



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

November 7, 2022

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Jean Claude Marcelin
Authorized Representative
Professional Disposables International, Inc. (PDI)
400 Chestnut Ridge Road
Woodcliff Lake, NJ 07677
Electronic Transmittal: jmarcelin@pdipdi.com

Subject: Notification per PRN 98-10 – Minor Label Changes
Product Name: PDI Sani-Cloth Bleach Wipes
EPA Registration Number: 9480-8
Received Date: 6/8/2022
Action Case Number: 00370505

Dear Mr. Marcelin:

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

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

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

If you have any questions, you may contact Melanie Bolden at (202) 566-0674 or via email at Bolden.Melanie@epa.gov.

Best,

A handwritten signature in cursive script that reads "Melanie Bolden for".

Demson Fuller, Product Manager 32
Antimicrobials Division (7510P)
Regulatory Management Branch I
Office of Pesticide Programs

PDI SANI-CLOTH® BLEACH WIPES

[Alternate brand names]:

- Sani-Cloth® Bleach Germicidal Disposable Wipe]
- Sani Professional® Brand Noro-X™]
- Sani Professional® Brand Noro-X™ Wipes]
- Sani Professional® Brand NoroCloth]
- Sani Professional® Brand NoroCloth Germicidal Disposable Wipe]

ACTIVE INGREDIENTS:

Sodium Hypochlorite..... 0.63%

OTHER INGREDIENTS.....99.37%

TOTAL..... 100.00%

[Does not include the weight of the [cloth] [towelette] [or] [wipe]]

[Available chlorine...0.60%]

[Approximately 6300 ppm [parts per million] available Sodium hypochlorite]

[Approximately 6000 ppm [parts per million] available chlorine]

[Premoistened wipe with a stabilized bleach solution (equivalent to a 1:10 dilution)]

KEEP OUT OF REACH OF CHILDREN CAUTION

See [back] [outer carton] [side] [container inside] [panel] for additional precautionary statements

[Contains:] NET CONTENTS [and/or Net Wt.] _____oz (g) [or lbs. (kg)]

___ [# OF CLOTHS] [SIZE of each cloth]

NOTIFICATION

9480-8

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

11/07/2022

EPA Reg. No.: 9480-8

EPA Est. No.: 9480-NY-1 [or others]

or

EPA Est. No. A=9480-NY-1 [or others]

Alpha character will precede batch code on product

[Manufactured by [or for]]:

Professional Disposables International, Inc.

400 Chestnut Ridge Road, Woodcliff Lake, NJ 07677 [USA]

[For information call: *[phone number to be inserted]*]

[Made in USA] [of Domestic and [Foreign] [Imported] Materials]

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Back panel: "+Kills Salmonella enterica, Staphylococcus aureus, Herpes Simplex Type 2, and Influenza A H3N2"

Sequence and placement of phrases is optional unless specified in 40 CFR 156.10.

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May 2, 2022

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: Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

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.

Physical or chemical hazard

This product contains bleach. Do not use this product with other chemicals such as ammonia, toilet bowl cleaners, rust removers, or acid, as this releases hazardous gases.

[Use one of the following as applicable to type of container:]

[To Dispense TOWELETTES] [or WIPES] [or TOWELS] [or CLOTHS]:

Remove lid [and discard inner seal] [from container or canister.] Find center of wipe roll, remove first wipe for use, twist corner of next wipe into a point and thread through the hole in the [container or] canister lid. Pull through about one inch. Replace lid. Dispense remaining wipes as necessary by pulling out at an angle. When not in use keep [center cap of] lid closed to prevent moisture loss.

TRAVEL PACK:

Peel back label slowly. Pull out wipes as needed and reseal label. Unfold wipe.

BOX:

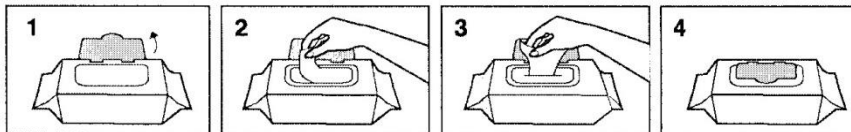
Open along perforations as indicated. Remove packets as needed.

PACKET/PACKAGE:

Tear open packet [package]. Unfold wipe and use as directed. Discard after single use.

SOLO® PAK:

Open package lid. Completely remove inner seal. Pull out wipe. (The next wipe pops up automatically.) Snap lid closed after use to retain moisture.



DO NOT FLUSH • STORE AT ROOM TEMPERATURE
DISPOSE OF USED WIPES IN TRASH RECEPTACLE • KEEP SOLO®
LID CLOSED WHEN NOT IN USE
SOLO® is a registered trademark of Nice-Pak Products, Inc.

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[For use on small single packets only: [Not labeled for individual sale [or distribution]] and/or [See dispenser [or container or box or case or outer packaging] for [additional or full label] information]

REFILL PACKET [or PACKAGE] [or POUCH]

This refill package is made for use only in a [product name] [container or] canister; do not use this product in a [container or] canister for another product. Do not use the refill wipes in a container that is cracked or broken. Discard the cracked or broken container in accordance with the container disposal instructions on the label.

[Option 1]

Remove [entire] lid from [container or] canister. Tear open refill [package] at [notch] [mark] [arrow] and place [wipe] roll in empty [container or] canister. Follow information on [container or] canister to dispense wipes.

[Option 2]

Remove [entire] lid from [container or] canister. Tear open refill [package] at [notch] [mark] [arrow]. Place [entire] refill package of wipes in empty [container or] canister. Follow information on [container or] canister to dispense wipes.

GENERIC:

Open lid. Pull out wipe. Close lid tightly.

Bucket [or pail or container]

1. Remove [the] lid from [the] [pail or bucket or container.]
2. [Use scissors] [to] [Cut] [Rip] [Tear] [Pull] [Open] refill pouch
3. Locate [the] first wipe at [the] center of [the] roll.
4. Feed [the] first wipe though [the] dispensing orifice.
5. Reapply [the] lid to [the] [pail or bucket or container.]
6. Dispense [the] wipe.

[For] [the] refill[s] [pouch]:

1. Remove [the] lid from [the] [pail or bucket or container.]
2. Remove [the] empty refill pack material from [the] [pail or bucket or container.]
3. Press open [the] dispenser at center of [the] lid.
4. Open [the] refill pack.
5. Locate [the] first wipe at [the] center of [the] roll.
6. Feed [the] first wipe though [the] dispensing orifice.
7. Reapply [the] lid to [the] pail.
8. Dispense [the] wipe.

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DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
[See directions for use on the container inside]

TO [CLEAN] [AND] [,] DISINFECT [AND DEODORIZE] HARD, NONPOROUS SURFACES: If present, use a wipe to remove visible soil prior to disinfecting. Unfold [a] [clean] wipe and thoroughly wet surface. Allow surface to remain visibly wet for four (4) minutes. [Use [additional] [enough] wipe(s) [, if needed,] to ensure [continuous] four (4) minute[s] wet contact time.] [Repeated use of the product may be required to ensure that the surface remains visibly wet for four (4) minutes]. Let air dry. A potable water rinse is required for food contact surfaces. [*When TB is included on the label, add the following:*] A precleaning step is required to kill *Mycobacterium bovis* BCG (TB). These directions also apply to *Mycobacterium bovis* BCG (TB) at 68°F (20°C). [*If label includes cleaning claims for grease, soap scum, grime, dirt, messes, soil, add the following as the first sentence:* A precleaning step is required for [grease], [soap scum], [grime], [dirt], [messes], [soil]].

[[Norovirus Disinfection]: This product is an effective disinfectant against Norovirus (as Feline calicivirus) in one minute at 68°F (20°C). Use a wipe to remove [visible] soil. Unfold a clean wipe and thoroughly wet surface. Allow surface to remain visibly wet for one (1) minute. [Use [additional] [enough] wipe(s) [, if needed,] to ensure [continuous] one (1) minute wet contact time.]] [Repeated use of the product may be required to ensure that the surface remains visibly wet for one (1) minute]. Let air dry. A potable water rinse is required for food contact surfaces.

[The following sets of directions are optional and for hospital/medical facility use only:]

[*Mycobacterium bovis*-BCG Disinfection:] This product is an effective disinfectant against *Mycobacterium bovis*-BCG (Tuberculosis) in two minutes at 68°F (20°C). Use a wipe to remove [visible] soil. Unfold a clean wipe and thoroughly wet surface. Allow surface to remain visibly wet for two (2) minutes. [Use [additional] [enough] wipe(s) [, if needed,] to ensure [continuous] [two (2) minute[s] wet contact time.]] [Repeated use of the product may be required to ensure that the surface remains visibly wet [for two (2) minute[s]].] Let air dry. Although efficacy at a two (2) minute contact time has been shown to be adequate against TB, this time is not sufficient for fungi listed on the label. Therefore a 4 minute wet contact time must be used if fungicidal disinfection is required.

and/or

[Ultrasound transducers and probes: For use on external surfaces of ultrasound transducers and probes only.
To disinfect: [Pre-] clean gel from external surface of ultrasound transducer or probe to be disinfected by using a clean washcloth. Then thoroughly wet the probe with a wipe. Allow surface to remain visibly wet for four (4) minutes. [Use [additional] [enough] wipe(s) [, if needed,] to ensure [continuous] four (4) minute[s] wet contact time.] [Repeated use of the product may be required to ensure that the surface remains visibly wet for four (4) minutes]. Let air dry.]

and/or

Special Instructions for Cleaning Prior to Disinfection against *Clostridium difficile* spores.

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

Cleaning Procedure: Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection by application with [Product name] [this product]. Cleaning is to include vigorous wiping and/or scrubbing, until all visible soil is removed. Special attention is needed for high-touch surfaces. Surfaces in patient rooms are to be cleaned in an appropriate manner, such as from right to left or left to right, on horizontal surfaces, and top to

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bottom, on vertical surfaces, to minimize spreading of the spores. Restrooms are to be cleaned last. Do not reuse soiled cloths. **Infectious Materials Disposal:** Materials used in the cleaning process that may contain feces/waste are to be disposed of immediately in accordance to local regulations for infectious materials disposal. **[Killing *Clostridium difficile* spores:** [Disinfect as directed [above or on this label] or Unfold a clean wipe and thoroughly wet surface. Allow surface to remain visibly wet for four (4) minutes. [Use [additional] [enough] wipe(s) [, if needed,] to ensure [continuous] four (4) minute[s] wet contact time.] [Repeated use of the product may be required to ensure that the surface remains visibly wet for four (4) minute[s]].

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1, HEPATITIS B VIRUS (HBV) AND HEPATITIS C VIRUS (HCV) ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS

Personal protection: When using this product, wear disposable protective gloves, protective gowns, face masks, and eye coverings [per facility protocol] when handling HIV-1 (AIDS Virus), HBV or HCV infected blood or body fluids.

Cleaning procedure: All blood and other body fluids must be thoroughly cleaned from surfaces and objects before disinfection by the germicidal wipe. Open, unfold and use first germicidal wipe to remove visible soil.

Disposal of infectious materials: Dispose of used wipe in accordance with local regulations for infectious waste disposal.

Contact time: Use second germicidal wipe to thoroughly wet surface. Allow surface to remain visibly wet one (1) minute, let air dry. [Although efficacy at a one (1) minute contact time has been shown to be adequate against HIV-1/HBV/HCV, this time is not sufficient for all organisms listed on this label. Therefore a four (4) minute wet contact time must be used] or [For all other organisms, see directions for contact times.] [use either: for other organisms listed on this label or for TB and pathogenic fungi].

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. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to [sterilization] [or] [high level disinfection.]

[Use storage/disposal statement A if container or canister directions used. Use storage/disposal statement B if travel pack or [refill] packet/package directions used.]

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal. [Statement not required for residential or household use products.]

Statement A: For [container or] [canisters and] refill dispensers:

Storage: Do not store near heat or open flame. When not in use keep center cap of lid closed to prevent moisture loss. **Towelette Disposal:** Do not reuse towelette. Dispose of used towelette in trash. Do not flush in toilet.

Dispenser [Container] Disposal: Non-refillable container. Do not reuse or refill this container. Offer for recycling. If recycling is not available, put in trash collection.

[If refillable container is being used, substitute the following: **[Refill] [Pail] [Dispenser] [Container] Disposal:** Offer for recycling. If recycling is not available, discard in trash.]

Statement B: For packets, travel packs, and [refill] packets or packages:

Storage: Do not store near heat or open flame.

Towelette Disposal: Do not reuse towelette. Dispose of used towelette in trash. Do not flush in toilet.

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Travel Pack [or Solo® Pak or Refill [Packet] or Packet] [or [bulk] package]] Disposal: Put empty travel pack [or Solo® Pak or refill packet] [or packaging]] in trash collection.

Areas of Use:

Hospital and Healthcare Settings: Ambulances, Ambulatory Surgical Centers (ASC), CAT Labs, CCU, Central Supply, Clinics, Dental Offices, Dialysis Clinics, Doctors Offices, Donation Centers [blood] [plasma] [semen] [milk] [apheresis], Emergency Medical Settings, Emergency Rooms, E.R., Emergency Vehicles, Eye Surgical Centers, Healthcare Settings, Health Care Facilities, Home Health Care, Hospices, Hospitals, ICU, Isolation Areas, Laboratory, Laundry rooms, Long Term Care Centers, Neonatal Intensive Care Units (NICU), Newborn nursery, Nursing homes, Operating Rooms (OR), Ophthalmic Offices, Orthopedics Unit, Out-Patient Surgical Centers (OPSC), Patient Care Areas, Pediatrics Unit, Pediatric Intensive Care Units (PICU), Physical therapy Unit, Physician's offices, Radiology Unit, Recovery Rooms, Rehabilitation Unit, Respiratory therapy Areas , Skilled Nursing Facility, Surgery Areas, Surgery Intensive Care Unit (SICU), Surgical Centers, Transport vehicles and Urgent Care Centers.

and/or

Critical Care Areas: CCU, Emergency Rooms, E.R., ICU, Neonatal Intensive Care Units (NICU), Operating Rooms, Pediatric Intensive Care Units (PICU) and Surgery and Surgical Intensive Care Unit (SICU).

and

Hospital, Healthcare, and Critical Care Use Sites: May be used on hard non-porous surfaces of: ambulance equipment surfaces; Anesthesia equipment surfaces, bed railings; bladder scan; blood glucose meters; blood pressure [BP] monitors; cabinets; cardiac gym equipment; carts; chairs; counters; defibrillators; dental chairs; dental countertops; dental unit instrument trays; dopplers; electronic thermometers; endodontic equipment such as apex locators; exam tables; gurneys; infant incubators [interior and exterior surfaces of]; infant warmers [interior and exterior surfaces of]; isolettes; IV poles; IV pumps; laboratory equipment and surfaces; loupes; operating room tables and lights; operatory light switches; Ophthalmoscopes; Oscopes; oxygen hoods; physical therapy (PT) equipment surfaces; patient lift equipment; pulse oximeter; radiology equipment; slit lamps; spine back boards; stethoscopes; stretchers; stools; tables; telemetry equipment; telephones; toilet seats; tympanic thermometers; and hard non-porous outside surfaces of: amalgamators and dental curing lights; anesthesia machines and respiratory therapy equipment; aphaeresis machines, diagnostic equipment, dialysis machines; patient monitoring equipment, patient support and delivery equipment, pulp testers and motors; toilets; ultrasound monitors; and ultrasound transducers and probes, X-ray equipment surfaces and other hard non-porous surfaces listed on this label.

Veterinary: Areas of Use: Animal Housing facilities; Animal Life Science Laboratories; [Animal] [or Pet] Grooming Facilities; Equine Farms; Farms; Kennels; Livestock [*and/or* Swine] [*and/or* Poultry Facilities]; Pet Areas; Pet Shops [or Pet Stores]; Small Animal Facilities; Veterinary Clinics [Facilities]; Veterinary Offices; Veterinary [Animal] Hospitals

Use Sites: animal equipment; automatic feeders; cages; external surfaces of [veterinary] equipment; feed racks; fountains; hard, non-porous surfaces [environmental] veterinary surfaces; pens; reception counters; stalls; troughs; veterinary care surfaces; watering appliances

Grocery Stores or Shopping Centers or Supermarkets or Delicatessens: Disinfects grocery cart handles and grocery cart child seats. Disinfects shopping cart handles and child seats.

Nursery or Daycare Centers: Bassinets [interior and exterior surfaces of], changing tables, cribs, diaper changing stations, diaper pails, infant/child care equipment surfaces, trash cans, toys and other hard, non-porous surfaces listed on this label.

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Bathroom[s] or Public Restrooms: Basins, [bath]tubs, bathroom fixtures, cabinets, countertops, doorknobs, faucet[s], handles, hampers, handrails, shower[s] [stalls], showers, sinks, glazed tiled walls, glazed tiles, toilet [handle] [rim] [seats] [tank] [and other exterior surfaces of], urinals [exterior surfaces of] and vanity tops, and other hard non-porous surfaces listed on this label.

Health club facilities and Gyms: Gym equipment, weight-lifting surfaces and other hard non-porous surfaces listed on this label.

Schools or Classrooms or Office Buildings or Public Facilities or Tattoo Parlors or Manufacturing Facilities or Libraries or Public Telephones: Cabinets, chairs, computers, computer monitors, computer mouse, counters, countertops, desks, desktops, door knobs, fax machines, filing cabinets, filing doors, filing handles, garbage cans, headsets, keyboards, railings, seats, sinks, tables, tabletops, telephones, toys, trash cans, work stations, and other hard non-porous surfaces listed on this label.

Cruise ships or Naval Vessels: Cabinets, chairs, computers, computer monitors, computer mouse, counters, countertops, desks, desktops, elevator [buttons], escalators, door knobs, garbage cans, hand railings, keyboards, railings, seats, sinks, tables, tabletops, telephones, toys, trash cans, and other hard non-porous surfaces listed on this label.

Transport vehicles, school buses, public buses, airplanes, fire trucks, police cars: Hard non-porous surfaces of vehicles including steering wheel, tray tables, arm rests, headsets, hard plastic or metal flooring, seats, and walls.

Restaurants: ^Hard non-porous surfaces including tables, chairs, display cabinets, garbage cans, booster seats, floor, sinks, bathroom surfaces, glazed tiled walls, telephones, cash registers, and doorknobs.

[^The following footnote is required: [^A thorough rinse with potable water is required for surfaces in direct contact with food.]

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[Symbols including asterisks, bullets or footnotes and similar may be used to designate categories of organisms.]
[ATCC numbers are not required to be listed on production label. Organisms may be listed in a table and in any order.]

Bacteria [(1 Minute Contact Time)]

Bordetella pertussis [ATCC 12743]
Burkholderia cepacia [ATCC 25416]
Campylobacter jejuni [ATCC 29428]
Escherichia coli [ATCC 11229]
Escherichia coli O157:H7 [ATCC 35150]
Klebsiella pneumoniae [ATCC 4352]
Legionella pneumophila [ATCC 33153]
Listeria monocytogenes [ATCC 19117]
Pseudomonas aeruginosa [ATCC 15442]
Salmonella enterica [ATCC 10708]
Serratia marcescens [ATCC 14756]
Staphylococcus aureus [ATCC 6538]
Streptococcus pyogenes [ATCC 12344]

C. difficile Spores [(4 Minute Contact Time)]

Clostridium difficile spores [ATCC 43598]

Mycobacterium (TB) [(2 Minute Contact Time)]

Mycobacterium bovis - BCG (TB)

Pathogenic Fungi [(4 Minute Contact Time)]

Aspergillus brasiliensis [ATCC 16404]
Candida albicans [ATCC 10231]
Trichophyton interdigitale [ATCC 9533]

Multi-Drug Resistant Bacteria [(1 Minute Contact Time)]

Acinetobacter baumannii Multi-Drug Resistant [ATCC 19606] [Effective against organism resistant to Ampicillin, Cefazolin, Gentamicin, Piperacillin, Trimethoprim/Sulfa and Intermediate resistance to Cefotaxime, Ceftriaxone.]
Enterobacter cloacae - NDM-1 positive [CDC 1000654]
Escherichia coli – NDM-1 positive [CDC 1001728]
ESBL Resistant *Escherichia coli* [ATCC BAA-196]
ESBL Resistant *Klebsiella pneumoniae* [ATCC 700603]
Klebsiella pneumoniae - Carbapenem Resistant [ATCC BAA-1705]
Klebsiella pneumoniae – NDM-1 positive [CDC 1000527]
Community Acquired Methicillin Resistant *Staphylococcus aureus* (CA-MRSA) [NARSA NRS384] [Genotype USA 300]
Community Acquired Methicillin Resistant *Staphylococcus aureus* (CA-MRSA) [NARSA NRS123] [Genotype USA 400]
Staphylococcus aureus Methicillin Resistant (MRSA) [ATCC 33592]
Streptococcus pneumoniae – Penicillin Resistant [ATCC 700677]
Vancomycin Intermediate *Staphylococcus aureus* (VISA) [HIP 5836]
Vancomycin Resistant *Staphylococcus aureus* (VRSA) [NARSA VRS1]
Vancomycin Resistant *Enterococcus faecalis* (VRE) [ATCC 51575]

Viruses* [(1 Minute Contact Time)]

[Enveloped Viruses]

*Avian Influenza A H5N1 virus [Strain VNH5N1-PR8/
CDC-RG CDC #2006719965]
*Cytomegalovirus (CMV) [ATCC VR-538]
*Herpes simplex virus type 2 [ATCC VR-734], [Strain G]
*Human Coronavirus [ATCC VR-740], [Strain 229E]
*Influenza A virus H3N2 Strain [ATCC VR-544]
*Influenza B virus / [Strain B/Hong Kong/5/72],
[ATCC VR-823]
*Respiratory syncytial virus (RSV) [ATCC VR-26],
[Strain Long]

*Severe Acute Respiratory Syndrome-Related
Coronavirus 2 (SARS-CoV-2) [(COVID-19 Virus)]
[[Strain] USA-WA1/2020]

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Bloodborne Pathogens [(1 Minute Contact Time)]

[Non-Enveloped Viruses]

- *Adenovirus type 2 [ATCC VR-846], [Adenoid 6 Strain]
- *Canine Parvovirus [ATCC VR-2017], [Cornell Strain]
- *Hepatitis A virus (Human) (HAV)[Strain HM-175]
- *Norovirus (Feline Calicivirus) [ATCC VR-782]
- *Poliovirus type 1[ATCC VR-1562], [Chat Strain]
- *Rhinovirus type 37 [ATCC VR-1147], [Strain 151-1]
- *Rotavirus [Strain WA]

- *Hepatitis B virus (HBV) - Duck HBV[†] [Strain 7/31/07]
- *Hepatitis C virus (Human) (HCV) - Bovine Diarrhea Virus[†]
[Strain Oregon C24v-genotype 1]
- *HIV-1 (AIDS virus)[†] [Strain HTLV-III_B]

[†]KILLS HIV-1 (AIDS VIRUS), HEPATITIS B VIRUS (HBV) AND HEPATITIS C VIRUS (HCV) ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS AND PRE-CLEANED EXTERNAL SURFACES OF ULTRASOUND TRANSDUCERS AND PROBES PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in one (1) minute at room temperature (68°- 77°F) or (20°- 25°C) in healthcare 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).

[Product name] is a one-step▲ disinfectant cleaner and odor neutralizer.¹ For use in hospitals and other critical care areas where the reduction of cross-contamination between treated surfaces is required. Suitable for use on equipment requiring bleach-based products. Use on hard non-porous surfaces and equipment listed on this label made of stainless steel, plastic, Formica® and glass. Organisms are killed in four (4) minutes by exposure to the liquid in the wipe.

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[Note: The following Emerging Viral Pathogen claims will not appear on product labels]

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.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral category[ies]:

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

<i>For an emerging viral pathogen that is a/an...</i>	<i>...follow the directions for use for the following organisms on the label:</i>
Enveloped virus	Adenovirus Type 2 (ATCC VR-846), Adenoid 6 Strain Canine Parvovirus (ATCC VR-2017), Cornell Strain Hepatitis A virus (Human)(HAV), Strain HM-175 Norovirus (Feline calicivirus), ATCC VR-782 Poliovirus type 1, ATCC VR-1562, Chat Strain Rhinovirus type 37, ATCC VR-1147, Strain 151-1 Rotavirus, Strain WA
Large, non-enveloped virus	Canine Parvovirus (ATCC VR-2017), Cornell Strain Hepatitis A virus (Human)(HAV), Strain HM-175 Norovirus (Feline calicivirus), ATCC VR-782 Poliovirus type 1, ATCC VR-1562, Chat Strain Rhinovirus type 37, ATCC VR-1147, Strain 151-1
Small, non-enveloped virus	Canine Parvovirus (ATCC VR-2017), Cornell Strain Hepatitis A virus (Human)(HAV), Strain HM-175 Norovirus (Feline calicivirus), ATCC VR-782 Poliovirus type 1, ATCC VR-1562, Chat Strain Rhinovirus type 37, ATCC VR-1147, Strain 151-1

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

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

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Optional Claims and Descriptors [Note: Deodorizing directions must be used when deodorizing claims (claims involving odor control) are used] [See end of Claims for Master Label Readers Notes]

Disinfecting Claims

An effective method to [clean] [deodorize and disinfect] against odor-causing organisms on hard non-porous surfaces listed on this label

An effective way to disinfect hard, non-porous environmental surfaces listed on this label.

Antibacterial

Antimicrobial

[Antibacterial] [Antimicrobial] health club equipment wipe

A One Step▲ Cleaner [and disinfectant] (except precleaning is required for blood and body fluids)¹

Approved for use against SARS-CoV-2 [Coronavirus] [,] [the virus that causes COVID-19] [the] [COVID-19 virus] [¢]

Bactericidal [(1 minute)]

Bactericidal, Fungicidal, Tuberculocidal and Virucidal* in 4 minutes

Bactericidal, Fungicidal, Tuberculocidal, Sporocidal and Virucidal* in 4 minutes

Cleans [,] [disinfects] [and] [deodorizes]

Cleans and disinfects [on the go] [¢]

[Cleans] [disinfects] [Cleaner and disinfectant] [in one] [all in one [easy] step [▲]]¹

Cleans [and /or Disinfects] grocery cart handles or shopping cart handles or grocery cart child seats or shopping cart child seats

Contains a 1:10 sodium hypochlorite solution similar to that recommended for effective disinfecting against *Clostridium difficile* [*C.difficile*] [*C.diff*] spores

Demonstrates 6 [six] log reduction against *Clostridium difficile* [*C. difficile*] [*C.diff*] spores [in [4][four] minutes]

Designed for killing *Clostridium difficile* [*C. difficile*] [*C.diff*] spores on surfaces in hospitals

Destroys [Deactivates] 99.999% *Clostridium difficile* spores [*C.difficile* spores] [*C.diff* spores] [on hospital surfaces] [Destroys] [Deactivates] SARS-CoV-2 [Coronavirus] [,] [the virus that causes COVID-19] [the] [COVID-19 virus] on hard, nonporous surfaces [in hospitals]

Disinfect external surfaces of ultrasound transducers

Disinfect the precleaned surface

Disinfecting towelettes

Disinfects and deodorizes in 4 minutes

Disinfects [as it cleans] [and scrubs in one easy step ▲]¹

Disinfects hard non-porous environmental surfaces listed on this label [Use to]

Disinfects hard, non-porous surface in 4 minutes

[Disinfects] hard surfaces [that people touch]

Disinfects [health club equipment] [treadmill handles] [elliptical handles] [exercise bike handles] [weight benches]

Disinfects [in [just] four [4] minutes]

Disinfects on the go [¢]

Easy [and convenient] way to clean [and] [disinfect]

Easy One Step▲ Cleaning [and disinfecting] (except precleaning is required for visible soil and blood and body fluids)¹

Easy way to [clean] [and] [disinfect] [bathroom] [or exterior toilet surfaces] [hard, non-porous surfaces]

Effective against bathroom bacteria and viruses* [use at least two bacteria and one enveloped and one non enveloped virus from the list of organisms on this label]

Effective against [the following micro-organisms on hard, non-porous surfaces] [list organisms]

Effective against *Clostridium difficile* [*C.difficile*] [*C.diff*] spores [[in [4] [four] minutes]

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Effective against SARS-CoV-2 [Coronavirus] [,] [the virus that causes COVID-19] [the] [COVID-19 virus] [in 1 minute] [¢]

Effective in the presence of 5% blood serum contamination

[Extra] large [disinfecting] [“Y” x “Z” compared to our “A” x “B” size] wipe[s]

[Convenient] [Portable] way to disinfect hard non-porous surfaces

Fungicidal [(4 minutes)]

Germicidal Disposable Wipes

Disinfectant cleaner [that cleans, disinfects and deodorizes] [in one step ▲] ¹

Helps reduce the spread of SARS-CoV-2 [Coronavirus] [,] [the virus that causes COVID-19] [the] [COVID-19 virus] [¢]

Hospital disinfectant [disinfection] [*use only when hospital use sites on label*]

Just [*or simply*] wipe exterior toilet surface [*or bathroom*] germs+ away in 4 minutes

Kills 99.9% odor-causing bacteria

Kill germs+ and bacteria instead of germ paper towels, sponges and rags [Use this product to]

Kills bacteria and viruses* in the bathroom [*or on the exterior toilet surfaces*] [*use at least two bacteria and one enveloped and one non-enveloped virus from the list of organisms on this label*]

Kills bacteria in 1 minute [use only when TB not listed on label or add ♦except TB in 2 minutes]

Kills *Clostridium difficile* [*C. difficile*] [*C.diff*] spores [in [4] [four] minutes]

Kills [Effective against] 99.9999% of *Clostridium difficile* [*C. difficile*] [*C.diff*] spores [in [4] [four] minutes]

Kills [effective against] pathogenic organisms including [*list organisms*]

[Kills] [Effective against] [MRSA] [(Methicillin Resistant *Staphylococcus aureus*)]

Kills enveloped and non enveloped viruses [*list organisms*]

Kills household [*or exterior toilet surface*] [*or bathroom*] germs+ [*use at least two bacteria and one enveloped and one non-enveloped virus from the list of organisms on this label*]

Kills SARS-CoV-2 [Coronavirus] [,] [the virus that causes COVID-19] [the] [COVID-19 virus] [in 1 minute] [¢]

*Kills SARS-CoV-2 [Coronavirus] [the virus that causes COVID-19] [in 1 minute] [in 60 seconds] on hard, nonporous surfaces

Kills the spore form of *Clostridium difficile* [*or C. difficile*]

Kills multi drug resistant organisms [*list organisms*]

Kills multi drug resistant bacteria [*list organisms*] [in [1] [one] minute]

Kills [Disinfects] Norovirus [Feline Calicivirus] [in] 1 [one] minute

Kills odor causing bacteria

Leaves [bathroom] [office] [clean [and disinfected] [and smelling fresh]

Multi-purpose [cleaner] [disinfectant] [Multi [-refill] pack] New [larger] thicker wipe with diamond-embossed design

[Now] tested [and proven [effective]] to kill [the] [COVID-19 virus] SARS-CoV-2 [¢]

[Now] tested [and proven [effective]] against [the] [COVID-19 virus] SARS-CoV-2 [¢]

[Now] tested [and proven [effective]] to help reduce [the spread of] [the] [COVID-19 virus] SARS-CoV-2 [¢]

One step ▲ [cleaning] [disinfecting] [wipe] ¹

One step ▲ cleaning [*and/or disinfecting*] [*and/or deodorizing*] disinfect *and/or* touch-up clean] [cleans *and/or* disinfects *and/or* deodorizes] [anytime] [daily] [every day] [in one easy step ▲] [on hard non-porous] [bathroom *and/or* kitchen] surfaces [on household surfaces] ¹

One step ▲ disinfectant and bactericidal according to the current AOAC Germicidal Spray Products as Disinfectants Method modified in the presence of 5% organic serum against [insert any bacteria from List of bacteria] 1

One step ▲ disinfectant cleaner that is effective against a broad spectrum of bacteria when used as directed ¹

One step ▲ germicide ¹

On-the-go disinfectant [Package] [*insert type of package*] made from [x%] recycled materials [¢]

Perfect for [cleaning] [disinfecting] exterior toilet surfaces [*or around the exterior toilet surface*]

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Proven efficacy against SARS-CoV-2[Coronavirus] [,] [the virus that causes COVID-19] [the] [COVID-19 virus] [in 1 minute] [¢]

Proven “one-step” ▲ disinfectant [cleaner] which is effective in the presence of 5% serum contamination¹

Scrubbing power of a sponge in a disinfecting wipe

[So] surfaces are more than [just] [clean] [they're] [disinfected]

The 4-minute germicidal wipe [disinfectant wipe]

Thick, wipes are bactericidal, tuberculocidal and virucidal* in 2 minutes

Thick, wipes are bactericidal, tuberculocidal, fungicidal and virucidal* in 4 minutes

Thick, large wipe [cleans] [disinfects] [¢]

Tuberculocidal [(2 minute)]

Two in one action [cleans and disinfects in one easy step▲] ¹

Virucidal* [(1 minute)]

[Wipes out] [Kills] [bacteria] [viruses*] [fungi] [germs+] on hard non-porous surfaces

[Wipes out] [Kills] [eliminates 99.9%] [*list organisms*] in [just] [___ minutes] [*minutes depend on organisms listed*] on hard non-porous surfaces

[Wipes out] [Kills] germs+ [*or bacteria*] [while it cleans] [that cause odor] on hard non-porous surfaces

[Wipes out] [Kills] [the] flu virus* (*Influenza A virus H3N2) on hard non-porous surfaces

[Wipes out] [Kills] viruses* and bacteria [including the flu virus* (*Influenza A virus H3N2)] on hard non-porous Surfaces

Wipes out SARS-CoV-2 [Coronavirus] [,] [the virus that causes COVID-19] [the] [COVID-19 virus] [in 1 minute] [¢]

[Wiping] [soft] side for disinfecting

[Wiping] [soft] side for [wiping] dirt away [and disinfecting]

[¢] [on] hard, nonporous surfaces [of] [identified on this label]

¹ When disinfection directions are used

General Cleaning and Deodorizing Claims

[Appropriate] [Perfect] [Ideal] [for] Cleaning Patient Discharge

Built-in [tough] scrubbing fibers help clean

Cleaning Wipe[s] [Towel] [s] refill[s] [able]

Cleans grocery carts and shopping carts

Deodorize hard, non-porous surfaces [Use to]

Eliminates [lingering] [food] odors [on surfaces]

Gets rid of [*or eliminates*] odors

Leaves bathroom fresh and clean in [just] minutes

Odor [elimination] [neutralization] One [wipe] at a time dispensing

[Soft] side for [cleaning] dirt away

Virtually [Lint Free] [streak free] [clean] [shine]

Wipe away odors

Formula Related Claims

Are pre-measured to have the recommended amount of germicidal solution, wipe after wipe.

Assures proper dilution strength, product effectiveness and standardized technique

Contains 0.63% sodium hypochlorite

Does not contain VOC's

No measuring

No mixing

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No sponges, no rags, no buckets, no mess
[Premixed], [premeasured], [premoistened]
Ready to Use
Requires no mixing or measuring and are ready-to-use
Shelf-stable formula
Suitable for use on equipment requiring bleach-based products

Packaging Related Claims

Contains [number] canisters [plus] [and] [number] refills
Dispenses one wipe at a time
[Easy] [convenient] [dispensing] lid [closure] [cap] [package]
Easy drop-in refill[s]
[Easy] pop-up-tub
Easy start lid [package]
Easy to use [easy to refill]
Easy to use package [canister] [container] keeps [your] wipes moist
[Economical] Refill[s] [one] [1] [two] [2] [three] [3] [four] [4] [various numbers] -pack
[Economical] Refills [now] available
Economy
Includes ___ count refill [pack] [contains] ___ wipes
Less [reduced] packaging [less to throw away]
Moisture lock lid
Multi-pack
Next wipe pops up automatically [every time] [!]
No canister needed
No threading [required]
Pop-up [dispensing] [top]
Portable
Pull n/ Go [pack]
Recyclable [package]
Reduces [packaging] waste [by x%] [when compared to regular canister or bucket or pail]
[Refill] package contains [one] [1] [two] [2] [three] [3] [four] [4] [various numbers] [wet] [pre-moistened] [wipe]
[refill[s]] [roll[s]]
Refill [size] [pack] [value pack]
Refillable [with ___# wipes] [dispenser] refill [pack] [for dispenser]
Resealable [stay-moist] pouch [package] [container] inside
Reuse your [empty] canisters [again [and again] [!]
This [outer] [selling] [package] [container] [canister] contains x% post consumer [material] [plastic] [resin]
Tub refill
Tub with pop-up action
Twin pack
[Use to] refill[s] [count] [wipe] canisters or tubs
X% [more] [wipes] [free] [vs. Z count] [canisters] [packs]
X% reduction in packaging [material]

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Towelettes Related Claims

X" x Y" [wipes]

___% bigger [[quilted] wipes] [vs. X" x Y" wipes]

___# pre-saturated towelettes X" x Y"

[Absorbs] [Absorbent] [wipe]

Cellulosic non-woven disposable cloth

[Cloth-like texture] [Textured] [strong] [for] [with] scrubbing power

Diamond-embossed pattern [texture] provides effective cleaning

Diamond-embossed wipe is low-linting [for sensitive equipment surfaces]

Double-sided scrubbing wipes

Durable, low-lint wipe designed for sensitive equipment surfaces

Low linting [wipe]

No [pinched fingers] [rips] [tears]

Non-scratching [wipe]

Non-woven disposable cloth

Picks up [particles] [dust] [dirt] [hair] [crumbs]

Strong, durable diamond-embossed textured wipe [cleans] [and] [deodorizes]

Strong, durable low-lint wipe [designed for sensitive equipment surfaces]

Tear at perforation

Textured diamond-embossed design [cleans] [deodorizes] hard, non-porous surfaces] [helps remove soil from surfaces]

Textured for better [cleaning] [scrubbing] power

[Textured] [scrubby] [rough] side for [scrubbing] [cleaning] [removing] [wiping] [tough] [stains] [soils] [messes]

Textured wipe for effective cleaning

Thick, textured wipe with diamond-embossed design

Other Product Related Claims

© [insert year] [insert company name]

After use, just toss wipe(s) away

Always ready to use

A non-woven disposable cloth for use in hospitals and other critical care areas where reduction between treated hard, nonporous surfaces is required

A Sani-Surface® Brand

Can help reduce the risk of cross contamination on treated hard, nonporous surfaces

Contains [name of active ingredient], the [same] active ingredient used in [Brand-name® or ™] ^ψ

^ψ This product is not manufactured or distributed by [company name® or ™] The owner of the

Registered Trademark [Brand name® or ™]

Convenient

[Designed] [for] [with] [the] Environmental Services Professionals[s] [in mind]

Does not produce mist or overspray

Easy

Easy [and convenient] way to [touch-up] [bathroom] [office] everyday

Eliminates potential for overspray

EVS [Environmental Services] Us

Expiration date [or EXP] [insert date]

For daily use

Helps reduce cross contamination on treated surfaces

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A footnote can be used to list organisms. Bacteria and virus can be separated into footnotes 1 and 2 if desired.

When organisms are listed next to a claim, the organisms may be listed in a footnote instead of directly next to the claim

+All pesticidal "germ" claims must be linked to bacteria (minimum: Salmonella and Staph) and at least one virus. For example: Front panel: "Kills germs+"

Back panel: "+Kills Salmonella enterica, Staphylococcus aureus, Herpes Simplex Type 2, and Influenza A H3N2"

Sequence and placement of phrases is optional unless specified in 40 CFR 156.10.

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The terms "Wipe(s)", "Towel(s)", "Towelette(s)" and "Cloth(s)" can be used interchangeably throughout except for the product primary brand name which can be only changed by notification or amendment.

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May 2, 2022

Just [pull] wipe and toss

Not for in-home sale [or use] [or Not for home owner use] [for use only on product made especially for institutional use and marketed only to institutions including hospitals, medical centers, etc.]

Not for sale in [insert name of state(s)]

Not for sale [or use] after [insert date]

Premoistened [wet] household cleaning wipe

Premoistened with specially formulated cleaners to handle daily clean-ups without bottles, sponges or buckets

Reduce risk of cross contamination on treated hard non-porous surfaces

Sample

Time to reorder

Trial

Use on hard, non-porous surfaces only: [stainless steel] [Formica®] [glass] [glass tables] [glazed tile] [Test wipe on small inconspicuous area first.]

Value

Versatile

Wet wipes

Where reduction of cross contamination between treated hard, nonporous surfaces is of prime importance

[Note: The following claims can be used only for 6 months]

[Better] [New] [Stronger] [Thicker] Wipe [!]

[Better] [new] [&] [dispensing] lid [closure] [cap] [package] [dispensing] [better [than before]

New

[New] [Package] [packaging] uses [x%] less material (plastic) [then] [when compared to] [regular] containers [or canisters]

New thicker and larger diamond-embossed wipe cleans more surface area

[Now] [Reinforced] [With] Quilted [strength]

Now with [%] more towel

Now with [#] more wipes

[Scrubs] (&) [cleans] [better than ever]

[Stronger] more durable [wipe]

Thick[er] [wipe] [with] cloth-like texture

X% [Bigger] [larger] [quilted] wipes

[x%] thicker wipes

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[Master Label Reader Notes

+ All pesticidal “germ” claims must be linked to bacteria (minimum: *Salmonella* and *Staph*) and at least one virus and/or fungi. For example: Front panel: “Kills germs+” Back panel: “+Kills *Salmonella enterica*, *Staphylococcus aureus*, *Herpes Simplex virus type 2*, and *Influenza A virus H3N2*”.

A footnote can be used to list organisms. Bacteria, virus and fungi can be separated into footnotes 1, 2 and 3 if desired.

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If one step cleaner claims used and HIV-1/HBV/ HCV claims and/or directions for ultrasound transducers are included on the label, then the following also must be included on the same panel of the label:

▲ a pre-cleaning step is required for HIV-1, HBV and HCV [and] [or] use on ultrasound transducers [or probes]. If HIV-1, HBV or HCV or ultrasound transducers are not listed on the label, any of the one step cleaning/disinfecting claims may be used without the phrase requiring pre-cleaning.

Latin organism names are in italics, otherwise italics in brackets indicate reader’s notes and are not part of labeling text.]

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May 2, 2022

[The following graphics and statements are optional. They may be placed anywhere on label/container.]



This graphic shows use of the wipe dispenser.



DO NOT FLUSH

NOT A BABY WIPE

NOT FOR USE ON SKIN

NOT A SKIN WIPE

FOR USE ON HARD, NON POROUS SURFACES ONLY

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May 2, 2022



Not a Skin Wipe.
For Use on Hard Surfaces Only.



Not a Skin Wipe.
For Use on Hard Surfaces Only.

[The following graphics and statements are optional. They may be placed anywhere on label/container.]



FINISHED FLOORS



**SHOPPING
CARTS**



[One side scrubs] [One side wipes]

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GYM



OFFICE



TABLES



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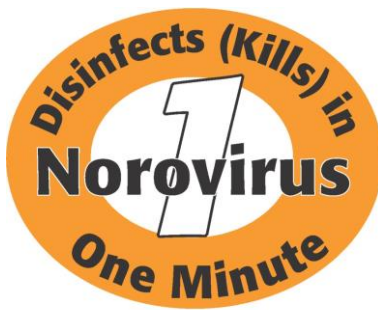
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Professional Disposables International, Inc.



* Although efficacy in one minute has been shown to be adequate against Norovirus, this contact time is not sufficient for other organisms listed on the label.

*

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[The following are company logos for use on PDI product labels. The purpose of the logo is for easy recognition of PDI products in the marketplace.]



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