



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 5, 2019

Jean Claude Marcelin
Regulatory Affairs Manager
PDI
400 Chestnut Ridge Road
Woodcliff Lake, NJ 07677

Subject: PRIA Label Amendment – Adding Claims
Product Name: Wonder Woman Formula B
EPA Registration Number: 9480-10
Application Date: 07/25/2019
Decision Number: 553672

Dear Mr. Marcelin:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. “To distribute or sell” is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

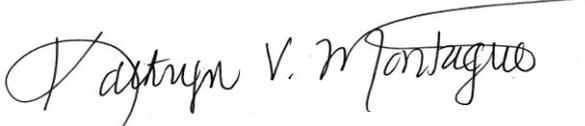
Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded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

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

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with FIFRA section 6. If you have any questions, please contact Terria Northern by phone at 703-347-0265, or via email at northern.terria@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "Kathryn V. Montague". The signature is written in a cursive style with a long horizontal flourish extending to the right.

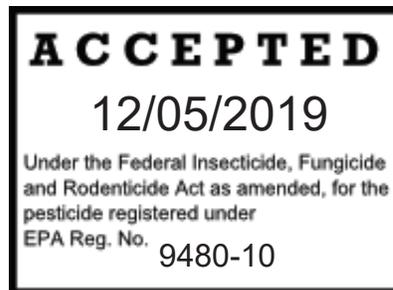
Kathryn Montague, Acting Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: Approved label

WONDER WOMAN FORMULA B
GERMICIDAL SPRAY

Alternate brand names:

SANI-PRIME [™] [®] GERMICIDAL SPRAY
PDI® SANI-PRIME [™] [®] GERMICIDAL SPRAY
SANI-Prime [™][®] SPRAY
PDI® SANI-Prime [™][®] SPRAY
SANI-PRIME [™] [®] DISINFECTING SPRAY
PDI® SANI-Prime [™][®] DISINFECTING
SPRAY
SANI-PRIME [™] [®] DISINFECTANT SPRAY
PDI® SANI-Prime [™] [®] DISINFECTANT
SPRAY



ACTIVE INGREDIENTS:

Didecyl Dimethyl Ammonium Chloride.....	0.61%
Ethyl Alcohol.....	27.30%
Isopropyl Alcohol.....	28.70%
<u>OTHER INGREDIENTS</u>	43.39%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN
WARNING

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

[CONTAINS:] [or Net Contents] [and/or Net Wt.] _____ fl. oz. (mL) [or (qt). or (L)]

EPA Reg. No.: 9480-10

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

Or

EPA Est. No. A=9480-NY-1, B=72956-AR-1 [or others]

Alpha character will precede batch code on product [OR Beginning of batch code indicates Est No.]

[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] [with] [domestic and [foreign] [imported] materials] [insert country]]

THE INFORMATION IN BOX IS NOT PART OF THE LABELING

[] - Statements in brackets are optional or instructional. Italicized words in brackets are not included
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/Hong Kong"

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

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[On any panel]

PRECAUTIONARY STATEMENTS:

Hazards to humans and domestic animals

WARNING:- Causes substantial but temporary eye injury. Harmful if inhaled or swallowed. Do not get in eyes or on clothing. Wear safety glasses. Avoid breathing spray mist. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet or restroom. Remove and wash contaminated clothing before reuse.

FIRST AID: Contact a poison control center or healthcare professional or doctor for treatment advice. Have the product container or label with you when contacting a poison control center or healthcare professional or doctor, or going for treatment. For additional information or in case of emergency contact the Poison Control Center toll free at 1-800-222-1222.

If in eye[s]: Hold eye[s] open, rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.

If inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.

If swallowed: Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything to an unconscious person.

Physical or chemical hazard[s]:

Flammable. Keep away from heat and open flame.

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 container[s] inside.][Peel [back] for additional labeling.][Peel [back] for additional information.][Consult equipment manufacturers' instructions prior to use.] [Please be sure to [check] [OR consult][equipment][manufacturers][instructions for use][IFU(s)][before][OR [prior][to] use.][[For surfaces,] Test product on small inconspicuous area before use.]

[Dispensing Directions]

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

[For bottles with cap:] Unscrew cap and place the [trigger] sprayer on the bottle. Ensure the trigger sprayer is securely fastened.

[For bottles with sprayer:] To Operate: [Adjust] [Or Turn] nozzle [counterclockwise] to desired setting.

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[DISINFECTION DIRECTIONS]

TO [CLEAN] [AND] [,] DISINFECT [AND DEODORIZE] HARD, NONPOROUS SURFACES: If present, remove soil prior to disinfecting. Spray [*product name*] 6-8 inches from surface until thoroughly wet. Allow surface to remain wet for one (1) minute [OR for (60) seconds]. Let air dry [OR allow to air dry] [and] [or] wipe [excess] liquid using a [towel] [clean cloth per facility protocol]]. A potable water rinse is required for food contact surfaces. A precleaning step is required to kill *Mycobacterium bovis* BCG (TB). [*When TB is included on the label, add the following:*] These directions also apply to *Mycobacterium bovis* BCG (TB) at 72.6°F (22.6°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 (Feline Calicivirus): Allow surface to remain wet for three (3) minutes] (*Note: This direction will be used only if Norovirus is on container label*)

[The following sets of directions are optional]

ULTRASOUND TRANSDUCERS AND PROBE[S]: For use on external surfaces of ultrasound transducers, scopes, [and] [or] probe[s] only prior to high-level disinfection [(HLD)].

To disinfect prior to high-level disinfection [HLD]: Preclean gel from external surface of ultrasound transducer, scope, [and] [or] probe[s] by using a clean washcloth. Then, follow instructions to disinfect.

[The following instructions are to be included on production labels when claims against HIV, and/or HBV and/or HCV are listed; one, two or all three of the viruses may be included on claims and directions in production labels.]

+KILLS HIV-1 (AIDS VIRUS), HEPATITIS B VIRUS (HBV) AND HEPATITIS C VIRUS (HCV) ON THE PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS [AND PRECLEANED EXTERNAL SURFACES OF ULTRASOUND TRANSDUCERS AND PROBE[S]] PREVIOUSLY SOILED WITH BLOOD/ BODILY FLUIDS 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 bodily fluids, and in which the surfaces/objects likely to be soiled with blood or bodily fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV).

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

Personal protection: When handling HIV-1 (AIDS Virus), HBV or HCV infected blood or bodily fluids; wear disposable protective gloves, protective gowns, masks and eye coverings, per facility protocol.

Cleaning procedure: All blood and other bodily fluids must be thoroughly cleaned from surfaces and objects before disinfection by the [germicidal] spray.

Disposal of infectious materials: Used towels that may be contaminated with blood and other bodily fluids should be disposed of according to local regulation for infectious waste disposal.

Contact time: Use [germicidal] spray to thoroughly wet surface. Allow surface to remain wet for contact time(s) listed on the label [OR for one (1) minute] [OR for (60) seconds]]. [Wipe to ensure there is [even] [uniform] coverage [and] [let air dry] [allow to air dry] [and] [or] wipe [excess] liquid using a [towel] [clean cloth per facility protocol]].

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[The following instructions are to be included on production labels when claims against C.auris are listed]

Special Instructions for cleaning prior to disinfection against *Candida auris*.

Personal Protection: Wear appropriate barrier protection such as gloves, gowns, masks, and eye coverings per facility protocol.

Cleaning Procedure: Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection by application with a clean cloth, mop, and/or sponge saturated with the product. Pre-cleaning is to include vigorous wiping and/or scrubbing and all visible soil is removed. 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 the organism. Restrooms are to be cleaned last. Do not reuse soiled cloths.

Infectious Waste Disposal: Materials used in the cleaning process that may contain feces/wastes are to be disposed of immediately in accordance with local regulations for infectious materials disposal.

Contact time: Use [germicidal] spray to thoroughly wet surface. Allow surface to remain wet for contact time(s) listed on the label [OR for one (1) minute] [OR for (60) seconds]]. [Wipe to ensure there is [even] [uniform] coverage [and] [let air dry] [allow to air dry] [and] [or] wipe [excess] liquid using a [towel] [clean cloth per facility protocol]].

[Terminal Sterilant Disclaimer per PR Notice 94-4]

[The following paragraph must be used if hospital and healthcare use sites are on the label.]

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 and decontaminate critical or semi-critical medical devices prior to [sterilization] [or] [high-level disinfection] [or HLD].

STORAGE AND DISPOSAL:

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

Storage: Do not store near heat or open flame.

Spray Bottle [or Container] [or Jug] Disposal: Non-refillable container. Do not reuse or refill this container. Offer for recycling if available or put in trash.

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[Optional Use Sites]

**[Areas of Use] [Hospital and Healthcare Settings] [May be used on hard, nonporous surfaces in] [:]
[Optional Use Sites]**

[Hospital and Healthcare Settings:] Ambulance equipment surfaces, Ambulatory Surgical Centers (ASC), Anesthesia equipment surfaces, 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, Medical Intensive Care Units (MICU), Neonatal Intensive Care Units (NICU), Newborn nursery, Nursing homes, Operating Rooms (OR), Oncology Facilities, Ophthalmic Offices, Orthopedics, Out-Patient Surgical Centers (OPSC), Patient Care Areas, Pediatrics, Pediatric Intensive Care Units (PICU), Physical therapy areas, Physicians' offices, Radiology Unit, Recovery Rooms, Rehabilitation Center, Respiratory therapy areas, Skilled Nursing Facility, Surgery areas, Surgery Intensive Care Unit (SICU), Surgical Centers, Transport vehicles, Urgent Care Centers, and X-Ray equipment.

and/or

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

and

Hospital, Healthcare, and Critical Care Use Sites: May be used on hard nonporous surfaces of: ambulance equipment surfaces; bed railings; bladder scan; blood glucose meters; blood pressure cuffs; cabinets; cardiac gym equipment; carts; chairs; cardiac monitors; workstations on wheels (WOW); 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; Otoscopes; 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 nonporous outside surfaces of: amalgamators and dental curing lights; anesthesia machines and respiratory therapy equipment; apheresis 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.

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Surface Materials:		
ABS plastic	Aluminum	Brass
Copper	Corian® ²	Chrome
Formica® ¹	Glass	Glazed ceramic
Laminate Surfaces	Linoleum	Polycarbonate
Polyester	PVC	Plexiglas® ³
Porcelain	Polybutylene Terephthalate (PBT)	Rubber
Stainless Steel	Treated Wood Surfaces	Titanium
Vinyl	Zinc	

¹ Formica® is a registered trademark of The Diller Corporation.

² Corian® is a registered trademark of E. I. du Pont de Nemours and Company.

³ Plexiglas® is a registered trademark of Arkema France.

Additional optional settings:

Grocery Stores or Shopping Centers or Supermarkets or Delicatessens: Disinfects hard, nonporous surfaces such as grocery cart handles and grocery cart child seats. Disinfects shopping cart handles and child seats.

Nursery or Daycare Centers: Disinfects hard, nonporous surfaces such as 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, nonporous surfaces listed on this label.

Bathroom[s] or Public Restrooms: Disinfects hard, nonporous surfaces such as 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 nonporous surfaces listed on this label.

Health Club Facilities, Fitness Centers, and Gyms: Disinfects hard, nonporous surfaces such as gym equipment, weight-lifting surfaces and other hard nonporous surfaces listed on this label.

Schools or Classrooms or Churches or Office Buildings or Public Facilities or Manufacturing Facilities or Libraries or Public Telephones: Disinfects hard, nonporous surfaces such as cabinets, chairs, computers, computer monitors, computer mice, 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 nonporous surfaces listed on this label.

Transport Vehicles, School Buses, Public Buses, Fire Trucks, Police Cars, Airplanes, Cruise Ships, Cargo Vessels: Disinfects hard, nonporous surfaces of vehicles including steering wheels, hard plastic or metal flooring, seats, and walls.

Restaurants: Disinfects hard nonporous, nonfood contact surfaces only including chairs, display cabinets, garbage cans, booster seats, floor, sinks, bathroom surfaces, glazed tiled walls, telephones, cash registers, and doorknobs.

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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.]

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

<i>Acinetobacter baumannii</i> – Multi-drug Resistant (MDR) [ATCC 19606] [resistant to Cefazolin, Gentamicin, Trimethoprim/Sulfa and Intermediate resistance to Cefepime, Ceftazidime, Ceftriaxone]	[ATCC 33592] Methicillin Resistant <i>Staphylococcus epidermidis</i> [ATCC 51625]
Carbapenem Resistant - <i>Klebsiella pneumoniae</i> [(CRKP)] [ATCC BAA-1705]	Community Acquired Methicillin Resistant <i>Staphylococcus aureus</i> [CA-MRSA Genotype USA 300] [NRS 384]
Carbapenem Resistant - <i>Escherichia coli</i> [CDC 81371]	Community Acquired Methicillin Resistant <i>Staphylococcus aureus</i> [CA-MRSA Genotype USA 400] [NRS 123]
ESBL Positive <i>Escherichia coli</i> [ATCC BAA-196]	NDM-1- Positive <i>Enterobacter cloacae</i> [CDC 1000654]
ESBL Positive <i>Klebsiella pneumoniae</i> [ATCC 700603]	NDM-1- Positive <i>Escherichia coli</i> [CDC 1001728]
Multi-drug Resistant (MDR) <i>Klebsiella pneumoniae</i> - KPC-2 positive (ST258) [CDC 2008030] [resistant to Ampicillin, Ampicillin/Sulbactam, Cefazolin, Ceftazidime, Ciprofloxacin, Ertapenem, Imipenem, Levofloxacin, Piperacillin/Tazo, Tobramycin, Trimethoprim/Sulfa, Meropenem and Intermediate resistance to Amikacin, Ceftriaxone]	NDM-1- Positive <i>Klebsiella pneumoniae</i> [CDC 1000527]
Metallo-beta lactamase (MBL) positive <i>Pseudomonas</i> <i>aeruginosa</i> [CDC 2012059] [resistant to Ampicillin, Ampicillin/Sulbactam, Ciprofloxacin, Gentamicin, Imipenem, Ertapenem, Levofloxacin, Piperacillin/Tazo, Tobramycin, Trimethoprim/Sulfa and Intermediate resistance to Cefepime, Ceftazidime]	Multi-drug Resistant <i>Proteus mirabilis</i> [ATCC BAA-856] Multi-drug Resistant <i>Stenotrophomonas maltophilia</i> [ATCC BAA-85]
Multi-drug Resistant <i>Serratia marcescens</i> [ATCC 43297]	<i>Streptococcus pneumoniae</i> - Penicillin Resistant [ATCC 700677]
Methicillin Resistant <i>Staphylococcus aureus</i> (MRSA)	Vancomycin Intermediate Resistant <i>Staphylococcus</i> <i>aureus</i> (VISA) [HIP 5836]
	Vancomycin Resistant <i>Enterococcus faecalis</i> (VRE) [ATCC 51575]
	Vancomycin Resistant <i>Staphylococcus aureus</i> (VRSA) [VRS1]
	Vancomycin Resistant <i>Enterococcus faecium</i> [ATCC 700221]

Bacteria [(1 Minute Contact Time)]

- Bordetella pertussis* [ATCC 12743]
- Burkholderia cepacia* [ATCC 25416]
- Campylobacter jejuni* [ATCC 29428]
- Enterobacter aerogenes* [ATCC 13048]
- Escherichia coli* (*E. coli*) [ATCC 11229]
- Escherichia coli* O157:H7 [ATCC 35150]
- Klebsiella pneumoniae* [ATCC 4352]
- Legionella pneumophila* [ATCC 33153]
- Listeria monocytogenes* [ATCC 19117]
- Proteus vulgaris* [ATCC 9920]
- Pseudomonas aeruginosa* [ATCC 15442]
- Salmonella enterica* [ATCC 10708]
- Shigella dysenteriae* [ATCC 11835]
- Staphylococcus aureus* [ATCC 6538]
- Streptococcus pyogenes* [ATCC 12344]
- Streptococcus pneumoniae* [ATCC 6305]

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Bloodborne Pathogens [(1 Minute Contact Time)]

- *Hepatitis B virus (HBV) - Duck HBV[†] [Strain 10/29/11]
- *Hepatitis C virus (Human) (HCV) – Bovine Diarrhea Virus[†] [Strain Oregon C24v-genotype 1]
- *HIV-1[†] (AIDS virus) [Strain HTLV-III_B]

Non-Enveloped Viruses* [(1 Minute Contact Time)]

- *Adenovirus type 5 [ATCC VR-5] [Strain Adenoid 75]
- *Enterovirus EV-D68 [ATCC VR-561]
- *Rhinovirus type 1A [ATCC VR-1559] [Strain 2060]
- *Rotavirus [(Strain WA)]

Non-Enveloped Viruses* [(3 Minute Contact) Time]

- *Norovirus (Feline Calicivirus) [ATCC VR-782] [Strain F9]

Enveloped Viruses* [(1 Minute Contact) Time]

- *Cytomegalovirus [ATCC VR-538] [Strain AD-169]
- *Herpes Simplex virus type 1 [ATCC VR-733] [Strain F(1)]
- *Herpes Simplex virus type 2 [ATCC VR-734] [Strain G]
- *Human Coronavirus [Strain 229E] [ATCC VR-740]
- *Avian Influenza A (H7N9) virus [CDC 2013759189] [Strain wildtype A/Anhui/1/2013]
- *Avian Influenza A (H5N1) virus [CDC 2006719965] [Strain VNH5N1-PR8/CDC-RG]
- *Influenza A virus (H3N2) / Strain Hong Kong [ATCC VR-544]
- *Influenza B virus [ATCC VR-823], Strain B/Hong Kong/5/72
- *Respiratory Syncytial virus (RSV) [ATCC VR-26], [Strain Long]
- *Vaccinia virus [(Strain WR)] [ATCC VR-119]

Pathogenic Fungi [(1 Minute Contact Time)]

- Candida albicans* [ATCC 10231]
- Candida auris* [AR-BANK#0381]
- Trichophyton interdigitale* [(Formerly known as) [(Tested as) *Trichophyton mentagrophytes*]] [ATCC 9533]

Mycobacterium (TB) [Tuberculocidal] [(1 Minute Contact Time)]

- Mycobacterium bovis* BCG [(Tuberculosis)] (TB) [Organon Teknika]

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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 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 categories [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	<u>One of the following:</u> Adenovirus Type 5, Strain Adenoid 75 (ATCC VR-5) (1-min.) Enterovirus EV-D68 (ATCC VR-561) (1-min.) Rotavirus, Strain WA (ATCC VR-2018) (1-min.) Rhinovirus Type 1A, Strain 2060 (ATCC VR-1559) (1-min.) Feline Calicivirus, Strain F-9 (ATCC VR-782) (3-min.)
Large, non-enveloped virus	<u>One of the following:</u> Rhinovirus Type 1A, Strain 2060 (ATCC VR- 1559) (1-min.) Feline Calicivirus, Strain F-9 (ATCC VR-782) (3-min.)
Small, non-enveloped virus	<u>Two of the following:</u> Rhinovirus Type 1A, Strain 2060 (ATCC VR- 1559) (1-min.) Feline Calicivirus, Strain F-9 (ATCC VR-782) (3-min.)

[Product name] [has demonstrated effectiveness against viruses similar to **[name of emerging virus]** on hard, **[porous/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, porous/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, porous/nonporous surfaces]**. Refer to the **[CDC or OIE]** website at **[website address]** for additional information.

[Reference: August 19, 2016 Guidance to Registrants: Process for Making Claims against Emerging Viral Pathogens Not on EPA-Registered Disinfectant Labels ("Guidance"):
https://www.epa.gov/sites/production/files/201609/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf]

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Optional Claims and Descriptors [Note: Deodorizing directions must be used when deodorizing claims (claims involving odor control) are used]

© [insert year] [insert company name]

[Always] ready to use

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

An effective way to disinfect hard, nonporous environmental surfaces listed on this label.

Antibacterial

Antimicrobial

[Antibacterial] [Antimicrobial] health club equipment spray

A Quaternary [ammonium chloride]/alcohol solution

A [Sani-Surface®] [Sani-Cloth®] Brand

[Bactericidal], [Tuberculocidal], [Fungicidal] and [Virucidal*] in [[1 [one] minute] [60 seconds]][⊖] [3 minutes][⊙] [[⊙]To include if container label has *Norovirus (Feline Calicivirus)*]

Bactericidal [(1 minute)] [in 1 [or one] minutes] [in 60 seconds][⊖]

Broad range of disinfection against Multi-drug resistant organisms [or MDROs][⊖]

Broad Spectrum Disinfectant

Broad spectrum [microorganism coverage]

Broad spectrum efficacy

Brought to you by [the makers of] [product name] [Sani-Cloth®] [PDI®] [Sani Professional®] [products] [brand]

Can help reduce cross contamination on treated hard, nonporous surfaces

Cleans as it disinfects

Compatible for use on [hard, nonporous] surfaces commonly found in healthcare settings [listed on this label]

Compatible with commonly used materials [in healthcare settings]

Compatible [with equipment surfaces]

Compatibility tested

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

[⊖] This product is not manufactured or distributed by _____® [or ™] The owner of the Registered Trademark [Brand name ® or ™]

Contains [number] bottles [plus] [and] [number] [refills]

Convenient

Deodorize hard, nonporous surfaces [Use to]

Deodorizes, and kills common household germs* [*use at least two bacteria and two viruses from the organism list*]

Disinfect external surfaces of ultrasound transducers and probes

Disinfect precleaned surfaces

Disinfectant spray

Disinfects [and deodorizes] [hard] [nonporous surface(s)] [that people touch] [just] [in 1 minute] [60 seconds][⊖]

Disinfects [grocery cart handles] [shopping cart handles] [grocery cart child seats] [shopping cart child seats]

[Disinfects] nonporous hard surfaces

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

Disinfects on the go

Do not use on natural marble, windows, unpainted wood, brass, clear plastic, or colored grout.

Does not contain bleach [*this is included as useful info for users needing a bleach-free product*]

Easy [and convenient] way to [touch-up] [bathroom] [office] [and other sites listed on this label] everyday

Easy to use [easy to refill]

Easy to use trigger spray

Effective against bathroom bacteria and viruses* [*use at least two bacteria and two viruses from the organism list*]

[Effective against all listed organisms in the presence of organic soil (5% blood serum)] (*This is an already approved claim that was previously on page 10*)

Effective against [:] [the following micro-organisms on hard, nonporous surfaces] [*list organisms*]

Effective against a broad range of microorganisms

Effective in the presence of 5% blood serum contamination

Eliminates odors

Eliminates daily mixing and measuring

Environmental services [or EVS] [or ES] [or Housekeeping][Services] use

Everyday disinfection against [*insert microorganism*]

Exclusive to PDI, Inc.

Expiration date [or EXP] [*insert date*]

[For] daily use

For [hospital] [healthcare] use

[For] nonfood contact surfaces [only]

From the makers of Sani-Cloth® [products] [brand]

Fungicidal [(1) minute] [in 1[or one] minutes] [60 seconds]°

[Gets rid of] [Eliminates] odors

Germicidal* [Spray] [*use at least two bacteria and two viruses from the organism list*]

[Helps] [Kill(s)] [Eliminate(s)] odor-causing bacteria

Helps reduce cross contamination on treated hard, nonporous surfaces

Hospital [or *Insert area of use facility*] disinfectant [disinfection]

Ideal for use on high-touch, hard nonporous surfaces

Kills bacteria and viruses* [in the bathroom] [on the exterior toilet surfaces] [*use at least two bacteria and two viruses from the organism list:*]

Kills bacteria [[in 1 minute] [in 60 seconds]]°

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

[Kills] [Effective against] CRKP [(Carbapenem Resistant *Klebsiella pneumoniae*)]

[Kills][Effective against] [the following micro-organisms on hard, nonporous surfaces] [*list organisms*] [in][just] [[one][1][minute][60 seconds]]°

Kills [household] [exterior toilet surface] [bathroom] germs* [*use at least two bacteria and two viruses from the organism list*]

Kills *Candida auris* in [1 minute] [or 60 seconds]°

Kills Norovirus (Feline calicivirus) [in 3 minutes]

Kills odor causing bacteria

[Kills] [Effective against] TB in [1] [one] [minute] [60 seconds]°

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Kills 99.9% of bacteria in [just] [one][1][minute][60 seconds]°
Leaves [bathroom] [office] [and other sites listed on this label] disinfected [and smelling fresh]
[Made] [or manufactured] in [USA] [of Domestic and [Foreign][Imported] Materials] [insert country]]
Meets surface disinfection recommendations from OSHA Bloodborne Pathogen Standard
Multi-pack
Multi-purpose disinfectant [Multi [-refill] pack]
New (*may be used for 6 months on marketed label*)
No diluting or mixing required
Non-bleach [*this is included as useful info for users needing a bleach-free product*]
Non-corrosive
Not available in private label
Not for sale in [insert name of state(s)]
Not for sale [or use] after [insert date]
Odor [eliminator] [neutralizer]
One [1] minute [or 60 seconds]° [kill][contact] time reduces time to turnover room

One [1] minute [or 60 seconds]° [Bactericidal] [,] [Virucidal*] [,] [Fungicidal] [,] [and] [Tuberculocidal]
One-Step Cleaner/Disinfectant [*Grease and soap scum claims are not to be used on labeling with one-step cleaning/disinfection claims*]
Overall [1] [one] minute° contact time
Overall 60 second° contact time
[Package] [insert type of package] made from [x%] recycled materials
Perfect for disinfecting [exterior toilet surfaces] [around the exterior toilet surface]
Please be sure to [check] [or consult][equipment][manufacturers][instructions for use][IFU(s)][before][OR prior][to] use
Powers through tough messes

[Product name] is a germicidal liquid containing a quaternary/alcohol based solution. 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 alcohol-based products.] Use on hard nonporous surfaces and equipment listed on this label such as materials made of stainless steel, plastic, Formica® and glass.**** [Formica® is a registered trademark of The Diller Corporation] (*This is an already approved claim that was previously on page 10*)

[*][Product name] is virucidal against Adenovirus type 5, Avian Influenza A (H7N9) virus, Cytomegalovirus, Enterovirus EV-D68, Hepatitis B virus (HBV), Hepatitis C virus (Human) (HCV), Herpes Simplex virus type 1, Herpes Simplex type 2 (causative agent of genital herpes), HIV-1, Human Coronavirus, Avian Influenza A virus (H5N1), Influenza A virus (H3N2)/Hong Kong strain (representative of the common flu virus), Influenza B virus, Respiratory Syncytial Virus [RSV], Rhinovirus type 1a, Rotavirus (Strain WA), Vaccinia virus, and Norovirus (Feline calicivirus) in the presence of organic soil (5% blood serum). (*This is an already approved claim that was previously on page 10*)

Proprietary Formulation [product]
[Quickly] eliminates [lingering] [food] odors on surfaces
Ready to Use [disinfectant] [on the following nonporous surfaces]
Recyclable [package]

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Reduce cross contamination between treated hard, nonporous surfaces

Refills [now] available

[Refill] package contains [various numbers] [refill(s)]

Refill [size] [pack] [value pack]

Removes odors

Sani-Prime [™] [®] [disinfectant(s)] [disinfecting] [spray] [products]

Suitable for use on equipment requiring alcohol-based products

Surface disinfectant

The [[1-minute] [60 seconds] [Ⓞ] [germicidal+ spray] [disinfectant spray]

Trial [pack]

Tuberculocidal [(1) minute] [in 1[or one] minute]] [Ⓞ]

Twin pack

Use by [insert date]

Use on hard, nonporous surfaces : [stainless steel] [Formica®] [Formica® is a registered trademark of The Diller Corporation] [glass] [glass tables] [glazed tile] [Refer to surfaces listed on page 6] [Test solution on a small inconspicuous area first.]

[Use to] disinfect(s) hard nonporous environmental surfaces listed on this label

Use to preclean or decontaminate critical or semi-critical medical devices prior to sterilization / high-level disinfection

Versatile

Virucidal*

Where control of the hazards of cross contamination between treated surfaces is of prime importance

With a bleach-free formula [this is included as useful info for users needing a bleach-free product]

[Ⓞ]Does not include Norovirus (Feline Calicivirus)

[Ⓜ]Reference the organism list or individual organisms that are multi-drug resistant

Master Label Reader Notes

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[Graphics depicting use sites listed on this label can appear on product label and labeling.]
 [The following graphics and statements are optional.
 They may be placed anywhere on label/container.]

The following is optional and may appear as verbiage or as a graphic:

- Quat [&[/] Alcohol formulation
- Effective against [*insert microorganism from pages 8-9*]
- Quat [&[/] Alcohol formulation effective against [*insert microorganism from pages 8-9*]
- [Bactericidal][Fungicidal][Tuberculocidal][Virucidal*] formulation effective against [*insert microorganism from pages 8-9*]
- Non-bleach formula
- **FOR USE ON HARD, NONPOROUS SURFACES ONLY**
- Do not freeze
- Do not allow to freeze



*Will be used only if 1 minute
 Organisms on container label*



*Will be used only if 1 minute
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*Will be used only if 1 minute
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Sani-Prime™

Sani-Prime®



Will be used only if Norovirus is on container 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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