

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

September 28, 2023

Jennifer Eck Regulatory & Scientific Affairs Steward Spartan Chemical Company, Inc. Electronic Transmittal: jeck@spartanchemical.com

Subject: PRIA Label Amendment – Amendment to add fungicidal claim for Candida auris and other updates. Product Name: Profect HP EPA Registration Number: 5741-33 Received Date: 12/1/2022 Action Case Number: 00412620

Dear Jennifer Eck:

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 <u>fife.aidan@epa.gov</u>.

Sincerely,

Steven Ingderman

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

Enclosure: Stamped Final Label

9/27/2023

Profect<sup>TM</sup> HP

## FRONT PANEL

ACTIVE INGREDIENTS:	
Hydrogen Peroxide	0.5%
INERT INGREDIENTS:9	9.5%
TOTAL:10	0.0%

E.P.A. Reg. No. 5741-33

E.P.A. Est. No. 5741-OH-1

Keep out of Reach of Children CAUTION See (side) (back) panel for additional precautionary statements

## FRONT, BACK, OR SIDE PANEL:

FOR INSTITUTIONAL AND INDUSTRIAL USE SPARTAN CHEMICAL COMPANY, INC. 1110 Spartan Drive Maumee, Ohio 43537 1-800-537-8990 /www.spartanchemical.com

NET CONTENTS:

## PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

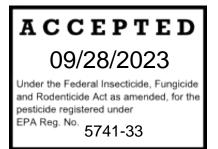
**CAUTION.** Causes moderate eye irritation. Avoid contact with eyes or clothing. Wear (specify appropriate protective eyewear, if applicable). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

(NOTE TO EPA - The following text will be used on five-gallon pails and larger containers only)

## ENVIRONMENTAL HAZARDS

This product is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Bracketed information is denoted as: [required qualifier], (optional text), {insert as noted}. The term "this product" used throughout this document may be replaced with the marketed product brand name. Punctuation and plural or singular word forms may be adjusted to allow for grammatical correctness. Statements may be combined to form complete sentences.



FIRST AID				
If in eyes:	<ul> <li>-Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>-Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>-Call a poison control center or doctor for treatment advice.</li> </ul>			
24 HOUR MEDICAL EMERGENCY NUMBER: 888- 314-6171				
Have the product container or label with you when calling a poison control center or doctor or going for treatment.				

## MEDICAL EMERGENCY: 888-314-6171

SPARTAN CHEMICAL COMPANY, INC. 1110 Spartan Drive, Maumee, Ohio 43537 1-<u>800-537-8990/ www.spartanchemical.com</u>

## (Note to EPA: the following statements are optional)

Hydrogen Peroxide RTU Disinfectant Hydrogen Peroxide Disinfectant Hydrogen Peroxide based Disinfectant RTU Handi Spray

## (Note to EPA: the following marketing claims are optional)

- Kills bacteria, enveloped<sup>7</sup> and non-enveloped<sup>8</sup> viruses, and fungi
- Offers broad spectrum kill in one product
- For use as a one-step, general, (healthcare) disinfectant, virucide\*, deodorizer, and cleaner on hard, inanimate nonporous environmental surfaces.<sup>3</sup>
- Effective Against Antibiotic-Resistant Bacteria\*\*
- [Product Name] is a (one-step) healthcare disinfectant that delivers effective performance against {insert pathogen(s) from efficacy table} (when the use directions for disinfection are followed or <sup>3</sup>).
- Use [Product Name] daily as part of a simple and effective cleaning and disinfection program for your entire facility on hard, non-porous surfaces.
- [Product name] is a (patented) hydrogen peroxide formulation designed to provide effective cleaning, deodorizing, and disinfection for [insert use site(s) from table].<sup>3</sup>
- Use [Product Name] for all your one-step disinfecting, deodorizing, and cleaning needs.<sup>3</sup>
- (This Product or Product Name) Disinfects, cleans, and deodorizes in one labor-saving step.<sup>3</sup>
- \*Kills Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), HIV-1 (AIDS Virus), Influenza A Virus, Influenza B Virus, Norovirus, Rotavirus, and SARS-CoV-2 [USA-WA1/2020] viruses on hard, inanimate nonporous environmental surfaces.
- \*\*Methicillin Resistant Staphylococcus aureus MRSA

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- Kills bacteria and viruses in 60 seconds
- Kills (TB) (Tuberculosis) in 3 minutes
- Kills Norovirus in (1 minute) (60 seconds)
- (For daily use)
- (One or 1) minute contact time ensures efficacy and compliance
- Features patented hydrogen peroxide technology
- Broad spectrum kill
- Ready to use formula ensures proper ppm required for disinfection.
- Pre-labeled, pre-filled quart containers offer safety and convenience without the need to dilute concentrated chemicals.
- One-step cleaner, sanitizer, viricidal\*, fungicidal disinfectant.<sup>3</sup>
- Deodorizes by killing microorganisms that cause offensive odors
- Effective against a broad spectrum of bacteria (such as {insert bacteria from efficacy table})
- Meets the surface disinfection recommendations of OSHA bloodborne pathogen standard.
- We make clean simple
- Compatible with equipment and other hospital surfaces
- Can be used on {insert types of surface(s) from table} in {insert use sites(s) from table}
- Cleans, disinfects, and deodorizes in one step.<sup>3</sup>
- Effective disinfection on high touch surfaces<sup>2</sup>
- Disinfects high touch surfaces<sup>2</sup> in (60 seconds) (1 minute)
- Disinfects critical touch surfaces<sup>2</sup> in (60 seconds) (1 minute)
- (One or 1) minute contact times for your most critical disinfection needs<sup>2</sup>
- Cleaner
- Deodorizer
- Disinfectant
- Sanitizer
- Virucide\*
- Virucidal\*
- Bactericidal
- Tuberculocidal
- Fungicide (against pathogenic fungi)
- Fungicidal
- All Purpose Cleaner
- Ready-To-Use (RTU) (Disinfectant Spray)
- Eliminates Odors
- Cleans and Deodorizes in One Easy Step
- Cuts (Tough) Grease and Grime (without Scrubbing)
- Kills Germs
- Kills Bacteria
- Kills 99.9% of Household Bacteria<sup>4</sup>
- Kills Pandemic 2009 H1N1 Influenza A Virus (formerly called swine flu)
- Kills Pandemic 2009 H1N1 Influenza A Virus.
- EFFICACY TESTS HAVE DEMONSTRATED THAT (THIS PRODUCT or PRODUCT NAME) IS AN EFFECTIVE BACTERICIDE, FUNGICIDE\*, AND VIRUCIDE IN THE PRESENCE OF ORGANIC SOIL (5% BLOOD SERUM).<sup>3</sup>
- (Clean) (and) (Disinfect) after spills(!)

- (This product) (Product name) is (designed) (formulated) for use (in/with) (refillable spray bottle) (mechanical spray device) (cordless) (backpack) (handheld) (sprayer) (low-pressure sprayer) (trigger sprayer) (handheld mechanical sprayer) (or insert specific applicator/sprayer name].
- An effective (cleaner and disinfectant) (standardized cleaning and disinfecting procedure) following a spill [(involving bodily fluids) OR (of bodily fluids)]
- (Helps) (employees) (staff) involved (with) (in) the cleanup of (spills) (spills containing potentially infectious material) [(involving bodily fluids) OR (of bodily fluids)]
- (Can be used to) (Helps) (employers) (institutions) meet surface disinfection recommendations from OSHA's bloodborne pathogen standard
- To confirm surface compatibility for plastic and painted surfaces, spot test on an inconspicuous area before use.
- For best (cleaning) (disinfection) results, always test a small inconspicuous area first to confirm surface compatibility.
- Cost effective and time efficient when used with (the) (refillable spray bottle) (mechanical spray device) (cordless) (backpack) (sprayer) (low pressure sprayer) (trigger sprayer) (handheld mechanical sprayer) (applicator/sprayer name).
- (This product) (Product name) is (designed) (formulated) for use with (refillable spray bottle) (mechanical spray device) (cordless) (backpack) (handheld) (sprayer) (low pressure sprayer) (trigger sprayer) (handheld mechanical sprayer) (applicator/sprayer name).
- (Refer to (applicator) (sprayer) (equipment) (user) manual for (additional) (specific) operation instruction before use.
- Refer to the *insert applicator/sprayer name* -and/or- user manual -or- safety data sheet (SDS) for (more information) (any additional PPE).
- See (online) (service) (instruction) manual (insert) for (more) (detailed) (usage) information. The most restrictive (label language or instructions or language or statements) will apply.
- (This product) (Product name) is a one-step (hospital-use) germicidal (disinfectant) cleaner and deodorant (odor-counteractant) (odor neutralizer) designed for general cleaning, (and) disinfecting (deodorizing) (of) hard, non-porous inanimate surfaces.<sup>3</sup> Quickly removes dirt, grime, food residue, blood and other organic matter commonly found in hospitals (in health care facilities) (on medical surfaces). It (also) eliminates odors leaving (restroom) surfaces smelling clean and fresh.
- Use where odors are a problem.
- (Effective against) (Disinfects) (Kills) (99.9%) SARS-CoV-2<sup>2</sup>
- (Effective against) (Disinfects) (Kills) (99.9%) SARS-CoV-2<sup>2</sup>, the cause of COVID-19
- (Kills) (Eliminates) 99.9% SARS-CoV-2<sup>2</sup> (USA-WA1/2020) (causative agent of COVID-19) (the virus that causes COVID-19)
- Disinfects surfaces by killing (99.9%) SARS-CoV-2 (USA-WA1/2020) (in One step)<sup>2</sup>
- Kills (99.9% of) SARS-CoV-2<sup>2</sup> virus, which causes COVID-19
- (Kills) (Effective against) the virus that causes COVID-19<sup>1,2</sup>
- (This Product) (Product Name) kills SARS-CoV-2<sup>2</sup> the virus that causes COVID-19
- (This Product) (Product Name) kills SARS-CoV-2<sup>2</sup> virus
- (This Product) (Product Name) kills (99.9% of) the virus that causes COVID-19<sup>1,2</sup>
- (This Product) (Product Name) kills SARS-CoV-2<sup>2</sup> in (just) (30 seconds)
- (This Product) (Product Name) kills SARS-CoV-2<sup>2</sup> the virus that causes COVID-19 in (just) 30 seconds.
- (This Product) (Product Name) has demonstrated effectiveness against (SARS-CoV-2) (SARS-CoV-2 the virus that causes COVID-19) on hard, nonporous surfaces.
- (This Product) (Product Name) kills (SARS-CoV-2) the virus that causes COVID-19 in just one step(!)<sup>3</sup> on hard, nonporous surfaces.

- (This Product) (Product Name) kills SARS-CoV-2 (the virus that causes COVID-19) in one step(!)<sup>2,3</sup>
- (This Product) (Product Name) kills (SARS-CoV-2 or the virus that causes COVID-19) in one easy step(!)<sup>3</sup> on hard, nonporous surfaces.
- Profect HP kills (insert pathogen(s) from Efficacy Table) (.) (!)
- (Great) For use as a spot sanitizer on soft surfaces (composed of cotton or polyester/cotton blend). (This product) (Product Name) Kills (removes) (sanitizes) microorganisms (or list pathogens from Efficacy Table) on soft surfaces or fabric including: (Insert from Types of Surfaces table)<sup>5,6</sup>
- (This product) (can be used to pre-clean and disinfect (healthcare) items (such as): (select from use sites and types of surfaces tables) (where disinfection is required). (A potable water rinse is required when disinfecting food contact surfaces.)
- When used as directed, this product (or product name) is effective against a wide variety of pathogenic microorganisms (including bacteria, viruses, and fungi or select pathogens from Efficacy table).
- One minute contact times ensure efficacy and compliance for your most critical disinfection needs.<sup>2,3</sup>
- Ideal for daily use on high-touch surfaces<sup>2</sup>, (Profect HP) (or Product Name) (or this product) is available in a convenient ready-to-use (RTU) quart.
- This product (or Profect HP) can be used in multiple areas including {insert use sites from table} (and either (on {insert types of surfaces from table}) or (and is compatible with most hard, non-porous surfaces)).<sup>2,3</sup>
- Offers convenience (of an RTU product) and broad spectrum kill (or broad-spectrum efficacy) in one (easy to use<sup>3</sup>) product
- Candida auris is an emerging fungus that presents a serious (global) health threat.
- (Profect HP) (Product Name) (Kills) (effective against) (inactivates) Candida auris<sup>2</sup> in 5 minutes
- (Profect HP) (Product Name) (Kills) (effective against) (inactivates) Candida auris in 5 minutes on hard, non-porous surfaces.

## (claim qualifiers)

<sup>1</sup>SARS-CoV-2 <sup>2</sup>On hard, non-porous surfaces <sup>3</sup>When the use-directions for disinfection are followed.

<sup>4</sup>Pseudomonas aeruginosa, Salmonella enterica, Staphylococcus aureus

<sup>5</sup>on 100% Cotton

<sup>6</sup>on Polyester/Cotton Blend

<sup>7</sup>Human Coronavirus, Influenza B, SARS-CoV-2

<sup>8</sup>Feline Calicivirus, Rhinovirus type 37, Rotavirus

## (Note to EPA: the following graphics are optional)



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## EMERGING VIRAL PATHOGENS:

*Product Name* – or - 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.

*Product Name* – or - this product meets the criteria to makes claims against certain emerging viral pathogens from the following viral category:

## -Enveloped virus -Large, non-enveloped virus -Small, non-enveloped virus

For an emerging viral pathogen that is a/an:	follow the direction for use for the following organisms on the label:
Enveloped virus	Feline Calicivirus
	Human Rotavirus
Large, non-enveloped virus	Feline Calicivirus
	Rhinovirus type 37
Small, non-enveloped virus	Feline Calicivirus
	Rhinovirus type 37

[Product Name] has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard non-porous surfaces. Therefore, this product can be used against [name of emerging virus] when used in accordance with the directions for use against [name of supporting virus] on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [website address] for additional information.

## **Efficacy Table:**

Lineacy Tuble:			
<b>BACTERICIDAL ACTIVITY (BACTERI</b>	A): (Using approved AOAC test metho	ds (under Good Laboratory Practices,	
[GLPs]), in the presence of 5% blood serum a	and a 1-minute contact time, (this produ	act or product name) kills the following	
organisms on hard, inanimate nonporous envi	ronmental surfaces:)		
Organism	ATCC Number Contact Time		
Pseudomonas aeruginosa	(ATCC 15442)	1 minute	
Salmonella enterica	(ATCC 10708)	1 minute	
Staphylococcus aureus	(ATCC 6538)	1 minute	
Acinetobacter baumannii	(ATCC BAA-1709)	1 minute	
Carbapenem Resistant Escherichia coli	(CDC 81371)	1 minute	
Escherichia coli O157:H7	(ATCC 35150)	1 minute	
Extended-Spectrum beta-lactamase (ESBL) producing <i>Escherichia coli</i>	(ATCC BAA-196)	1 minute	
Metallo-beta lactamase (MBL) producing Pseudomonas aeruginosa	(CDC 2012059)	1 minute	
Methicillin Resistant <i>Staphylococcus</i> aureus - MRSA	(ATCC 33592)	1 minute	
Multi-drug Resistant (MDR) Enterococcus faecium	(ATCC 51559)	1 minute	
Multi-drug Resistant (MDR) Klebsiella pneumoniae	(ATCC 51503)	1 minute	
New Delhi metallo-beta-lactamase 1 (NDM-1) producing Escherichia coli	(CDC 1001728)	1 minute	
<b>FUNGICIDAL ACTIVITY:</b> (Using approve or product name) is an effective disinfectant a a <b>1-minute</b> contact time, unless otherwise not	against the following organism(s) on vis ted, at room temperature:)		
Organism	ATCC Number	Contact Time	
Candida auris	(CDC AR-0385)	5 minutes	
Trichophyton interdigitale	(ATCC 9533)	1 minute	
Candida albicans	(ATCC 10231)	1 minute	
		i	

VIRUCIDAL ACTIVITY (VIRUSES): (Using approved AOAC test methods (under Good Laboratory Practices, [GLPs]), in the presence of 5% blood serum and a **1-minute** contact time, unless otherwise noted, (this product or product name) kills the following organisms on hard, inanimate nonporous environmental surfaces:)

Organism	ATCC Number or Strain	Contact Time
Avian Influenza A (H5N1) Virus	(CDC #2006719965)	1 minute
Herpes Simplex Virus Type 1	(ATCC VR-733)	1 minute
Herpes Simplex Virus Type 2	(ATCC VR-734)	1 minute
Human Coronavirus	(ATCC VR-740)	1 minute
Human Hepatitis B Virus (Duck Hepatitis B virus as surrogate) (HBV)	(Hepadnavirus Testing, 9/1/15 strain)	1 minute
Human Hepatitis C Virus (Bovine Viral Diarrhea Virus as surrogate) (HCV)	(ATCC VR-1422)	1 minute
Human Immunodeficiency Virus type 1 (HIV-1) (AIDS Virus)	(HTLV-III <sub>B</sub> strain)	1 minute
Human Rotavirus	(ATCC VR-2018)	1 minute
2009 H1N1 Influenza A Virus (Novel H1N1)	(A/Mexico/4108/2009 strain)	1 minute
Influenza B	(ATCC VR-823)	1 minute
Norovirus (Feline Calicivirus)	(ATCC VR-782)	1 minute
Respiratory syncytial virus (RSV)	(ATCC VR-26)	1 minute
Rhinovirus type 37	(ATCC VR-1147)	1 minute
Vaccinia virus	(ATCC VR-119)	1 minute
Severe Acute Respiratory Syndrome-related Coronavirus 2 (SARS-CoV-2)	(USA-WA1/2020 strain)	30 seconds

Bracketed information is denoted as: [required qualifier], (optional text), {insert as noted}.

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Organism	ATCC Number	Contact Time		
Mycobacterium bovis	(ATCC 35743)	3 minutes		
	ACT SANITIZER: For spot treat	ment of cotton or polyester/cotton blend (fabrics		
(materials) (Insert types of surface(s))				
(materials) (Insert types of surface(s))				
(materials) (Insert types of surface(s)) Organism	ATCC Number	Contact Time		
Organism	ATCC Number (ATCC 13048)	Contact Time           1 minute		
Organism				
Organism Klebsiella aerogenes	(ATCC 13048)	1 minute		

Hospital(s)	Nursing Home(s)	Healthcare (Settings)	Clinic(s)
	e c	(Facilities)	
Patient Care (Rooms) (Areas) (Facility) (Facilities)	Emergency Room(s)	Recovery Room(s)	(Long-term) (Acute) Healthcare (Facility) (Facilities)
Hospice Facilities	(Surgery) (Operating) Room(s)	(Dental) (Medical) Office(s)	Home Healthcare Institutions
Daycare Center(s)	Nurseries	Laundromat(s)	Laundry room(s)
(Dentist's) (Doctor's) (Physician's) (Office)	Medical Related Facilities	Rehabilitation Center(s) (Facility) (Facilities)	Childcare (centers) (facilities)
(Athletic) (Recreational) facilities	Schools	Offices	Lodging/Hospitality (Establishments)
Dining (rooms) (halls)	(Public) (Office) Buildings	Restaurants	Quick Service Restaurants
Hotels	Motels	Supermarkets	Convenience Stores
Veterinarian (offices)(clinics)	Kennels	Animal Hospitals (facilities)	Animal Care facilities
Pet Care(s) (Areas)	Bars	Kitchens	(Barber) (Beauty) Shop(s)
Shopping malls	Food Processing Plants	Correction(al) facilities	Manufacturing Sites/Facilities
Travel Rest (Areas) (Stops)	Transportation Terminal(s)	(Train)(Bus) Stations	Airports
Factories	Apartment Buildings	Cruise Ships	Airline Terminals
Federally Inspected Meat and Poultry Plants	Detention Centers	Jail(s)	Prison(s)
Housekeeping – and/or – Janitorial (Janitors) Room(s)	Business(es) (and Office Buildings)	Workplace(s)	Exercise (Facility) (Facilities)
Grocery Stores	Fitness Center(s)	College(s)	Dorm rooms (Dormitories)
Gyms (Gymnasium(s))	Health Club(s)	Lodging (Facilities)	Shelters
Breakrooms	Institutional Facilities	Nursing Home(s)	(Schools) (Universities)
Locker Room(s)	Military (installations) (locations)	Tanning Salon(s)	Washroom(s)
public restrooms	bathroom(s)	restroom(s)	Casino(s)
(Medical) (neonatal) (pediatric) intensive care units.	(ICUs) (MICUs) (NICUs) (PICUs) (SICUs) (areas)	Isolation Rooms	waiting rooms (areas)
reception areas	recovery rooms	Airports	Long-term facilities
medical facilities	animal treatment facilities	retail (establishments) (businesses)	schools (colleges and universities)
A(mbulatory) S(urgical) C(enters) (ASC)	Business Centers	Emergency Medical Transport Vehicles	Meeting Rooms
Outpatient (Surgical Centers) (OPSC)	Surgical Clinics (or Facilities)	Outpatient Surgical (Clinics or Facilities)	Stadiums
Public Transportation	School Buses	Guest Rooms	Guest Facilities
Convention centers			

Bracketed information is denoted as: [required qualifier], (optional text), {insert as noted}.

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## **Types of Surfaces:**

Countertops	Floors	Walls	Glazed (ceramic) tile
(glazed) porcelain (tile)	Enameled surfaces	Shower Walls	Exposed Surfaces of Toilet Bowls and Urinals
Commodes	Shower Curtains and Doors	Chrome	Vanity (tops)
Tub and Sink Surfaces and Fixtures	Bathtubs	Shower stalls	Shower handles
Sinks	bed (railings) (frames)	Exam(ination) Tables	Exam(ination) Rooms
Mattress Covers	High Touch Surfaces	(Critical) (High) Touch Points	Light (Fixtures) (switches)
Elevator Buttons	Remote Controls	Carts	Bed Pans
Tables	Door Handles and Knobs	(Trash) (Garbage) cans	Waste Receptacles
Dumpsters	Cages	Crates	Veterinary surfaces
Railings	Reusable Restraints	Exercise Equipment	Weights and Sports equipment
Wrestling and Gymnastic mats	Athletic (mats) (training	Physical Therapy tables	Shared work (equipment)
	tables)		(stations)
Fiberglass	Linoleum	Stainless Steel	Vinyl Tile
Vinyl	Hard Plastic Desks	Folding Tables	Tables
Bathroom (counter tops) (surfaces)	Nonporous Flooring material	Sealed stone and concrete	Other hard, nonporous bathroom surfaces
Laundry Hampers	(Medical) (Hospital) Beds	Grocery Cart(s) (Handles)	Recycling Bin(s)
Racks	Over-Bed Tables	Wheelchair(s)	Flexible non-porous surfaces
coated (removable) (plastic) covers for mattresses	coated (removable) (plastic) covers for pillows	docking stations	exercise equipment
computer mouse, keyboards, peripherals, tables	handheld (electronic) devices	mobile workstations	
		other hard, nonporous env	vironmental surfaces

Use this product (product name) on soft, cotton or polyester/cotton surfaces of (like):				
upholstery	fabric	drapes	window treatment(s)	
curtain(s)	draperies	shower curtain(s)	cushions	
fabric barriers	(fabric or upholstered) seats	upholstered furniture	linen(s)	
	and couches			
exercise mats	gym bags	chairs	seat (soft) cushions	
sofas	couches	equipment (lining)	towels	
mattresses	headrest(s)	Soft (fabric) surfaces	Jerseys	
Uniforms	Sports equipment (lining)	Upholstered (arm)chairs	Upholstered couches	
		other soft exterior surfaces (of -or- only)		

Bracketed information is denoted as: [required qualifier], (optional text), {insert as noted}.

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9/27/2023

#### **Directions for Use:**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Visibly soiled areas must be pre-cleaned prior to treatment.

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.

#### For use as a One-Step Disinfectant, Deodorizer, and Cleaner on Hard, Inanimate Nonporous

**Environmental Surfaces:** Hold (container) (sprayer) six to eight inches from the surface to be treated. For one-step disinfecting, deodorizing, and cleaning in the presence of 5% organic soil, spray (Product Name) through a trigger sprayer, mechanical sprayer, or other coarse spray device. Make sure to wet surfaces thoroughly. Treated surfaces must remain visibly wet for 1 minute. Visibly soiled areas must be pre-cleaned prior to treatment. Wipe off with a clean cloth or allow to air dry. When used as directed, this product is effective against {insert selected pathogens from the efficacy table} or {Pseudomonas aeruginosa, Salmonella enterica, Staphylococcus aureus, Acinetobacter baumannii, Carbapenem Resistant Escherichia coli, Escherichia coli O157:H7, Extended-Spectrum beta-lactamase (ESBL) producing Escherichia coli, Metallo-beta lactamase (MBL) producing Pseudomonas aeruginosa, Methicillin Resistant Staphylococcus aureus (MRSA), Multi-drug Resistant (MDR) Enterococcus faecium, Multidrug Resistant (MDR) Klebsiella pneumoniae, New Dehli metallo-beta-lactamase 1 (NDM-1) producing Escherichia coli}

**Tuberculocidal Activity:** (This product) (Product Name) exhibits disinfectant efficacy against Mycobacterium bovis (TB) when the treated surface is allowed to remain wet for **3 minutes** at 68°F (20°C). Visibly soiled areas must be pre-cleaned prior to treatment.

Before using this product in food processing areas, all food products and packaging materials must be removed from the room or carefully protected. After use, all food contact surfaces must be thoroughly rinsed with potable water before reuse. Do not use this product to disinfect or clean utensils, glasses, dishes or cookware.

#### **Fungicidal Activity:**

(This product) (Product Name) is an effective disinfectant against the pathogenic fungus, Trichophyton interdigitale (Athlete's Foot Fungus) (a cause of ringworm) (a cause of ringworm of the foot) and Candida albicans, on visibly clean, hard, non-porous surfaces (such as those found in locker rooms, dressing rooms, shower and bath areas, and exercise facilities) for a 1-minute (60 second) contact time at room temperature. (This product) (Product Name) is effective against *Candida auris* at a contact time of 5-minutes. Follow the special label instructions for cleaning prior to disinfection against *Candida auris*.

# SPECIAL LABEL INSTUCTIONS FOR CLEANING PRIOR TO DISINFECTION AGAINST CANDIDA AURIS:

**PERSONAL PROTECTION:** Wear (appropriate) barrier protection such as gloves, gowns, masks, or eye covering.

Bracketed information is denoted as: [required qualifier], (optional text), [insert as noted]. The term "this product" used throughout this document may be replaced with the marketed product brand name. Punctuation and plural or singular word forms may be adjusted to allow for grammatical correctness. Statements may be combined to form complete sentences. **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. Precleaning 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 MATERIALS 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.

**DISINFECTION PROCEDURE:** Pre-clean visibly soiled areas. Spray 6 - 8 inches from hard, nonporous surfaces until completely wet. Allow to remain visibly wet for 5 minutes. Wipe surfaces and let air dry.

## \*Virucidal Activity on Hard, Inanimate Nonporous Environmental Surfaces:

Apply through a trigger sprayer, mechanical sprayer, or other coarse spray device. Make sure to wet surfaces thoroughly. Treated surfaces must remain visibly wet for 1 minute unless otherwise noted. Visibly soiled areas must be pre-cleaned prior to treatment. Wipe off with a clean cloth or allow to air dry. When used as directed, (this product) (Product Name) is effective against Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), Avian Influenza A (H5N1) Virus, Human Immunodeficiency Virus Type 1 (HIV-1), Herpes Simplex Virus Type 1, Herpes Simplex Virus Type 2, Human Coronavirus, Human Rotavirus, Influenza A Virus, Influenza B Virus, Norovirus, Respiratory syncytial virus (RSV), Rhinovirus type 37, and Vaccinia virus when the treated surface is allowed to remain wet for 1 minute. When used as directed, (this product) (Product Name) is effective against Severe Acute Respiratory Syndrome-related Coronavirus 2 (SARS-CoV-2) in 30 seconds(.) (!)

**\*KILLS HCV, HBV AND HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in 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 Hepatitis C Virus (HCV), Hepatitis B Virus (HBV) and Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS).

# SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HCV, HBV AND HIV-1 ON SURFACES OR OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

**PERSONAL PROTECTION:** Exposure to blood or body fluids must be avoided by use of barrier protection such as latex or other impervious gloves. Face shields and impervious gowns must also be worn if splashing of blood or body fluids may occur.

**CLEANING PROCEDURES:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of (Product Name).

**CONTACT TIME:** Leave surfaces wet for 1 minute.

**DISPOSAL OF INFECTIOUS MATERIAL:** Contaminated cleaning materials, blood and other body fluids must be autoclaved and/or disposed of according to local regulations for infectious waste disposal

## To Sanitize Soft, Non-Food Contact Surfaces for Spot Treatment:

Visibly soiled areas must be pre-cleaned prior to treatment. Apply (Product Name) (this product) with a trigger sprayer, mechanical sprayer, or other coarse spray device. Hold sprayer six to eight inches from the surface and spray until fabric is wet. Fabric must remain wet for 1 minute. Allow fabric to air dry. Reapply as necessary. (Prior to first use on a particular surface, it is recommended to test in a small, discreet area if there is concern of colorfastness.) When used as directed this product is effective against

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Klebsiella aerogenes<sup>5</sup>, Staphylococcus aureus<sup>5</sup>, Acinetobacter baumannii<sup>6</sup>, and Vancomycin Resistant Enterococcus faecalis (VRE) <sup>5,6</sup> (on soft (materials) (surfaces) (and) (fabric(s))).

## For Use as a Cleaner and/or Deodorizer:

Spray (this product) (Product Name) evenly over hard, nonporous inanimate surfaces to be cleaned, 6-8 inches from surface, making sure to wet surfaces thoroughly. Wipe surfaces dry (or rinse) (or allow to air dry).

## Malodor(s) (Activity) (Counteractant):

Eliminates (destroys) odors and odor-causing bacteria on hard, nonporous surfaces in restroom areas, behind and under sinks and counters, and storage areas (and other places where bacterial growth can cause malodors).

## (NOTE TO EPA – The following text will be used on containers of 1 gallon or less which are unable to be rinsed.)

## STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a cool, dry area inaccessible to children.

**Container Disposal:** Nonrefillable container. Do not reuse or refill this container. Replace cap and discard in trash.

# (NOTE TO EPA – The following text will be used on containers of 5 gallons or less which can be rinsed.)

## STORAGE AND DISPOSAL

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

**Pesticide Storage:** Store in a cool, dry area inaccessible to children.

**Pesticide Disposal:** Pesticide wastes may be hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**Container Handling:** Nonrefillable container. Do not reuse or refill container. Triple rinse as follows: Fill container <sup>1</sup>/<sub>4</sub> full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill.

## (NOTE TO EPA – The following text will be used on containers of 5 gallons or greater.)

## STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a cool, dry area inaccessible to children.

**Pesticide Disposal:** Pesticide wastes may be hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**Container Handling:** Nonrefillable container. Do not reuse or refill container. Triple rinse as follows: Fill container <sup>1</sup>/<sub>4</sub> full with water. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn container over onto its other end and tip it back and forth several times. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill.

SPARTAN CHEMICAL COMPANY, INC. 1110 Spartan Drive, Maumee, Ohio 43537 Questions? 800-537-8990/ www.spartanchemical.com

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complete sentences.