ANNON THE REPORT	Antimicrobials 1200 Pennsyl	sticide Programs s Division (7510F Ivania Avenue N	; >) W	EPA Reg. Number: 9480-8	Date of Issuance: JAN <b>13</b> 2011
	Washington, D.C. 20460		1460	Term of Issuance:	
	·	ESTICIDE: tration istration		Conditional Name of Pestic PDI Sani-Clot	ide Product: h Bleach Wipes
(under FIFRA, as	amended)			*	
Name and Address	of Registrant (include	ZIP Code):			COPY
Professional Dia Two Nice-Pak F Orangeburg, N		nal, Inc. (PDI)			
number	ior to use of the label in comme				n na san an tana tana tana sa
Number On the basis of informa Insecticide, Fungicide a the Agency. In order to of a pesticide in accord	tion furnished by the registrant, and Rodenticide Act. Registratic protect health and the environi ance with the Act. The accepta registrant a right to exclusive u	, the above named pest on is in no way to be co ment, the Administrator ance of any name in co	ticide is hereby regi nstrued as an endo r, on his motion, ma nnection with the re	stered/reregistered und rsement or recommend by at any time suspend gistration of a product	der the Federal dation of this product by or cancel the registratio
Number On the basis of informa Insecticide, Fungicide a the Agency. In order to of a pesticide in accord construed as giving the	tion furnished by the registrant, and Rodenticide Act. Registration protect health and the environmance with the Act. The accepta registrant a right to exclusive u uct (OPP Decision No.	, the above named pest on is in no way to be co ment, the Administrator ance of any name in co use of the name or to its	ticide is hereby reginstrued as an endo r, on his motion, mannection with the results use if it has been o	stered/reregistered und rsement or recommend by at any time suspend gistration of a product covered by others.	der the Federal dation of this product by or cancel the registratio under this Act is not to b
Number On the basis of informa Insecticide, Fungicide a the Agency. In order to of a pesticide in accord construed as giving the This prod provided that you 1. Submit and/or Agency requires	tion furnished by the registrant, and Rodenticide Act. Registration protect health and the environmance with the Act. The accepta registrant a right to exclusive u uct (OPP Decision No.	the above named pest on is in no way to be co ment, the Administrator ance of any name in co use of the name or to its D-438938) is reg or registration of y r products to sub	ticide is hereby reginstrued as an endo r, on his motion, mannection with the result of the subscription with the result of the subscription of th	stered/reregistered und rsement or recommend by at any time suspend gistration of a product covered by others. cordance with FIF	der the Federal dation of this product by or cancel the registratio under this Act is not to b FRA sec 3(c)(7)(A . 3(c)(5) when the
On the basis of informa Insecticide, Fungicide a the Agency. In order to of a pesticide in accord construed as giving the This prod provided that you 1. Submit and/or Agency requires required for re-re	tion furnished by the registrant, and Rodenticide Act. Registratic protect health and the environ ance with the Act. The accepta registrant a right to exclusive u uct (OPP Decision No. I: cite all data required for all registrants of simila	the above named pest on is in no way to be co ment, the Administrator ance of any name in cou use of the name or to its D-438938) is req or registration of y r products to sub uct under FIFRA	ticide is hereby reginstrued as an endo r, on his motion, mannection with the result of the subscription of the subscripti	stered/reregistered und rsement or recommend y at any time suspend gistration of a product covered by others. cordance with FIF ander FIFRA sec. and submit acce	der the Federal dation of this product by or cancel the registratio under this Act is not to b FRA sec 3(c)(7)(A . 3(c)(5) when the eptable responses
On the basis of informa Insecticide, Fungicide a the Agency. In order to of a pesticide in accord construed as giving the This prod provided that you 1. Submit and/or Agency requires required for re-re 2. Make the labe	tion furnished by the registrant, and Rodenticide Act. Registration protect health and the environ ance with the Act. The accepta registrant a right to exclusive u uct (OPP Decision No. I: cite all data required for all registrants of simila gistration of your produ	the above named pest on is in no way to be co ment, the Administrator ance of any name in cou use of the name or to its D-438938) is req or registration of y r products to sub uct under FIFRA ow before you rel	ticide is hereby reginstrued as an endo r, on his motion, mannection with the result of the subscription with the result of the subscription with the result of the subscription with the subscription with the subscription of th	stered/reregistered und rsement or recommend ugistration of a product covered by others. cordance with FIF ander FIFRA sec. and submit according fuct for shipment	der the Federal dation of this product by or cancel the registratio under this Act is not to b FRA sec 3(c)(7)(A . 3(c)(5) when the eptable responses
On the basis of informa Insecticide, Fungicide a the Agency. In order to of a pesticide in accord construed as giving the This prod provided that you 1. Submit and/or Agency requires required for re-re 2. Make the labe	tion furnished by the registrant, and Rodenticide Act. Registration protect health and the environ ance with the Act. The accepta registrant a right to exclusive u uct (OPP Decision No. I: cite all data required for all registrants of simila gistration of your produ- ling changes listed below he "EPA File Symbol to	the above named pest on is in no way to be co ment, the Administrator ance of any name in cou use of the name or to its D-438938) is req or registration of y r products to sub uct under FIFRA ow before you rel	ticide is hereby reginstrued as an endo r, on his motion, mannection with the result of the subscription with the result of the subscription with the result of the subscription with the subscription with the subscription of th	stered/reregistered und rsement or recommend ugistration of a product covered by others. cordance with FIF ander FIFRA sec. and submit according fuct for shipment	der the Federal dation of this product by or cancel the registratio under this Act is not to b FRA sec 3(c)(7)(A . 3(c)(5) when the eptable responses

b. Revise the Precautionary statement to read "Cause moderate eye irritation. Avoid contact with eves or clothing. Wear protective evewear when dispensing and using this product. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet."

c. The "Outbreaks" implies that it is treating the disease not the organisms. Therefore, we have removed the term from the Norovirus and Tuberculosis disinfection claims.

d. The directions for use that include "Ultrasound transducers and probes" must be gualified with a double asterisk, which connect it to the following statement that must appear on the label for this product.

> \*\*This product is not to be used as a terminal sterilant/high level disinfectant on any surface of 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 bold 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 of high level disinfection.

3. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records. Should you have any questions regarding this letter, please contact me either by phone at (703) 308-6345 or email at Henson.Wanda@epa.gov.

Sincerely.

Wanda Y. Henson

Acting Product Manager Team 32 Regulatory Management Branch II Antimicrobials Division (7510P)

Enclosures: (Stamped Label)

## PDI SANI-CLOTH<sup>®</sup> BLEACH WIPES

### ACTIVE INGREDIENTS:

### 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-EPA Est. No. : or EPA Est. No. A=9480-NY-1 [or others] Alpha character will precede batch code on product ACCULTED with the ACT**S** in Richard by D**aled:** 

JAN 1 3 2011 Under the Federal Incerticide, Panglicite, und Redenticide Act as amended, for the pesticide, registered under EPA Reg. No. 9480-8

3/16

[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.

F/shared/PDI/Bleach Wipe/Labels/9480- I Clean copy incorp EPA comments rev1/7/11.doc

Page 1 of 14

### **Precautionary Statements**

Hazards to Humans and Domestic Animals

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wear protective eyewear and gloves when dispensing and using this product. 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:

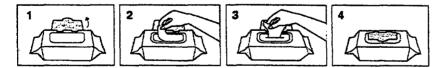
Open along perforations as indicated. Remove packets as needed.

#### 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<sup>®</sup> 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.

F/shared/PDI/Bleach Wipe/Labels/9480- I Clean copy incorp EPA comments rev1/7/11.doc

Page 2 of 14

### 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 though 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 though the dispensing orifice.
- 7. Reapply the lid to the pail.
- 8. Dispense the wipe.

### 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 **Contract Set 1** This product is effective 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:]

Tuberculosis (TB) This product is effective 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.

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.

F/shared/PDI/Bleach Wipe/Labels/9480- bleach wipe 082010.doc

Page 3 of 14

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.

# 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, or 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.

# [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, 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, Surgery, Surgical Centers, Transport vehicles 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

Hospital, Healthcare, and Critical Care Use Sites: May be used on hard non-porous surfaces of: ambulance equipment surfaces; bed railings; blood glucose meters; blood pressure [BP] monitors; cabinets; carts; chairs; counters; dental chairs; dental countertops; dental unit instrument trays; 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; laboratory equipment and surfaces; loupes; operating room tables and lights; operatory light switches; oxygen hoods; physical therapy (PT) equipment surfaces; slit lamps; spine back boards; stethoscopes; stretchers; stools; tables; telephones; toilet seats; 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; and ultrasound transducers and probes and other hard non-porous surfaces listed on this label.

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.

F/shared/PDI/Bleach Wipe/Labels/9480- I markup addressing EPA efficacy comments rev 1/7/11.doc Rev. 1/7/11 Pag

**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.

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 Manufacturing Facilities or Libraries or Public Telephones: Cabinets, chairs, computers, computer monitors, computer mouse, counters, countertops, desks, desktops, doorknobs, 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.

Transport vehicles, school busses, public busses, fire trucks, police cars: Hard non-porous surfaces of vehicles including steering wheel, 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.

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

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.

F/shared/PDI/Bleach Wipe/Labels/9480- I Clean copy incorp EPA comments rev1/7/11.doc

Page 5 of 14

[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)]

[\*]

Campylobacter jejuni [ATCC 29428] Escherichia coli O157:H7 [ATCC 35150] Klebsiella pneumoniae [ATCC 4352] Listeria monocytogenes [ATCC 19117] Pseudomonas aeruginosa [ATCC 15442] Salmonella enterica [ATCC 10708] Staphylococcus aureus [ATCC 6538] Streptococcus pyogenes [ATCC 12344]

### 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 [ATCC 19606] ESBL Resistant Escherichia coli [ATCC BAA-196] ESBL Resistant Klebsiella pneumoniae [ATCC 700603] Klebsiella pneumoniae - Carbapenem Resistant [ATCC BAA-1705] 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 300] Staphylococcus aureus Methicillin Resistant (MRSA) [ATCC 33592] Streptococcus pneumoniae – Penicillin Resistant [ATCC 700677] Vancomycin Intermediate Staphylococcus aureus (VISA) [HIP 5836] Vancomycin Resistant Staphylococcus faecalis (VRE) [ATCC 51575]

### Viruses\*\* [(1 Minute Contact)]

### **Enveloped Viruses**

\*\*Avian Influenza A H5N1 virus [Strain VNH5N1-PR8/CDC-RG CDC #2006719965]

\*\*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]

\*\*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<sup>†</sup> [Strain 7/31/07]

\*\*Hepatitis C virus (Human) (HCV) - Bovine Diarrhea Virus<sup>†</sup> [Strain Oregon C24v-genotype 1]

\*\*HIV-1 (AIDS virus)<sup>†</sup> [Strain HTLV-III<sub>B</sub>]

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.

F/shared/PDI/Bleach Wipe/Labels/9480- I Clean copy incorp EPA comments rev1/7/11.doc

#### [Optional: Choose one of the following statements:]

[Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by influenza A virus. This product is a broadspectrum 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.]

<sup>†</sup>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<sup>a</sup>- 77<sup>a</sup>F) or (20<sup>a</sup>- 25<sup>a</sup>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. Recommended 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.

F/shared/PDI/Bleach Wipe/Labels/9480- I Clean copy incorp EPA comments rev1/7/11.doc

**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 A Cleaner [and disinfectant] (except precleaning is required for blood and body fluids) [Appropriate] [Perfect] [Ideal] [for] Terminal 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 Built-in [tough] scrubbing fibers help clean Can help reduce the risk of cross contamination on treated surfaces Cellulosic non-woven disposable cloth 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 [name of active ingredient], the [same] active ingredient used in [Brand-name@ [or 71]] U Ψ This product is not manufactured or distributed by \_\_\_\_ \_*®* [or *™*] Contains [number] canisters [plus] [and] [number] refills Convenient Deodorize hard, non-porous surfaces [Use to] Deodorizes, and kills common household germs\* [Designed] [for] [with] [the] Environmental Services Professionals[s] [in mind] 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 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

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.

F/shared/PDI/Bleach Wipe/Labels/9480- I markup addressing EPA efficacy comments rev 1/7/11.doc Rev. 1/7/11

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 two viruses from this list.] (Escherichia coli O157:H7. Salmonella enterica, Staphylococcus aureus, Herpes simplex virus type 2 (causative agent of genital herces), \*Influenza A virus/Hong Kong (representative of the common flu virus), Rhinovirus, Rotavirus) Effective against [the following micro-organisms on hard, non-porous surfaces] [list organisms] Effective in the presence of 5% blood serum contamination Eliminates [lingering] [food] odors [on surfaces] Eliminates potential for overspray **EVS** [Environmental Services] Use 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<sup>+</sup> and bacteria instead of germy 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 two viruses from this list:] (Escherichia coli O157:H7, Salmonella enterica, Staphylococcus aureus, Herpes simplex virus type 2 (causative agent of genital herpes), \* Influenza A virus/Hong Kong (representative of the common flu virus), Rhinovirus, Rotavirus) Kills bacteria in 1 minute [use only when TB not listed on label or add +except TB in 2 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 two viruses from this list:] (Escherichia coli O157:H7, Salmonella enterica, Staphylococcus aureus, Herpes simplex virus type 2 (causative agent of genital herpes), \* Influenza A virus/Hong Kong (representative of the common flu virus), Rhinovirus, Rotavirus) Kills multi drug resistant organisms [list organisms] 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

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.

F/shared/PDI/Bleach Wipe/Labels/9480- I Clean copy incorp EPA comments rev1/7/11.doc

Page 9 of 14

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 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 [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 A disinfectant cleaner that is effective against a broad spectrum of bacteria when used as directed One step ▲ germicide One step▲ [terminal] [cleaning] [disinfecting] [wipe] 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" A 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 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 Terminal Cleaning Wipe[s] [Towel][s] refill[s] [able] 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 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.

F/shared/PDI/Bleach Wipe/Labels/9480- I Clean copy incorp EPA comments rev1/7/11.doc

Rev. 1/7/11

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

Wipe [material] made from [x] % [sustainable] [ingredients] [fibers] [May be used only when cellulose wipe material used] [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 nonporous 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]

[Note: The following claims can be used only for 6 months] [Better] [New] [Improved] [Stronger] [Thicker] Wipe [!] [Better] [new] [&] [improved] [dispensing] lid [closure] [cap] [package] [dispensing] [better [than before] New and improved [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

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.

F/shared/PDI/Bleach Wipe/Labels/9480- I Clean copy incorp EPA comments rev1/7/11.doc

Rev. 1/7/11

## [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 <u>and</u> 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.]

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.

F/shared/PDI/Bleach Wipe/Labels/9480- I Clean copy incorp EPA comments rev1/7/11.doc

Rev. 1/7/11

[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 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.

F/shared/PDI/Bleach Wipe/Labels/9480- I Clean copy incorp EPA comments rev1/7/11.doc

Page 13 of 14

Rev. 1/7/11

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



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.

F/shared/PDI/Bleach Wipe/Labels/9480- I Clean copy incorp EPA comments rev1/7/11.doc

Page 14 of 14

Rev. 1/7/11