clubs, Schools, Transportation Terminals, Vehicles, Aircraft.
- Banquet Halls, Catering Facilities, Delicatessens, Grocery stores, Shopping Centers, Restaurants.
- Schools, Childcare Facilities, Daycare Centers, Nurseries
- Libraries
- Business offices and manufacturing facilities
- Households, Homes, Residences, and/or Bathrooms.
- Institutional Bathrooms [Restrooms] [Toilet Facilities].
- Police / Fire / EMS facilities and vehicles.
- Government offices.
- Military bases, facilities, vehicles, [and] aircraft.
- Detention and Correctional Facilities [and] vehicles.
- Animal Housing/Holding Facilities [Areas]
- Animal Hospitals, Animal Life Science Laboratories, Animal Transportation Vehicles, Breeding Establishments, Grooming Establishments, Kennels, Pet Shops, Tack Shops, Veterinary Clinics, Veterinary Examination Rooms, Veterinary Operating Rooms, Veterinary Waiting Rooms, Veterinary X-Ray Rooms, Zoos.

#### Alternative Language May Include the Following Options in Addition to or Instead of Those Above

[This product or product name] is intended for use on hard non-porous surfaces in:

- Hospitals and other institutional acute and long term Healthcare facilities, Ambulatory Care Centers, Medical/Dental/Veterinary Offices
- Barber Shops, Salons, Spas, Tattoo Parlors, and similar establishments
- Athletic facilities
- Transportation centers, vehicles, [and] aircraft.

# [Optional Areas of Use/Industries]

**[Disinfectant for use on hard, non-porous surfaces in:]** *{optional sites will be selected from the following}* Animal Life Science Laboratories, Bathrooms, Churches, [ISO Class (number)] Cleanrooms, (Sterile) Compounding Facilities, Clinics, Colleges, Cosmetic Processing Facilities, Critical Care Units, Cruise Ships, Dialysis Centers, Funeral Homes, Dental Offices, Health Clubs, Hospices, Hospitality Establishments, Hospitals, Home Health Care, Hotels, Industrial Facilities, Institutions, Laboratories, Nail Salons, Nursing Homes, Medical Device Manufacturing, Morgues, Office Buildings, Oncology Centers, Outpatient Centers, Pharmaceutical Production Facilities, Pharmacies, Physical Therapy Locations, Physicians' Offices, Public Facilities, Radiology, Recreational Facilities, Rehabilitation Centers, Research Laboratories, Retail and Wholesale Establishments, Shelters, Storage Areas, Surgery Centers, Locker Rooms, Long-Term Care Facilities, The interior areas of the following Transport Vehicles: including ships, airplanes, automobiles, trucks, ambulances, and trains.

When Animal Housing/Holding Facilities are included on the label, the following directions must be added:

# Veterinary Clinics, Animal Life Science Laboratories, Pet Shops

Remove all animals and feed from premises, vehicles, and enclosures. Remove all litter and manure from floors, walls, and surfaces of facilities and fixtures occupied or traversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Use one or more wipes to wet surfaces for 1 minute. Immerse all handling and restraining equipment as well as forks, shovels, and scrapers used for removing litter and manure. Ventilate buildings, vehicles, and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set, or dried. Thoroughly scrub treated feed troughs, racks and other feeding and watering appliances with soap or detergent, then rinse with potable water before reuse.

- [This product or product name] will clean and disinfect hard, non-porous, surfaces of: bed railings, cabinets, carts, chairs, counters, infant incubators, infant warmers, Isolettes, IV poles, IV pumps, stretchers, stools, tables, toilet seats, toilets, bathtubs, bathroom fixtures, shower stalls, sinks, tiles, vanity tops, hospital beds, traction devices, MRI, CAT, scales, paddles, and workstations on wheels (WOW).
- [This product or product name] can be used to clean external surfaces of ultrasound transducers and probes, prior to any required high level disinfection or sterilization. Thoroughly remove any gel and gel residue prior to disinfection with this product.
- [This product or product name] can be used to disinfect EKG cables, leads, clips, plate electrodes, welsh cups and bulbs, and straps. Thoroughly remove any gel and gel residue prior to disinfection with this product.
- [This product or product name] will clean and disinfect the outside surfaces of blood glucose meters, PT/INR meters, and similar diagnostic instruments and measuring devices.
- [This product or product name] will clean and disinfect cardiac gym equipment, cardiac monitors, defibrillators, dopplers, oxygen hoods, physical therapy (PT) and occupational therapy (OT) equipment surfaces, patient lift equipment, slit lamps, spine back boards, stethoscopes, telemetry equipment, telephones, toilet seats, and hard nonporous outside surfaces of anesthesia machines, dialyzers, electronic thermometers, Ophthalmoscopes, Otoscopes, pulse oximeters, radiology equipment, tympanic thermometers, respiratory therapy equipment, apheresis machines, diagnostic equipment, dialysis machines, patient monitoring equipment, patent support and delivery equipment, pulp testers, and motors.
- [This product or product name] will clean and disinfect dental unit instrument trays, endodontic equipment such as apex locators, amalgam separators, dental impression material, and hard outside nonporous surfaces of amalgamators and dental curing lights.
- [This product or product name] will clean and disinfect hard outside non-porous surfaces of dental instruments that are not required to be treated with a high level disinfectant or sterilant.
- [This product or product name] will clean and disinfect hard, non-porous, surfaces of: [exam tables, gurneys, stretchers, wheel chairs, and patient transport chairs], [and vinyl or nylon covered mattresses] [or other nonporous upholstered materials such as blood bank chairs, and dental chairs]. When using [this product or product name] on chairs, mattresses, or other upholstered surfaces or materials that had previously been treated with a product containing a higher percentage of quaternary ammonium compounds, or bleach, it is recommended that the surface be thoroughly cleaned with an alcohol based cleaner, or in accordance with the upholstery material manufacturer's recommendations or directions to remove any built-up residue from the previously used product, before applying this product.
- [This product or product name] will clean and disinfect hard, non-porous surfaces of: grocery cart handles, grocery carts, shopping carts, grocery cart child seats.
- [This product or product name] will clean and disinfect hard, non-porous surfaces of: changing tables, cribs, diaper pails, trashcans, garbage cans.
- [This product or product name] will clean and disinfect hard, non-porous surfaces of: cabinets, chairs, computers, countertops, desks, desktops, doorknobs, fax machines, garbage cans, headsets, keyboards, railings, seats, sinks, tables, tabletops, telephones, trashcans, appliance exteriors, [bathroom] faucets, bathtubs, and shower [doors][stalls].
- [This product or product name] will clean and disinfect hard, non-porous surfaces of: gym equipment, exercise machines, non-porous wrestling/gymnastic/exercise/yoga mats, gymnastic [athletic] equipment.

- Use [this product or product name] to clean and disinfect non-porous personal protective safety equipment, protective headgear, PPE, hard hats, half mask respirators, full face breathing apparatus, gas masks, goggles, spectacles, face shields, silicone rubber or PVC hearing protectors and vinyl covered ear muffs. Rinse all equipment that comes in prolonged contact with skin before reuse with clean warm water [about 120°F], and allow to air dry. [Caution: Cleaning at the 120°F temperature will avoid overheating and distortion of the personal safety equipment that would necessitate replacement.]
- [This product or product name] is formulated to disinfect hard, non-porous, inanimate environmental surfaces such as floors, walls, metal surfaces, stainless steel surfaces, glazed porcelain, glazed ceramic tile, plastic surfaces, bathrooms, shower stalls, bathtubs, and cabinets.
- [This product or product name] helps reduce cross contamination from contact with treated surfaces.
- [This product or product name] [can be used as a] disinfecting wipe for hard non-porous surfaces, [patient care equipment] [and] [point-of-care equipment]
- [This product or product name] will clean and disinfect hard nonporous surfaces found in Nursery or Daycare Centers, including but not limited to bassinets, changing tables, cribs, diaper changing stations, diaper pails, infant/child care equipment surfaces, trash cans, toys and other such surfaces found elsewhere on this label.
- [This product or product name] can be used to clean and disinfect nonporous surfaces in vehicles, aircraft, and other conveyances, which can otherwise be cleaned and/or disinfected with alcohol based liquid cleaning/disinfecting products.

# DIRECTIONS FOR USE

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

For labels that list medical premises one of the following statements must be used:

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 bloodstream 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.

or

This product is not for use on critical and semi-critical medical device surfaces.

**CLEANING:** Use one or more wipes, as necessary, to wet surface sufficiently and to thoroughly clean the surface.

**DISINFECTING:** To disinfect hard, non-porous surfaces, use one or more wipes, as necessary, to thoroughly wet the surface to be treated. Treated surface must remain visibly wet for one [1] minute to achieve complete disinfection [*or* kill] of all pathogens listed on this label. For visibly soiled surfaces, clean before following disinfecting instructions. Allow surfaces to air dry.

These Virucidal, Bactericidal, Tuberculocidal, and Fungicidal, Efficacy Claims are Optional and May Appear Anywhere on the Label

\*VIRUCIDAL [EFFICACY] [AGAINST THE FOLLOWING ORGANISMS] [IN ONE [1] MINUTE]: [This product or product name] is *or* are an effective virucide on hard, non-porous surfaces, in the presence of an organic load, against *Adenovirus type 5* [ATCC VR-5], *Avian Influenza A Virus* [ATCC VR-798], *Cytomegalovirus* [ATCC VR-538], *Enterovirus EV-D68* [ATCC VR-1826], *Hepatitis B Virus*, *Hepatitis C Virus*, *Herpes Simplex Virus Type 1* [ATCC VR-539], *Human Coronavirus* [ATCC VR-1558], *Human Immunodeficiency Virus* [HIV-1] [AIDS], *Influenza Virus type A*<sub>2</sub> [ATCC VR-544], *Influenza B* [ATCC VR-102], *Norovirus*, *Poliovirus serotype 1* [PV-1] [ATCC VR-1562], *Respiratory Syncytial Virus* [ATCC VR-26], *Rhinovirus* [ATCC VR-340], *Rotavirus Strain WA* [ATCC VR-2018], [and] *Vaccinia virus* [ATCC VR-119], when the treated surface is allowed to remain wet for 1 minute. Allow surfaces to air dry.

[The following information specifically applicable to HIV-1, HBV, and HBC, may appear grouped together anywhere on the label and is required if human healthcare sites including but not limited to hospitals, clinics, physicians' offices, and/or dental offices/operatories are included on the label]

**KILLS HIV-1, HBV and HCV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in health care settings [Hospitals, Nursing Homes] 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], and Hepatitis C Virus [HCV]

# SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1, HBV, and HCV FOR SURFACES OR OBJECTS SOILED WITH BLOOD OR BODY FLUIDS.

**<u>PERSONAL PROTECTION</u>**: When handling items soiled with blood or body fluids, use disposable latex gloves, gowns, masks and eye coverings.

<u>CLEANING PROCEDURES</u>: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of [this product or product name].

**CONTACT TIME:** Allow surface to remain wet for 1 full minute.

**DISPOSAL OF INFECTIOUS MATERIALS**: Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

These Influenza Related Optional Statements May Appear Elsewhere on the Label

- Kills Pandemic 2009 H1N1 Influenza A virus [formerly called swine flu].
- Kills Pandemic 2009 H1N1 Influenza A virus

# [BACTERICIDAL] [EFFICACY] [AGAINST THE FOLLOWING ORGANISMS] [IN ONE [1] MINUTE]:

# DRUG RESISTANT AND MULTI-DRUG RESISTANT BACTERIA

[This product or product name] is an effective disinfectant on hard non-porous surfaces, in the presence of an organic load, against Acinetobacter baumannii – Multi-Drug resistant [MDR] [ATCC 19606], *Carbapenem resistant Enterobacter cloacae* (CRE) (KPC) [Multi-Drug resistant] [MDR] [ATCC BAA-2341], *Carbapenem resistant Enterobacter cloacae* (CRE) (New Delhi) [Multi-Drug resistant] [MDR] [ATCC BAA-23468], *Enterococcus faecium* – Vancomycin resistant (VRE) [ATCC 51559], *Escherichia coli* – ESBL Producing [Multi-Drug resistant] [MDR] [ATCC BAA-196], *Klebsiella pneumoniae* – ESBL Producing [Multi-Drug resistant] [MDR] [ATCC 700603], *Staphylococcus aureus* – Methicillin resistant (MRSA) [ATCC 33591], *Staphylococcus aureus* – Vancomycin resistant (VRSA) [ATCC NR-49120], [and] *Staphylococcus aureus Panel* – Vancomycin intermediate (VISA) [CDC AR-Bank 0216], when the treated surface is allowed to remain wet for 1 minute. Allow surfaces to air dry.

## **BACTERIA**

[This product or product name] is an effective disinfectant on hard non-porous surfaces, in the presence of an organic load, against Bordetella *pertussis [ATCC 12743], Burkholderia cepacia [ATCC 25416], Campylobacter jejuni* [ATCC 29428], *Enterobacter aerogenes* [ATCC 13048], *Escherichia coli* [E. coli] O157:H7 [ATCC 35150], *Klebsiella pneumoniae* [ATCC 4352], *Legionella pneumophila* [ATCC 33153], *Listeria monocytogenes* [ATCC 984], *Proteus vulgaris* [ATCC 9920], *Pseudomonas aeruginosa* [ATCC 15442], *Salmonella enterica* [Salmonella] [ATCC 10708], *Shigella dysenteriae* [ATCC 13313], *Staphylococcus aureus* [ATCC 6538], *Streptococcus pyogenes* [Strep] [ATCC 19615], [and] *Streptococcus pneumoniae* [ATCC 6305], when the treated surface is allowed to remain wet for 1 minute. Allow surfaces to air dry.

#### TUBERCULOCIDAL:

[This product or product name] is an effective disinfectant on hard non-porous surfaces, in the presence of an organic load, against *Mycobacterium bovis* [ATCC 35743], [at room temperature], when the treated surface is allowed to remain wet for 1 minute. Allow surfaces to air dry.

#### FUNGICIDAL:

[This product or product name] is an effective fungicide on hard non-porous surfaces against Trichophyton interdigitale [ATCC 9533] [causative agent of Athlete's Foot Fungus] [a cause of ringworm] [a cause of ringworm of the foot], when used as directed [in bathrooms, shower stalls, locker rooms, exercise facilities or other surfaces commonly contacted by bare feet], [and] *Candida albicans* [ATCC 10231], when the treated surface is allowed to remain wet for 1 minute. Allow surfaces to air dry.

The Following Optional Claims Are Intended For Veterinary or Other Animal Related Facilities

# ANIMAL PATHOGENS:

[This product or product name] is an effective disinfectant on hard non-porous surfaces against *Avian Influenza A Virus* [ATCC VR-798], *Bordetella bronchiseptica* [ATCC 4617], *Bovine Diarrhea Virus* [(BVDV)], *Canine distemper Virus* [ATCC VR-1587], *Canine parvovirus* [ATCC VR-953], *Duck Hepatitis B Virus* [(BVDV)], *Feline calicivirus*, and *Feline leukemia Virus* [ATCC VR-1373].

#### EFFICACY TESTS HAVE DEMONSTRATED THAT [THIS PRODUCT OR PRODUCT NAME] IS AN EFFECTIVE, VIRUCIDE, BACTERICIDE, TUBERCULOCIDE AND FUNGICIDE IN THE PRESENCE OF [5%] ORGANIC SOIL.

As An Alternative the Following Consolidated Format for Stating Pathogen Claims May Be Used

[This product or product name] is or are an effective [v][V]irucide, [b][B]actericide, [t][T]uberculocide and [f][F]ungicide on hard non-porous surfaces, in the presence of an organic load, against Adenovirus type 5 [ATCC VR-5], Avian Influenza A Virus [ATCC VR-798], [Canine distemper Virus [ATCC VR-1587], Canine parvovirus [ATCC VR-953]], Cytomegalovirus [ATCC VR-538], Enterovirus EV-D68 [ATCC VR-1826], [Feline calicivirus, Feline leukemia Virus [ATCC VR-1373]], Hepatitis B Virus, Hepatitis C Virus, Herpes Simplex Virus Type 1 [ATCC VR-539], Human Coronavirus [ATCC VR-1558], Human Immunodeficiency Virus [HIV-1] [AIDS], Influenza Virus type A<sub>2</sub> [ATCC VR-544], Influenza B [ATCC VR-102], Norovirus, Poliovirus serotype 1 [PV-1] [ATCC VR-1562], Respiratory Syncytial Virus [ATCC VR-26], Rhinovirus [ATCC VR-340], Rotavirus Strain WA [ATCC VR-2018], Vaccinia virus [ATCC VR-119], Acinetobacter baumannii Multi-Drug resistant [MDR] [ATCC 19606], [Bordetella bronchiseptica [ATCC 4617]], Bordetella pertussis [ATCC 12743], Burkholderia cepacia [ATCC 25416], Campylobacter jejuni [ATCC 29428], Enterobacter aerogenes [ATCC 13048], Enterobacter cloacae (CRE) MDR [ATCC BAA-2341], Enterobacter cloacae (CRE) (New Delhi) MDR [ATCC BAA-2468], Escherichia coli [E. coli] O157:H7 [ATCC 35150], Escherichia coli [E. coli] (ESBL) TEM-10 MDR [ATCC BAA-196], Klebsiella pneumoniae [ATCC 4352], Klebsiella pneumoniae (ESBL) SHV-18 MDR, Legionella pneumophila [ATCC 33153], Listeria monocytogenes [ATCC 984], Proteus vulgaris [ATCC 9920], Pseudomonas aeruginosa [ATCC 15442], Salmonella enterica [Salmonella] [ATCC 10708], Shigella dysenteriae [ATCC 13313], Staphylococcus aureus [ATCC 6538], Staphylococcus aureus Methicillin Resistant (MRSA) [ATCC 33591], Streptococcus pyogenes [Strep] [ATCC 19615], Streptococcus pneumoniae [ATCC 6305], Vancomycin Intermediate Staphylococcus aureus Panel (VISA) [CDC AR-Bank 0216], Vancomycin Resistant Enterococcus faecium (VRE) [ATCC 51559], Vancomycin Resistant Staphylococcus aureus (VRSA) [ATCC NR-49120], Mycobacterium bovis [ATCC 35743] [at room temperature], Trichophyton interdigitale [ATCC 9533]; [and] Candida albicans [ATCC 10231], when the treated surface is allowed to remain wet for 1 minute. Allow surfaces to air dry.

The Following Listing of Pathogens, By Category, May Appear on the Front Label Panel or Elsewhere on the Label, In Any Order, Together or Divided, When Used in Conjunction With the Above Listing of All Pathogens Grouped Together, Elsewhere on the Label

#### BACTERICIDAL

Acinetobacter baumannii [Bordetella bronchiseptica] Bordetella pertussis Burkholderia cepacian Campylobacter jejuni Enterobacter aerogenes Enterobacter cloacae (CRE) MDR Enterobacter cloacae (CRE) (New Delhi) MDR Escherichia coli O157 [E. coli] Escherichia coli (ESBL) TEM-10 MDR Klebsiella pneumoniae Klebsiella pneumoniae(ESBL) SHV-18 MDR Legionella pneumophila Listeria monocytogenes Proteus vulgaris Pseudomonas aeruginosa Salmonella enterica Shigella dysenteriae Staphylococcus aureus [Staph] Streptococcus pneumoniae [Strep] Streptococcus pyogenes [Strep] Vancomycin Intermediate Staphylococcus aureus Panel [VISA] Vancomycin Resistant Enterococcus faecium [VRE] Vancomycin Resistant Staphylococcus aureus [VRSA]

North American Infection Control Ltd. Toronto, Ontario M6C1S5 Canada EPA Reg. No. 88494-4

#### +VIRUCIDAL

+Adenovirus type 5 +Avian Influenza A Virus [+Canine distemper Virus] [+Canine parvovirus] +Cytomegalovirus +Enterovirus EV-D68 [+Feline calicivirus] +[Feline leukemia Virus] +Hepatitis B Virus [HBV] +Hepatitis C Virus [HBC] +Herpes Simplex Virus Type +Human Coronavirus +Human Immunodeficiency Virus [HIV-1] [AIDS] +Influenza Virus type A<sub>2</sub>[Flu] +Influenza B [Flu] +Norovirus +Poliovirus +Respiratory Syncytial Virus [RSV] +Rhinovirus +Rotavirus Strain WA +Vaccinia virus

#### TUBERCULOCIDAL Mycobacterium bovis

FUNGICIDAL Trichophyton interdigitale

Trichophyton interdigitale [Athletes Foot fungus] Candida albicans

#### Emerging Viral Pathogens

This product meets the criteria for use against the following categories of emerging viral pathogens when used in accordance with the use directions for

Poliovirus type 1 (ATCC VR-1562) and Rhinovirus (ATCC VR-340):

-Enveloped Viruses

-Large Non-Enveloped Viruses

-Small Non-Enveloped Viruses

Per EPA "Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels".

Statements intended for technical literature, "1-800" consumer information services, social media sites and company websites (non-label related). Information is NOT to appear on marketed product labels. One or both statements below may be used.)

[Product name] has demonstrated effectiveness against viruses similar to [name of emerging virus, which must be a small non-enveloped, large non- enveloped, or enveloped virus] on [eligible surface type(s)]. Therefore, [product name] can be used against [name of emerging virus, which must be a small non-enveloped, large non-enveloped, and/or enveloped virus] when used in accordance with the directions for use against [name of supporting virus(es)] on [hard, non-porous surfaces]. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.

or

[Name of illness/outbreak] is caused by [name of emerging virus, which must be a small nonenveloped, large non-enveloped, and/or enveloped virus]. [Product name] kills similar viruses and therefore can be used against [name of emerging virus, which must be a small nonenveloped, large non-enveloped, and/or enveloped virus] when used in accordance with the directions for use against [name of supporting virus(es)] on [hard, non-porous surfaces]. Refer to the [CDC or OIE] website at [website address] for additional information.

For an emerging viral pathogen that is a/an	follow the directions for use for the	
	following organisms on the label:	
Enveloped virus	Poliovirus type 1 (ATCC VR-1562	
Large, non-enveloped virus	Rhinovirus (ATCC VR-340)	
Small, non-enveloped virus		

# **PRECAUTIONARY STATEMENTS**

Hazards to Humans and Domestic Animals:

**CAUTION**: Causes moderate eye irritation. Avoid contact with eyes or clothing. 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 eyes 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. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center, doctor, or going for treatment. For emergency information concerning this product, call the National Pesticides Information Center [NPIC] at 1-800-858-7378 seven days a week, 6:30 am to 4:30 pm Pacific Time [NPIC Web site: www.npic.orst.edu].

## PHYSICAL OR CHEMICAL HAZARDS:

Flammable. Keep away from heat or open flame.

#### STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Always store this product and all pesticides in the original container. If a leaky container must be contained within another, mark the outer container to identify the contents. Protect from extreme heat or cold.

PESTICIDE [(wipe)] DISPOSAL: Waste resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

#### For nonrefillable containers

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

#### For refillable containers where refill rolls in sealed bags are used to refill containers

CONTAINER DISPOSAL: Refillable container. Refill plastic canister with this brand of pesticide product only. Do not reuse this container for any other purpose. Offer empty roll packaging, or plastic canister, for recycling if available, or discard in trash.

#### Statement Regarding Surface Compatibility Which May Appear Anywhere on the Label

[This product or product name] will not harm most surfaces: including stainless steel, aluminum, other hard and soft metals, sealed quartz or other solid man-made counter top materials, most plastics, fiberglass, vinyl, nylon, and other non-porous upholstery materials used in a [medical] [or] [veterinary] [or] [dental] environment, and most painted surfaces. For plastic and painted surfaces, spot test on an inconspicuous area before use. Not recommended for use on acrylic plastics or coated optical surfaces. Do not use on unpainted wood, or leather. Not for use on people or pets.

- disinfects [odor causing] [household] [bathroom] bacteria
- maximum cleaning, minimum effort
- easy to [carry] [use] [container] [dispensing system]
- for all [household] [institutional] hard, nonporous surfaces
- great for clean-up at school, daycare or community center
- uses [x]% less plastic than other [bottles] [containers] [in the market]
- uses [x]% less packaging than similar products
- uses [x]% recycled materials in the packaging
- packaging made from [x]% renewable resources

The Following Optional Warranty and Disclaimer Statement[s] May Appear Anywhere on the Label

# LIMITED WARRANTY AND DISCLAIMER NOTICE:

The manufacturer of this product and/or it's affiliates and distributors warrant that this product conforms to the chemical description on this label and is reasonably fit for the purposes referred to in the Directions For Use and elsewhere on this label. Buyer assumes all risks of use and handling which is a variance in any way with the directions herein. The manufacturer makes no other express or implied warranty of fitness or merchantability. In no case shall the manufacturer or the seller of this product be liable for consequential, special or indirect damages resulting from the use or handling of this product. The manufacturer, distributor, and seller, and the buyer and user of this product acknowledge and accept the foregoing Limited Warranty and Disclaimer which may be varied only by agreement in writing signed by a duly authorized representative of the manufacturer.

or

No warranty, either expressed or implied, is given to the usage contrary to the instructions given herein.

#### Use Below Instructions Depending on the Type of Dispensing System

#### For Nonrefillable Wipes Canister

To Dispense Wipes: Open lid, remove entire cover, remove and discard seal. From center of wipes roll pull up a corner of the wipe, twist it and thread it through the hole in the container cover. Pull through about one inch. Replace cover tightly. Pull out first wipe and tear off at a 45° angle. Remaining wipes feed automatically, ready for next use. When not in use, keep the tip of the exposed wipe inside the well in the cover, and the lid snapped closed.

#### For Refillable Wipes Canister

To Insert Wipes Roll: Open lid and remove entire cover. Cut or tear on line of Wipes Refill Pack to completely expose wipes roll. Place entire bagged roll of wipes inside canister.

To Dispense Wipes: From center of wipes roll pull up a corner of the wipe, twist it and thread it through the hole in the container cover. Pull through about one inch. Replace cover tightly. Pull out first wipe and tear off at a 45° angle. Remaining wipes feed automatically, ready for next use. When not in use, keep the tip of the exposed wipe inside the well in the cover, and the lid snapped closed.

#### For Wipes Soft Pack with Plastic Snap Lid

To Dispense Wipes: Open lid, remove and discard seal. Reach into pack and pull up first wipe. Pull straight up to dispense wipe. Reach into pack for additional wipes. When not in use be sure that the lid is snapped closed to prevent drying of the wipes.

#### For Wipes Soft Pack with Peel and Reseal Closure

To Dispense Wipes: Peel open package closure tab. Do not completely remove closure tab from package. Reach into pack and pull up first wipe. Pull straight up to dispense wipe. Reach into pack for additional wipes. When not in use, press closure tab flat to prevent drying of the wipes.

#### For Individually Wrapped Wipes

Tear open packet at top and remove wipe completely from packaging. Offer packaging for recycling if available, or discard empty packaging in trash.

#### For Canisters and Canisterless Wipes Hybrid

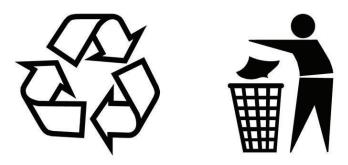
[To dispense wipes from this flexible wipe package using a wall or countertop mounted dispensing system, tear off the top of the flexible wipe pack at the perforation and insert the open end of the wipe pack into the dispenser, closing the dispenser on the flexible wipe package to secure the flexible wipe pack to allow pull/removal of the perforated wipes.]

[To dispense wipes using a wall or countertop mounted dispensing system, insert the fitment at top of the wipe pack into the dispenser, closing the dispenser on the fitment to secure the flexible wipe pack to allow pull/removal of the perforated wipes.]

[To dispense wipes from the flexible wipe pack using a canister system, tear off the top of the flexible wipe pack at the perforation and insert the wipe pack closed-end down into the canister, pulling the wipe tail through the canister lid closure for dispensing.]

This Product [product name] Kills the Following Pathogens in One Minute				
		Organic		
Pathogen	ATCC Number	Load	Kill Time	
Acinetobacter baumannii	19606	5%	1 minute	
Bordetella bronchiseptica	4617	5%	1 minute	
Bordetella pertussis	12743	5%	1 minute	
Burkholderia cepacia	25416	5%	1 minute	
Campylobacter jejuni	29428	5%	1 minute	
Enterobacter aerogenes	13048	5%	1 minute	
Enterobacter cloacae (CRE) multi-drug resistant	BAA-2341	5%	1 minute	
Enterobacter cloacae (CRE) (New Delhi) multi-drug resistant	BAA-2468	5%	1 minute	
Escherichia coli O157:H7 [E. coli]	35150	5%	1 minute	
Escherichia coli (ESBL) TEM-10 multi-drug resistant	BAA-196	5%	1 minute	
Klebsiella pneumoniae	4352	5%	1 minute	
Klebsiella pneumoniae (ESBL) SHV-18 multi-drug resistant	700603	5%	1 minute	
Legionella pneumophila	33153	5%	1 minute	
Listeria monocytogenes	984	5%	1 minute	
Methicillin resistant Staphylococcus aureus [MRSA]	33591	5%	1 minute	
Proteus vulgaris	9920	5%	1 minute	
Pseudomonas aeruginosa	15442	5%	1 minute	
Salmonella enterica	10708	5%	1 minute	
Shigella dysenteriae	13313	5%	1 minute	
Staphylococcus aureus [Staph]	6538	5%	1 minute	
Streptococcus pneumoniae	6305	5%	1 minute	
Streptococcus pyogenes [Strep]	19615	5%	1 minute	
Vancomycin Intermediate Staphylococcus aureus Panel [VISA]	CDC AR-Bank 0216	5%	1 minute	
Vancomycin Resistant Enterococcus faecium [VRE]	51559	5%	1 minute	
Vancomycin Resistant Staphylococcus aureus [VRSA]	NR-49120	5%	1 minute	
Mycobacterium bovis [Tuberculosis] [at room temperature]	35743	5%	1 minute	
Candida albicans	10231	5%	1 minute	
Trichophyton interdigitale [Athletes Foot fungus]	9533	5%	1 minute	
Adenovirus	VR-5	5%	1 minute	
Avian Influenza	VR-798	5%	1 minute	
Canine distemper virus	VR-1587	5%	1 minute	
Canine parvovirus	VR-953	5%	1 minute	
Coronavirus	VR-1558	5%	1 minute	
Cytomegalovirus	VR-538	5%	1 minute	
Enterovirus EV-D68	VR-1826	5%	1 minute	
Feline leukemia virus	VR-1373	5%	1 minute	
Hepatitis B	n/a	5%	1 minute	
Hepatitis C	n/a	10%	1 minute	
Herpes Simplex virus type 1	VR-539	5%	1 minute	
Human Immunodeficiency virus [HIV-1] [AIDS]	n/a	10%	1 minute	
Influenza virus type A2 [Flu]	VR-544	5%	1 minute	
Influenza virus type B [Flu]	VR-102	5%	1 minute	
Norovirus	n/a	5%	1 minute	
Poliovirus	VR-1562	5%	1 minute	
Respiratory Syncytial virus [RSV]	VR-26	5%	1 minute	
Rhinovirus	VR-340	5%	1 minute	
Rotavirus, Strain WA	n/a	5%	1 minute	
Vaccinia virus	VR-119	5%	1 minute	

The Following Graphic Symbols Are Optional and May Appear Anywhere On the Label in Color or Black and White Brackets [] Denote Optional Language











[Disinfecting wipe for hard, non-porous surfaces, patient care equipment and point-of-care equipment.]