

9480-8

5/9/2012

1 of 18



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

MAY - 9 2012

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION PREVENTION

Cristina Griffin
Professional Disposables International, Inc.
c/o Delta Analytical Corp.
12510 Prosperity Drive, Suite 160
Silver Spring, MD 20904

Subject: **PDI Sani-Cloth Bleach Wipes**
EPA Registration No.: 9480-8
Application Date: 12/21/2011
Receipt Date: 12/21/2011

Dear Ms. Griffin:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) 3 (c) 7 A as amended, is acceptable.

Proposed Amendment:

- Revision of basic formulation to change label concentration
- Additional alternate stabilizer, surfactant, and CAS numbers for wipe substrates

Data Summary

Data Requirement	Means of Support	Status
<i>Clostridium difficile</i> (ATCC 43598)	Submitted study, MRIDs 487037-02 to 487037-04	Acceptable @ 4 min
<i>Escherichia coli</i> (ATCC 11229)	Submitted study, MRID 487037-06	Acceptable @ 1 min
<i>Escherichia coli</i> NDM-1 positive (CDC 1001728)	Submitted study, MRID 487037-07	Acceptable @ 1 min
<i>Bordetella pertussis</i> (ATCC 12743)	Submitted study, MRID 487037-08	Acceptable @ 1 min
<i>Klebsiella pneumoniae</i> -NDM-1 positive (CDC1000527)	Submitted study, MRID 487037-09	Acceptable @ 1 min
<i>Burkholderia cepacia</i> (ATCC 25416)	Submitted study, MRID 487037-10	Acceptable @ 1 min.

CONCURRENCES

SYMBOL	<i>Serratia marcescens</i> (ATCC 14736)	Submitted study, MRID 487037-11	Acceptable @ 1 min
SURNAME	<i>Enterobacter cloacae</i> -NDM-1 positive	Submitted study, MRID 487037-12	Acceptable @ 1 min

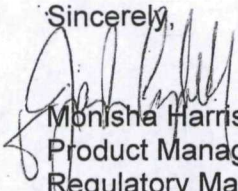
(CDC 1000654)		
Cytomegalovirus (ATCC VR-538)	Submitted study, MRID 487037-13	Acceptable @ 1 min
Influenza B virus (ATCC VR-823)	Submitted study, MRID 487037-14	Acceptable @ 1 min
<i>Legionella pneumophila</i> (ATCC 33153)	Proposed	Acceptable @ 1 min

General Comments

The basic Confidential Statement of Formula dated 12/1/11 was found acceptable as the current basic formulation.

A stamped label is enclosed for your records. Submit a final printed label before selling or distributing the product bearing the revised labeling. Should you have any questions concerning this letter, you may contact me by telephone or by email at: carl.jaclyn@epa.gov during the hours of 8:00 am to 4:00 pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,



Monisha Harris
 Product Manager (32)
 Regulatory Management Branch II
 Antimicrobials Division (7510P)

**Enclosed: Stamped Label with Conditions
 Efficacy and Product Chemistry Reviews**

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

30918

PDI SANI-CLOTH® BLEACH WIPES

[Alternate brand names EPA approved 3/30/11:
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:

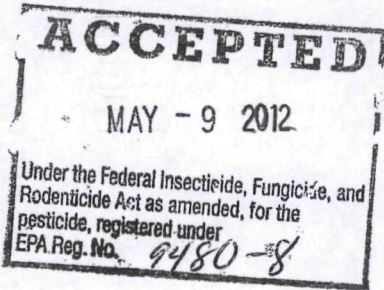
Sodium Hypochlorite..... 0.63%

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 [side] panel for additional precautionary statements

NET CONTENTS [and/or Net Wt.] _____ oz (g) [or lbs. (kg)]

___# OF CLOTHS [SIZE of each cloth]

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.
Two Nice-Pak Park, Orangeburg, NY 10962-1376
[For information call: [phone number to be inserted]]
[Made in USA]

The terms "wipe(s)", "towel(s)", "towelette(s)", and "cloth(s)" and the product name may be used interchangeably except for within the product primary brand name.

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:

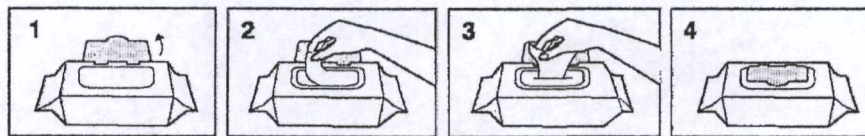
Open along perforations as indicated. Remove packets as needed.

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.

The terms "wipe(s)", "towel(s)", "towelette(s)", and "cloth(s)" and the product name may be used interchangeably except for within the product primary brand name.

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.
5. Feed the first wipe through the dispensing orifice.
6. Reapply the lid to the [pail or bucket or container.]
7. Dispense the wipe.

For the refills [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 through 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.

TO [CLEAN] [AND] [,] DISINFECT [AND DEODORIZE]: Use a wipe to remove gross filth [or heavy soil]. Unfold a clean wipe and thoroughly wet surface. Treated surface must remain visibly wet for a full four (4) minutes. Use additional wipe(s) if needed to assure continuous 4 minute wet contact time. [For food contact surfaces, rinse with potable water before use.] [When TB is included on the label, add the following or use the TB directions below:] These directions also apply to *Mycobacterium bovis*-BCG (Tuberculosis) at 68°F (20°C). [[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 heavy soil. Unfold a clean wipe and thoroughly wet surface. Treated surface must remain visibly wet for one (1) minute. Use additional wipe(s) if needed to assure continuous one (1) minute wet contact time. [Let air dry.] [For food contact surfaces, rinse with potable water before use.]]

[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 heavy soil. Unfold a clean wipe and thoroughly wet surface. Treated surface must remain visibly wet for two (2) minutes. Use additional wipe(s) if needed to assure continuous two (2) minute wet contact time. 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. Treated surface must remain visibly wet for a full four (4) minutes. Use additional wipe(s) if needed to assure continuous four (4) minute wet contact time. 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 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. Treated surface must remain visibly wet for a full four (4) minutes. Use additional wipe(s) if needed to assure continuous 4 minute wet contact time.]

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

Personal protection: When using this product, wear disposable protective gloves, protective gowns, face masks, and eye coverings as appropriate 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 heavy 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 to remain 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 [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.

The terms "wipe(s)", "towel(s)", "towelette(s)", and "cloth(s)" and the product name may be used interchangeably except for within the product primary brand name.

[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. Triple rinse and offer for recycling. If recycling is not available, put in trash collection.

[If refillable container is being used, substitute the following: **Refill Dispenser Disposal:** Triple rinse cracked or broken containers and 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.

Travel Pack [or Solo® Pak or Refill 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), Anesthesia, 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, Out-Patient Surgical Centers (OPSC), Patient Care Areas, Pediatrics, Pediatric Intensive Care Units (PICU), Physical therapy, Physician's offices, Radiology, Recovery Rooms, Rehabilitation, Respiratory therapy, Skilled Nursing Facility, Surgery, Surgery Intensive Care Unit (SICU), Surgical Centers, Transport vehicles, Urgent Care Centers and X-Ray.

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; 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; operator light switches; Ophthalmoscopes; Otopscopes; 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 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

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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.

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.]

[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)]

- [*]
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)]

- Clostridium difficile* spores [ATCC 43598]

TB [(2 Minute Contact)]

- Mycobacterium bovis* - BCG (TB)

Pathogenic Fungi[*] [(4 Minute Contact)]**

- [***]
Aspergillus brasiliensis [ATCC 16404]
- Candida albicans* [ATCC 10231]
- Trichophyton mentagrophytes* [ATCC 9533]

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

- [*]
Acinetobacter baumannii Multi-Drug Resistant [ATCC 19606] [Effective against organism resistant to Ampicillin, Cefazolin, Gentamicin, Trimethoprim/Sulfa and Intermediate resistance to Cefotaxime, Ceftriaxone, Piperacillin.]
- 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)]**

[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 /Hong Kong 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

[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]

Bloodborne Pathogens [(1 Minute Contact)]

- **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]

The terms “wipe(s)”, “towel(s)”, “towelette(s)”, and “cloth(s)” and the product name may be used interchangeably except for within the product primary brand name.

[Optional: Choose one of the following statements:]

[Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by influenza A virus. This product is a broad-spectrum hard surface disinfectant that has been shown to be effective against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).

This product has demonstrated effectiveness against influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus.

This product has demonstrated effectiveness against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).

Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu).

Kills Pandemic 2009 H1N1 influenza A virus.]

†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. For use in hospitals and other critical care areas where the control of the hazards 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.

The terms "wipe(s)", "towel(s)", "towelette(s)", and "cloth(s)" and the product name may be used interchangeably except for within the product primary brand name.

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]

X" x Y" [wipes]

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

___# pre-saturated towelettes X" x Y"

© [insert year] [insert company name]

[Absorbs] [Absorbent] [wipe]

After use, just toss wipe(s) away

Always ready to use

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.

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

Antibacterial

Antimicrobial

[Antibacterial] [Antimicrobial] health club equipment wipe

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

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

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

A Sani-Surface® Brand

Assures proper dilution strength, product effectiveness and standardized technique

Bactericidal [(1 minute)]

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

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

Built-in [tough] scrubbing fibers help clean

Can help reduce the risk of cross contamination on treated surfaces

Cellulosic non-woven disposable cloth

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

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

Cleans and disinfects [on the go]

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

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

Cleans grocery carts and shopping carts

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

Contains 0.63% sodium hypochlorite

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

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

Ψ This product is not manufactured or distributed by _____® [or ™]

Contains [number] canisters [plus] [and] [number] refills

Convenient

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

Deodorize hard, non-porous surfaces [Use to]

Deodorizes, and kills common household germs*

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

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

Destroys [Deactivates] [[Helps] Eliminate] [tough-to-kill] *Clostridium difficile* spores [C. difficile spores] [C. diff spores] [on hospital surfaces]

Diamond-embossed pattern [texture] provides effective cleaning

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

Disinfect external surfaces of ultrasound transducers

Disinfect the precleaned surface

Disinfecting towelettes

Disinfects and deodorizes in 4 minutes

The terms "wipe(s)", "towel(s)", "towelette(s)", and "cloth(s)" and the product name may be used interchangeably except for within the product primary brand name.

Disinfects [as it cleans] [and scrubs in one easy step ▲]
 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
 Dispenses one wipe at a time
 Does not contain VOC's
 Does not produce mist or overspray
 Double-sided scrubbing wipes
 Durable, low-lint wipe designed for sensitive equipment surfaces
 Easy
 Easy [and convenient] way to clean [and] [disinfect]
 Easy [and convenient] way to [touch-up] [bathroom] [office] everyday
 [Easy] [convenient] [dispensing] lid [closure] [cap] [package]
 Easy drop-in refill[s]
 Easy One Step▲ Cleaning [and disinfecting] (except precleaning is required for heavy soil and blood and body fluids)
 [Easy] pop-up-tub
 Easy start lid [package]
 Easy to use [easy to refill]
 Easy to use package [canister] [container] keeps [your] wipes moist
 Easy way to [clean] [and] [disinfect] [bathroom] [or exterior toilet surfaces] [hard, non-porous surfaces]
 [Economical] Refill[s] [one] [1] [two] [2] [three] [3] [four] [4] [various numbers] -pack
 [Economical] Refills [now] available
 Economy
 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]
 Effective in the presence of 5% blood serum contamination
 Eliminates [lingering] [food] odors [on surfaces]
 Eliminates potential for overspray
 EVS [Environmental Services] Us
 Expiration date [or EXP] [*insert date*]
 Extra large [disinfecting] [Y" x Z" compared to our A" x B" size] wipes
 [Convenient] [Portable] way to disinfect hard non-porous surfaces
 For daily use
 Fungicidal [(4 minutes)]
 Germicidal Disposable Wipes
 Gets rid of [or eliminates] odors
 Disinfectant cleaner [that cleans, disinfects and deodorizes] [in one step▲]
 [Helps] [kill][s] [eliminate][s] odor-causing bacteria
 Helps prevent cross contamination on treated surfaces
 Hospital disinfectant [disinfection] [*use only when hospital use sites on label*]
 Includes ___ count refill [pack] [contains] ___ wipes
 Just [or simply] wipe exterior toilet surface [or bathroom] germs+ away
 Just [pull] wipe and toss
 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*)]

The terms "wipe(s)", "towel(s)", "towelette(s)", and "cloth(s)" and the product name may be used interchangeably except for within the product primary brand name.

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 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 fresh and clean in *[just] minutes*
 Leaves *[bathroom] [office] [clean [and disinfected] [and smelling fresh]*
 Less *[reduced] packaging [less to throw away]*
 Low linting *[wipe]*
 Moisture lock lid
 Multi-pack
 Multi-purpose *[cleaner] [disinfectant] [Multi [-refill] pack] New [larger] thicker wipe with diamond-embossed design*
 Next wipe pops up automatically *[everytime] [!]*
 No canister needed
 No measuring
 No mixing
 No *[pinched fingers] [rips] [tears]*
 No sponges, no rags, no buckets, no mess
 No threading *[required]*
 Non-scratching *[wipe]*
 Non-woven disposable cloth
 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]*
 Odor *[elimination] [neutralization] One [wipe] at a time dispensing*
 One step▲ *[cleaning] [disinfecting] [wipe]*
 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]*
 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]*
 One step▲ *disinfectant cleaner that is effective against a broad spectrum of bacteria when used as directed*
 One step▲ *germicide*
 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]*
 Picks up *[particles] [dust] [dirt] [hair] [crumbs]*
 Pop-up *[dispensing] [top]*
 Portable
[Premixed], [premeasured], [premoistened]
 Premoistened *[wet] household cleaning wipe*
 Premoistened with specially formulated cleaners to handle daily clean-ups without bottles, sponges or buckets *[This product is]*
 Proven "one-step" ▲ *disinfectant [cleaner] which is effective in the presence of 5% serum contamination*
 Pull n/ Go *[pack]*
 Ready to Use
 Recyclable *[package]*
 Reduce *[risk of cross contamination] [on hard non-porous surfaces]*
 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]*
 Requires no mixing or measuring and are ready-to-use

The terms "wipe(s)", "towel(s)", "towelette(s)", and "cloth(s)" and the product name may be used interchangeably except for within the product primary brand name.

Resealable [stay-moist] pouch [package] [container] inside
 Reuse your [empty] canisters [again [and again] [!]
 Sample
 Scrubbing power of a sponge in a disinfecting wipe
 Shelf-stable formula
 [So] surfaces are more than [just] [clean] [they're] [disinfected]
 [Soft] side for [cleaning] dirt away
 Strong, durable diamond-embossed textured wipe [cleans] [and] [deodorizes]
 Strong, durable low-lint wipe [designed for sensitive equipment surfaces]
 Suitable for use on equipment requiring bleach-based products
 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
 The 4-minute germicidal wipe [disinfectant wipe]
 Thick, heavy duty wipes are bactericidal, tuberculocidal and virucidal* in 2 minutes
 Thick, heavy duty wipes are bactericidal, tuberculocidal, fungicidal and virucidal* in 4 minutes
 Thick, large wipe [cleans] [disinfects]
 Thick, textured wipe with diamond-embossed design
 This [outer] [selling] [package] [container][canister] contains x% post consumer [material][plastic][resin]
 Time to reorder
 Trial
 Tuberculocidal [(2 minute)]
 Tub refill
 Tub with pop-up action
 Twin pack
 Two in one action [cleans and disinfects in one easy step ▲]
 Use on hard, non-porous surfaces only: [stainless steel] [Formica®] [glass] [glass tables] [glazed tile] [Test wipe on small inconspicuous area first.]
 Use to preclean or decontaminate critical or semi-critical medical devices prior to sterilization / high-level disinfection
 [Use to] refill[s] [count] [wipe] canisters or tubs
 Value
 Versatile
 Virtually [Lint Free] [streak free] [clean] [shine]
 Virucidal* [(1 minute)]
 Wet wipes
 Where control of the hazards of cross contamination between treated surfaces is of prime importance
 Wipe away odors
 [Wipes out] [Kills] [common] [household] [bacteria] [viruses*] [fungi] [germs+] on hard non-porous surfaces
 [Wipes out] [Kills] [eliminates] [*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/Hong Kong) on hard non-porous surfaces
 [Wipes out] [Kills] viruses* and bacteria [including the flu virus* (*Influenza A virus/Hong Kong)] on hard non-porous surfaces
 [Wiping] [soft] side for disinfecting
 [Wiping] [soft] side for [wiping] dirt away [and disinfecting]
 X% [more] [wipes] [free] [vs. Z count] [canisters] [packs]
 X% reduction in packaging [material]

The terms "wipe(s)", "towel(s)", "towelette(s)", and "cloth(s)" and the product name may be used interchangeably except for within the product primary brand name.

[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

[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/Hong Kong*".

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

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.]

The terms "wipe(s)", "towel(s)", "towelette(s)", and "cloth(s)" and the product name may be used interchangeably except for within the product primary brand name.

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



This graphic shows use of the wipe dispenser.



NOT A BABY WIPE

NOT FOR USE ON SKIN

NOT A SKIN WIPE

FOR USE ON HARD [NON POROUS] SURFACES ONLY



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



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

The terms "wipe(s)", "towel(s)", "towelette(s)", and "cloth(s)" and the product name may be used interchangeably except for within the product primary brand name.

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



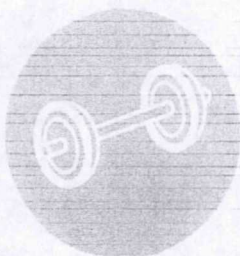
FINISHED FLOORS



**SHOPPING
CARTS**



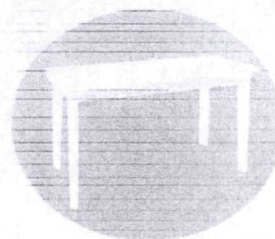
[One side scrubs] [One side wipes]



GYM



OFFICE

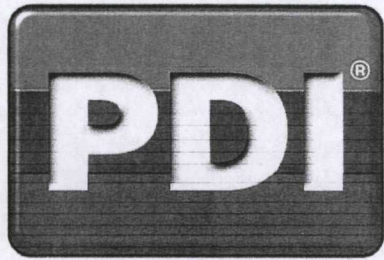


TABLES

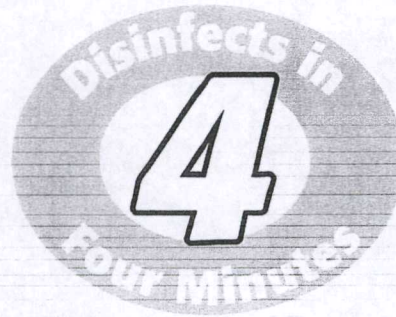


The terms "wipe(s)", "towel(s)", "towelette(s)", and "cloth(s)" and the product name may be used interchangeably except for within the product primary brand name.

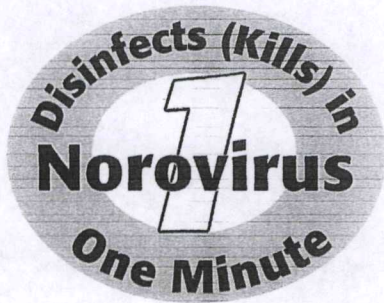
[The following graphics and statements are optional. They may be placed anywhere on label/container.]



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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