



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 6, 2021

Melissa Louis-Juste
Sr. Regulatory Affairs Manager
Professional Disposables International, Inc. (PDI)
400 Chestnut Ridge Road
Woodcliff Lake, NJ 07677

Subject: PRIA Label Amendment – Add Electrostatic Spray Directions for Use
Product Name: PROJECT FLASH SPRAY
EPA Registration Number: 9480-14
Received Date: 6/11/2021
Action Case Number: 00306095

Dear Melissa Louis-Juste:

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.

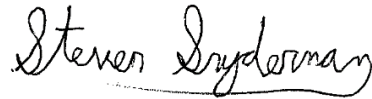
A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. Pursuant to 40 CFR 156.10(a)(6), you must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 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 FIFRA and is subject to review by the Agency. See FIFRA section 2(p)(2). If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process, FIFRA section 12(a)(1)(B). Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA’s Office of Enforcement and Assurance.

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Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Aidan Fife by phone at 202-566-0822 or via email at fife.aidan@epa.gov.

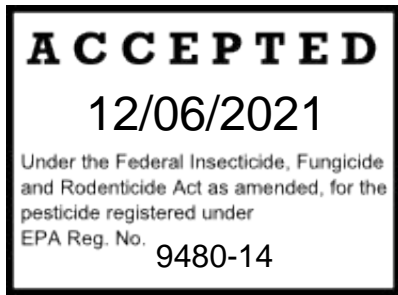
Sincerely,

A handwritten signature in black ink that reads "Steven Snyderman". The signature is written in a cursive style with a horizontal line underneath the name.

Steven Snyderman, Product Manager 33
Regulatory Management Branch II
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: Stamped Final Label

PROJECT FLASH SPRAY



Alternate brand names:

- Sani-Diff [™] [®] Germicidal Spray
- Sani-Diff HP [™] [®] Germicidal Spray
- Sani-HyPerCide [™] [®] Germicidal Spray
- Sani-HyPeroxide [™] [®] Germicidal Spray
- Sani-Diffex [™] [®] Germicidal Spray
- Sani-DiffX [™] [®] Germicidal Spray

ACTIVE INGREDIENTS:

Hydrogen Peroxide.....	4.04%
<u>OTHER INGREDIENTS</u>	95.96%
TOTAL	100.00%

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

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

[CONTAINS:] [or Net Contents] _____ fl. oz.(ml) [or (qt). or (L)]

EPA Reg. No.: 9480-14

EPA Est. No. : 9480-NY-1

Or

EPA Est. No. A=9480-NY-1, B=72956-AR-1

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

[On any panel]

PRECAUTIONARY STATEMENTS:

Hazards to humans and domestic animals

CAUTION: Causes moderate eye irritation. Avoid contact with eyes and clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet [or restroom].

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

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

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

Salmonella enterica, Staphylococcus aureus, Herpes Simplex Type 2, and Influenza A virus H3N2 strain"

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

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FIRST AID:

Call a poison control center [or healthcare professional] [or doctor] for treatment advice. Have the product container or label with you when calling a poison control center [or healthcare professional] [or doctor] or going for treatment. For additional information or in case of emergency call the Poison Control Center toll free at 1-800-222-1222.

If in eye: 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 eye.

Physical or chemical hazard:

This product contains an oxidizing agent. Avoid contact with other sanitizers, cleaners or organic substances.

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 manufacturer's instructions 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.

[[[This product] *[Insert product name]* is a "ready-to-use" liquid, comprised of 4.04% concentration of hydrogen peroxide.]
[[It] should be used at full strength and should not be diluted before use.]]

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DISINFECTION DIRECTIONS

TO [CLEAN] [AND] [,] DISINFECT [AND DEODORIZE] HARD, NONPOROUS SURFACES: If present, remove visible soil prior to disinfecting. Spray [*product name*] 6-8 inches from surface until thoroughly wet. Allow surface to remain visibly wet for one (1) minute [OR for (60) seconds]. For [*Clostridioides difficile*] [*C.difficile*] spores allow surface to remain visibly wet for five (5) minutes. Let air dry [or wipe excess liquid using a towel]. A potable water rinse is required for food contact surfaces. A precleaning step is required to kill [*Clostridioides difficile*] [or *C.difficile*] spores and *Mycobacterium bovis* BCG (TB). [*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].*]

Use Directions for Electrostatic Sprayer

For use with an electrostatic sprayer on hard, nonporous surfaces:

1. Consult User Manual for Electrostatic Sprayer before use.
2. Ensure no bystanders or pets are in the room that is to be treated. Operator should wear a half face respirator with chemical specific cartridges.
3. Place the electrostatic spray function in the ON position for electrostatic spray models that have the functionality to toggle ON/OFF. If the sprayer has the ability to change nozzles that impact particle size, set the particle size to a volume median diameter (VMD) $\geq 40 \mu\text{m}$.
4. Preclean visibly soiled areas.
5. Using the sprayer, apply disinfectant evenly over the hard, nonporous surface to be cleaned, 6-24 inches from surface, making sure to wet surfaces thoroughly.
6. All surfaces must remain visibly wet for 1 minute. Let air dry [or wipe excess liquid using a towel].

SOFT SURFACE SANITIZATION DIRECTIONS

TO SPOT SANITIZE SOFT SURFACES [(FABRICS)]: If present, remove visible soil prior to sanitizing. Spray [*product name*] 6-8 inches from surface until thoroughly wet. Allow surface to remain visibly wet for one (1) minute [OR for (60) seconds]. Let air dry [or wipe excess liquid using a towel]. A potable water rinse is required for food contact surfaces.

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

Ultrasound transducers and probes: For use on external surfaces of ultrasound transducers, scopes [and] [or] probes only prior to high-level disinfection [(HLD)].

To clean [and decontaminate] prior to high-level disinfection [HLD]: Preclean gel from external surface of ultrasound transducer or probe 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 are listed; one or two of the viruses may be included on claims and directions in production labels.]

†KILLS HIV-1 (AIDS VIRUS) AND HEPATITIS B VIRUS (HBV) IN 1 MINUTE ON THE PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS AND PRECLEANED EXTERNAL SURFACES OF ULTRASOUND TRANSDUCERS AND PROBES PREVIOUSLY SOILED WITH BLOOD/BODY 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 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) and Hepatitis B Virus (HBV).

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

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

Cleaning procedure: All blood and other body 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 body 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 visibly wet for one (1) minute. Let air dry.

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

Special Instructions for cleaning prior to disinfection against *Clostridioides 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 a clean cloth, mop, and/or sponge saturated with the disinfectant with sporicidal activity 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 Waste Disposal: Materials used in the cleaning process that may contain feces/waste are to be disposed of immediately in accordance with local regulations for disposal of infectious materials.

To Disinfect: Spray 6-8 inches from surface until surface is thoroughly wet. Allow surface to remain visibly wet for five (5) minutes, let air dry.

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

[The following instructions are to be included on production labels when claims against biofilm bacteria is listed]

Special Instructions for Use Against Biofilm bacteria^B: Preclean surfaces to remove soil and filth. Wipe dry. Thoroughly wet precleaned surface with product. Allow surface to remain wet for three (3) minutes. Rinse thoroughly.

[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].

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STORAGE AND DISPOSAL

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

Storage: Store this product in a cool, dry area, away from direct sunlight.

For a non-refillable container

Spray Bottle [or Container] [or Jug] Disposal: Nonrefillable container. Do not reuse or refill this container. Recycle empty container or discard in trash.

Or, if refillable dispenser is being used, use the following:

Refill Bottle [or Container] [or Jug] Disposal: Rinse cracked or broken containers and offer for recycling. If recycling is not available, discard in trash.

[Optional Use Sites]

[Areas of Use] [Hospital and Healthcare Settings] For use 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, 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; Oscopes; oxygen hoods; physical therapy (PT) equipment surfaces; patient lift equipment; pulse oximeter; radiology equipment; slit lamps; spine back boards; stethoscopes; stretchers; stools; tables; telemetry equipment; telephones; toilet seats; tympanic thermometers; and hard nonporous outside surfaces of: amalgamators and

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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.

Table 1: Surface Materials

Hard, Nonporous 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.

Table 2: Soft Surfaces

Soft surfaces:		
Blinds	Chairs	[Cotton][and][or][polyester] fabrics
Couches	Curtains	Furniture

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: disinfect 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: disinfect 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, exterior surfaces of toilet, toilet handle, toilet rim, toilet seats, exterior surface of toilet tank, 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: disinfect hard, nonporous surfaces such as gym equipment, weight-lifting surfaces and other hard nonporous surfaces listed on this label.

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Schools or Classrooms or Churches or Office Buildings or Public Facilities or Manufacturing Facilities or Libraries or Public Telephones: disinfect 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: Hard nonporous surfaces of vehicles including steering wheel, hard plastic or metal flooring, seats, and walls.

Restaurants: 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.]

Table 3 : List of Disinfection Organisms
Disinfection

Contact Time	Microorganism	Identification Number	Antibiotic Resistance demonstrated
1 Minute	Antibiotic Resistant Bacteria		
	Carbapenem Resistant - <i>Klebsiella pneumoniae</i>	[ATCC BAA-1705]	[(CRKP)]
	<i>Acinetobacter baumannii</i> – Multidrug Resistant (MDR)	[ATCC 19606]	[Effective against organism resistant to Gentamicin, Trimethoprim/Sulfa and Intermediate resistance to Cefepime, Ceftazidime, Ceftriaxone]
	Methicillin Resistant <i>Staphylococcus aureus</i> (MRSA)	[ATCC 33592]	
	Vancomycin Resistant <i>Enterococcus faecalis</i> (VRE)	[ATCC 51575]	
	NDM-1- Positive <i>Enterobacter cloacae</i>	[CDC 1000654]	
	ESBL Positive <i>Escherichia coli</i>	[ATCC BAA-196]	
	Bacteria		
	<i>Salmonella enterica</i>	[ATCC 10708]	
	<i>Pseudomonas aeruginosa</i>	[ATCC 15442]	
	<i>Staphylococcus aureus</i>	[ATCC 6538]	
	Bloodborne Pathogens		
	*Hepatitis B virus (HBV) - Duck HBV [†] [Strain 11/04/12]		
	*HIV-1 [†] (AIDS virus) [Strain HTLV-III _B]		
	Non-Enveloped Viruses*		
	*Adenovirus type 5 [Strain Adenoid 75]	[ATCC VR-5]	
	*Rhinovirus type 1A [Strain 2060]	[ATCC VR-1559]	
	*Rotavirus [Strain WA]	[ATCC VR-2018]	
	* Norovirus (Feline Calicivirus) [Strain F-9]	[ATCC VR-782]	
	Enveloped Viruses*		
	*Herpes Simplex virus type 2 [Strain G]	[ATCC VR-734]	
	*Influenza A virus H3N2 Strain	[ATCC VR-544]	
	*Respiratory Syncytial virus (RSV), [Strain Long]	[ATCC VR-26]	
	*Severe Acute Respiratory Syndrome-Related Coronavirus 2 (SARS-CoV-2) [(COVID-19 Virus)] [USA-WA1/2020]	[BEI Resources, NR-52281]	
	Pathogenic Fungi		
	<i>Candida albicans</i>	[ATCC 10231]	
	<i>Candida auris</i>	[AR-BANK #0381]	
	<i>Trichophyton interdigitale</i> [(Formerly known as) [(Tested as) <i>Trichophyton mentagrophytes</i>]]	[ATCC 9533]	
	Mycobacterium (TB) [Tuberculocidal]		
	<i>Mycobacterium bovis</i> BCG (Tuberculosis) (TB) [Organon Teknika]		

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3 min[utes]	Biofilm Bacteria		
	<i>Staphylococcus aureus</i>	[ATCC 6538]	
	<i>Pseudomonas aeruginosa</i>	[ATCC 15442]	
5 min[utes]	C.difficile [Spores]		
	<i>Clostridioides difficile</i> [spores]	[ATCC 43598]	

Table 4: List of Soft Surface Sanitization Organisms

Contact Time	Bacteria	Identification Number
1 Minute	<i>Klebsiella aerogenes</i>	[ATCC 13048]
	<i>Staphylococcus aureus</i>	[ATCC 6538]

[Effective against all listed organisms in the presence of organic soil (5% blood serum) ^{a]}
[Optional organism listings and claims:]

**[Product name]* is virucidal against Adenovirus type 5, Hepatitis B virus (HBV), Herpes Simplex Virus type 2 (causative agent of genital herpes), HIV-1, Influenza A virus H3N2 strain (representative of the common flu virus), Respiratory Syncytial Virus [RSV], Rhinovirus type 1a, Rotavirus (Strain WA), in the presence of organic soil (5% blood serum).

[Product name] is a germicidal liquid containing a Hydrogen peroxide based solution. Recommended for use in hospitals and other critical care areas where the reduction of cross-contamination between treated surfaces is required. Use on hard nonporous surfaces and equipment listed on this label made of stainless steel, plastic, Formica[®] and glass. [Formica[®] is a registered trademark of The Diller Corporation.]

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Emerging Viral Pathogen Claims

This product qualifies for emerging viral pathogen claims per the EPA’s ‘Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels’ when used in accordance with the appropriate use directions indicated below.

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

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

<i>For an emerging viral pathogen that is a/an...</i>	<i>...follow the directions for use for the following organisms on the label:</i>
Enveloped virus	Rhinovirus Type 1A, Strain 2060 (ATCC VR-1559)
Large, non-enveloped virus	Rhinovirus Type 1A, Strain 2060 (ATCC VR- 1559)
Small, non-enveloped virus	Rhinovirus Type 1A, Strain 2060 (ATCC VR- 1559) Feline Calicivirus, Strain F-9 (ATCC VR-782)

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

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

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

Disinfecting Claims

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 inanimate environmental surfaces listed on this label.

Antibacterial

Antimicrobial

[Antibacterial] [Antimicrobial] health club equipment spray

Bacteria tested as biofilm: *Staphylococcus aureus* and *Pseudomonas aeruginosa*

[Bactericidal], [Tuberculocidal], [Fungicidal] [Virucidal*] in 1 [one] minute

Bactericidal

Broad spectrum [microorganism coverage]

Broad Spectrum Disinfectant

Broad spectrum efficacy

Cleans [as it disinfects] [and disinfects]

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

Completely inactivates 99.9% of [viruses*] [insert virus(es)*]

[Convenient] [Portable] way to disinfect hard, nonporous surfaces

Demonstrates 6 [six] log reduction against [*Clostridioides difficile*] [*C. difficile*] [*C.diff*] spores in [5] [five] minutes

Demonstrates 99.9% reduction of [bacteria] [insert bacteria]

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

Designed for killing [*Clostridioides difficile*] [*C. difficile*] [*C.diff*] spores on hard, nonporous surfaces in hospitals

Destroys [Deactivates] [[Helps] Eliminate] 99.9999% of [*Clostridioides difficile* spores] [*C.difficile* spores] [*C.diff* spores] on hard, nonporous surfaces in hospital

[Destroys] [Deactivates] 99.9% [of] SARS-CoV-2 [the virus that causes COVID-19] [in hospitals]^c

Disinfect external hard, nonporous surfaces of ultrasound transducers

Disinfectant with sporicidal activity[^] (^ [*Clostridioides difficile*] or [*C. difficile*] spores)

Disinfects precleaned hard, nonporous surfaces

Disinfectant spray

Disinfects [,] [cleans] [and deodorizes] hard nonporous surface(s) [that people touch] in [just] 1 minute

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

[Disinfects] hard, nonporous surfaces

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

Disinfects on the go

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

Effective against biofilm bacteria^β on hard, nonporous surfaces

Effective against bacteria^β growing in biofilms on hard, nonporous surfaces [in 3 minutes]

Effective against [*Clostridioides difficile*] [*C.difficile*] [*C.diff*] spores in [5] [five] minutes

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

Effective in the presence of 5% blood serum^α

Effective against [*Candida auris*] [or] *C. auris*] in one [or 1] minute

Effective against [*Candida auris*] [or] *C. auris*]

Effective against SARS-CoV-2 [Coronavirus] [the virus that causes COVID-19] [in 1 minute] [in 60 seconds]^c

Formulated to kill 99.9999% of bacteria^β in biofilm on hard, nonporous surfaces

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Fungicidal

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

Hard, nonporous surface disinfectant

[Helps] [kill(s)] [eliminate(s)] odor-causing bacteria

Helps reduce the spread of SARS-CoV-2 [Coronavirus] [the virus that causes COVID-19][©] on treated, hard, nonporous surfaces.

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

[Hospital] disinfectant with sporicidal activity[^] ([^] [*Clostridioides difficile*] or [*C. difficile*] spores)

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 99.9999% of bacteria^β in biofilm on hard, nonporous surfaces

Kills bacteria in 1 minute

Kills biofilm bacteria^β on hard, nonporous surfaces

Kills [*Clostridioides difficile*] [*C. difficile*] [C.diff] spores in [5] [five] minutes

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

[Kills] [Effective against] 99.9999% of [*Clostridioides difficile*] [*C. difficile*] [C.diff] spores in [5] [five] minutes

[Kills] [Effective against] MRSA [(Methicillin Resistant *Staphylococcus aureus*)] in 1 (one) minute

[Kills] [Effective against] CRKP [(Carbapenem Resistant *Klebsiella pneumoniae*)] in 1(one) minute

Kills odor causing bacteria

[Kills] [Effective against] TB in [1] [one] minute

[Kills] [Effective against] the spore form of *Clostridioides difficile* [or *C. difficile*]

[Kills] [Effective against] viruses* in [only] [1] [one] minute

Kills microorganisms on hard, nonporous [hospital] surfaces

Kills [*Candida auris*] [or] *C. auris* in one [or 1] minutes

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

Kills SARS-CoV-2 [Coronavirus] [the virus that causes COVID-19] [in 1 minute] [in 60 seconds][©]

Leaves [bathroom] [office] [and other sites listed on this label] disinfected [and smelling fresh]

Multi-purpose disinfectant ^Ω

One-Step Cleaner/Disinfectant^Ω *[Grease and soap scum claims are not to be used on labeling with one-step cleaning/disinfection claims. One step cleaner/disinfectant claim should not be used for C.difficile.]*

Overall [5] [five] minute contact time

Penetrates biofilm, killing the bacteria^β living there

Perfect for disinfecting [exterior toilet surfaces] [around the exterior toilet surface]

Proven efficacy against SARS-CoV-2 [Coronavirus] [the virus that causes COVID-19] [in 1 minute] [in 60 seconds][©]

Ready to Use [disinfectant] [spray]

Reduces 99.9999% of bacteria^β growing in biofilm on hard, nonporous surfaces

The 5-minute [germicidal* spray] [disinfectant spray]

Tuberculocidal

[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

Virucidal*

Wipes out 99.9% of SARS-CoV-2 [Coronavirus] [the virus that causes COVID-19] [in 1 minute] [in 60 seconds][©]

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Ⓒ on hard, nonporous surfaces [identified on this label]

Ⓐ When used according to disinfection directions

Ⓑ *Staphylococcus aureus* and *Pseudomonas aeruginosa*

Ⓐ Does not apply to biofilm bacteria *Staphylococcus aureus* and *Pseudomonas aeruginosa*

Soft Surface Sanitization Claims

An [effective] soft surface spot sanitizer

Kills *Klebsiella aerogenes* and *Staphylococcus aureus* on [hospital] soft surfaces

[Sani-HyPerCide Germicidal Wipes] Provide[s] Soft Surface Spot Sanitization

Spot sanitizes soft surfaces by killing [*Klebsiella aerogenes*] [and] [*Staphylococcus aureus*] in one [or 1] minute [on
[cotton] [and] [or] [polyester] fabrics]

Spot sanitizes [cotton] [and] [or] [polyester] fabrics]

General Cleaning and Deodorizing Claims

Deodorize hard, nonporous surfaces [Use to]

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

Eliminates odors

Eliminates [lingering] [food] odors on surfaces

[Gets rid of] [Eliminates] odors

Odor [eliminator] [neutralizer]

Powers through tough messes

Removes [odors] [dirt]

Formula Related Claims

Contains no VOC-emitting ingredients

Non-corrosive

Proprietary Formulation [product]

Shelf-Stable formula

Packaging Related Claims

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

Convenient

Easy to refill

Easy to use trigger spray

Multi-pack

[Multi [-refill] pack]

[Package] [*insert type of package*] made from [x%] recycled materials

Recyclable [package]

Refills [now] available

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

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Refill [size] [pack] [value pack]
Trial [pack]
Twin pack

Other Product Related Claims

© [insert year] [insert company name]

Always ready to use

A Sani-Surface® Brand

Brought to you by [Sani-Cloth® Brand] [PDI] [Sani Professional]

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

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

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

Eliminates daily mixing and measuring

Environmental services use

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® Brand

Helps reduce cross contamination on hard nonporous treated surfaces

[Ideal] for use on high-touch, hard, nonporous surfaces

[Made in USA] [Of Domestic and [Foreign] [Imported] Materials] [Made in [insert country]]

Meets surface disinfection recommendations from OSHA Bloodborne Pathogen Standard [or AHE Practice Guidance for environmental cleaning]

New *(may be used for 6 months on marketed label)*

No diluting or mixing required

Not available in private label

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

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

Reduce [risk of] cross contamination on hard, nonporous surfaces

Use by [insert date]

Use on [couches] [chairs] [blinds] [curtains] [and other soft surfaces]

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

Value

Versatile

Where reduction of cross contamination between treated surfaces is of prime importance

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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:

- H₂O₂ [Hydrogen Peroxide] formulation
- Effective against [*C. difficile*][*C.diff*][*Clostridioides difficile*][spores]
- Effective against [*Candida auris*] [or *C. auris*] [in one [or 1 minute]
- Provides Soft Surface Spot Sanitization
- H₂O₂ [Hydrogen Peroxide] formulation effective against [*C. difficile*][*C.diff*]
[*Clostridioides difficile*][spores]
- Disinfectant With Sporicidal Activity formulation effective against [*C. difficile*][*C.diff*]
[*Clostridioides*][spores]
- Bactericidal formulation effective against [*insert microorganism*]
- Virucidal* formulation effective against [*insert microorganism*]
- Bactericidal, Virucidal*, Fungicidal, Tuberculocidal [1 minute or 60 seconds]
- Disinfectant with sporicidal^[^] activity formula
- FOR USE ON HARD, NONPOROUS SURFACES ONLY
- Do not freeze
- Do not allow to freeze

[(^ [*Clostridioides difficile*] or [*C. difficile*] [spores])]

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

¢ On hard, nonporous surfaces [identified on this 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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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 virus H3N2 strain"

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

Capitalization, plurals or singular, bold and italics are all variable unless specified in 40 CFR

The word "and" and symbol "&" can be used interchangeably

All directions may be written in numbered form or in paragraph form

Graphics, symbols, and logos may vary in color. All use surfaces and/or use sites on the label may be used in conjunction with an image of the use surface and/or use site.

June 11, 2021