

U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs Antimicrobials Division (7510P) 1200 Pennsylvania Ave., N.W.

Washington, D.C. 20460

NOTICE OF PESTICIDE:

X Registration Reregistration (under FIFRA, as amended) EPA Reg. Number:

Date of Issuance:

5741-35

6/15/22

Term of Issuance:

Conditional

Name of Pesticide Product:5741-

Profect Neutral 64TM

Name and Address of Registrant (include ZIP Code):

Nathan Gaubert

Manager of Research and New Product Development

Spartan Chemical Company, INC

Electronic Transmittal: ngaubert@spartanchemical.com

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/registration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Date:

6/15/22

Kathryn V. Montague

Senior Regulatory Advisor

Antimicrobials Division, 7510M

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US EPA

EPA Form 8570-6

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Action Case Number: 00336583

- 1. You are required to comply with the data requirements described in the DCI or EDSP Order identified below:
 - a. DDAC GDCI-069165-30870
 - b. DDAC GDCI-069166-30875
 - c. DDAC GDCI GDCI-069149-30869
 - d. ADBAC GDCI-069105-30882

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI Order listed above, you may contact the Reevaluation Team Leader (Team 36): http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division

- 2. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.
- 3. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 5741-35".
- 4. Submit one copy of the final printed label for the record before you release the product for shipment.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the 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/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf, you are subject to the following additional terms of registration:

- 1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.
- 2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
- 3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:

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- a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
 - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
 - A. CDC Current Outbreak List for "U.S. Based Outbreaks" (www.cdc.gov/outbreaks),
 - B. CDC Current Outbreak List for "Outbreaks Affecting International Travelers" with an "Alert" or "Advisory" classification (www.cdc.gov/outbreaks) (also released through the CDC's Health Alert Network (HAN) notification process)
 - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
 - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page (www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI).
 - A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup is large non-envelope and enveloped.
 - B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
- 4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE's publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.
- 5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Human Rotavirus, Feline Picornavirus is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

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

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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.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 5/26/2022)
- Alternate CSF #s 1-3 dated 5/26/2022)

The following alternate brand names have been added to the product record:

- Profect® 64
- Profect® GS Neutral Disinfectant
- PROFECT® Neutral 64 Fragrance Free
- Profect® 64 Fragrance Free
- PROFECT® HDQ 2
- Profect® hdqc2
- Profect® 64 hdqc2
- PROFECT® 64 HDQ
- PROFECT® GS Neutral 64
- Profect® GS Neutral 64 Fragrance Free
- Simplifill® 64 HDQ Neutral
- Simplifill® HDQ Neutral
- Simplifill® HDQ 2
- Simplifill® Neutral 64
- Simplifill® Neutral Disinfectant
- Simplifill® Neutral 64 Fragrance Free
- Simplifill® Neutral Disinfectant- Fragrance Free
- Simplifill® Neutral Disinfectant 64

If you have any questions, please contact Hebert.John@epa.gov or Oiguenblik.Emilia@epa.gov.

Enclosure: Stamped label

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PROFECT Neutral 64®

ACTIVE INGREDIENTS:
Alkyl (C ₁₄ -50%, C ₁₂ -40%, C ₁₆ -10%)
dimethyl benzyl ammonium chlorides 2.6150%
Octyl decyl dimethyl ammonium chloride1.9625%
Dioctyl dimethyl ammonium chloride0.9812%
Didecyl dimethyl ammonium chloride0.9812%
INERT INGREDIENTS: 93.4601%
TOTAL:100.0000%

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

ACCEPTED

06/15/2022

5741-35

Keep Out of Reach of Children **DANGER PELIGRO**

(See side panel for additional precautionary statements.)

FIRST AID		
If in eyes:	-Hold eye open and rinse slowly and gently with water for 15-20 minutesRemove contact lenses, if present, after the first 5 minutes, then continue rinsing eyeCall a poison control center or doctor for treatment advice.	
If on skin:	-Take off contaminated clothingRinse skin immediately with plenty of water for 15-20 minutesCall a poison control center or doctor for treatment advice.	
If inhaled:	-Move Person to fresh air -If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth to mouth if possible -Call a poison control center or doctor for further treatment advice.	
If swallowed:	-Call a poison control center or doctor immediately for treatment advice. -Have person sip a glass of water if able to swallow. -Do not induce vomiting unless told to do so by a poison control center or doctor. -Do not give anything by mouth to an unconscious person.	
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.		
NOTE TO PHYSICIAN Probable mucosal damage may contraindicate the use of gastric lavage.		

(*Note to Reviewer:* In accordance with 40 CFR 156.68(d), all first aid statements, as prescribed, will appear on the front panel of the product label)

FOR INSTITUTIONAL AND INDUSTRIAL USE SPARTAN CHEMICAL COMPANY, INC., 1110 Spartan Drive, Maumee, Ohio 43537

NET CONTENTS:

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.

List statements may be reduced to allow for reference to a single claim or type of microorganism found on this label

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Alternative Brand Names:

Profect® 64

Profect® GS Neutral Disinfectant

PROFECT® Neutral 64 – Fragrance Free

Profect® 64 – Fragrance Free

PROFECT® HDQ 2

Profect® hdqc2

Profect® 64 hdqc2

PROFECT® 64 HDQ

PROFECT® GS Neutral 64

Profect® GS Neutral 64 - Fragrance Free

Simplifill® 64 HDQ Neutral

Simplifill® HDQ Neutral

Simplifill® HDQ 2

Simplifill® Neutral 64

Simplifill® Neutral Disinfectant

Simplifill® Neutral 64 - Fragrance Free

Simplifill® Neutral Disinfectant- Fragrance Free

Simplifill® Neutral Disinfectant 64

(Note to EPA: the following statements are optional)

Clean on the Go® XX

For use only with Spartan Clean on the Go dispenser.

SimpliFill® X

Daily Cleaner Disinfectant

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

- -For use as a one-step¹, general, hospital disinfectant, virucide*, mildewstat, deodorizer, and cleaner on hard, non-porous, inanimate surfaces.
- -[Product Name] is a (one-step¹) (pH neutral formulation) healthcare disinfectant that delivers effective performance against {insert pathogen(s) from efficacy table}.
- -Use [Product Name] daily as part of a simple and effective cleaning and disinfection program⁸ for your entire facility.
- -[Product name] is a pH neutral formulation designed to provide effective cleaning, deodorizing, and disinfection for [insert use sites].
- -Use [Product Name] for all your one-step¹ disinfecting, deodorizing, and cleaning needs.
- -(This Product or Product Name) Disinfects, cleans, and deodorizes in one labor-saving step¹.
- -Sanitizer⁹ at 2 fl. oz. per gallon***
- -2 Minute Sanitizing Activity! ***
- -Sanitizes9 in 120 Seconds ***
- -Bactericide/Virucide*/Mildewstat
- -Effective against Antibiotic-Resistant Bacteria**
- -Effective against a broad spectrum of viruses (such as {insert virus from efficacy table}), bacteria (such as {insert bacteria from efficacy table}), and controls mildew (such as {insert mildew from efficacy table}).
- -Kills 99.9% of bacteria*** (in 120 seconds or 2 minutes) (on hard, non-porous surfaces)^{8,9}.
- -Kills 99.9% of bacteria*** on hard, nonporous surfaces (in 2 minutes or 120 seconds.) 8.9
- -Kills Pseudomonas aeruginosa, Staphylococcus aureus, Salmonella enterica, Escherichia coli O157:H7, Klebsiella pneumoniae (NDM-1), and Listeria monocytogenes.
- -Kills {insert pathogen from efficacy table}

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

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- Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), HIV-1 (AIDS Virus), Influenza A Virus, and Influenza B Virus
- -Disinfects against {insert pathogen from efficacy table}
- -PROFECTTM
- -SimpliFILL®
- -Sanitizes soft surfaces^{2,3} in 10 minutes
- -For use on [insert soft surfaces]³ in [insert use sites].
- -Eliminates or removes or destroys 99.9% of bacteria on {insert soft surface(s) from soft surface section} in {insert use sites from use site section}.
- -Meets surface disinfection recommendations of OSHA's Bloodborne Pathogen Standard
- -Ideal for use with microfiber cloths
- -Ideal for use in gyms -and/or- health clubs -and/or- wellness centers
- -Reduces the growth of odor-causing bacteria
- -Economically disinfects and deodorizes
- -Concentrated Neutral (pH) Disinfectant Cleaner
- -Kills {insert pathogen from efficacy table} in 10 minutes¹
- -Economical to use dilute at (2.0 or 2) fluid ounces per gallon of water
- -Kills {insert pathogen from efficacy table}
- -Versatile can be used to clean a variety of hard, non-porous surfaces (such as [List types of surfaces])
- -Odor remover eliminates the toughest odors from bodily fluids and soils
- -Disinfects hard, non-porous, high touch surfaces such as [insert/select surfaces from use sites and surfaces table]
- -For use on high touch surfaces such as [insert/select sites from use sites and surfaces table]
- -Tough on germs¹⁰, easy on surfaces
- -Will not dull high-gloss floor finishes with repeated use
- -One product for all your cleaning and disinfection needs
- -Leaves the room clean and disinfected^{1,8}
- -Disinfects as it cleans¹
- Approved for (use in) (the) (insert applicator/sprayer/dispenser/system name).⁶
- -When used with (the) (insert applicator/sprayer/dispenser name).⁶
- -Delivers powerful cleaning and excellent surface compatibility
- -Gentle enough for healthcare surfaces
- -Kills germs¹⁰ in 10 minutes.
- -Fragrance free (and or / or &) dye free
- -Features a fresh, (insert fragrance description) fragrance
- -Neutral (pH) disinfectant cleaner¹ concentrate designed for all hard, nonporous (environmental) surfaces
- -Economical to use dilute at 2 fluid ounce per gallon.
- -Economical concentrate
- -Concentrate(d)
- -Leaves the room clean and disinfected¹
- -One product for all your cleaning and disinfection needs
- -Economically disinfects and deodorizes
- -Delivers powerful cleaning and excellent surface compatibility
- -Removes soils, disinfects, and controls odor in one easy step¹.
- -Use to disinfect hard, non-porous, high touch surfaces

[Product Name] is a (one step¹ hospital) disinfectant cleaner¹ (and deodorant) formulated to kill a broad spectrum of microorganisms such as {insert pathogens from efficacy table}, on hard, nonporous environmental surfaces (or designed for general use on hard, nonporous environmental surfaces). With a neutral pH, (Profect 64 or Product Name) disinfects without damaging or dulling floor finish even with

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repeated use. Available in a (refreshing citrus scent or other fragrance description) or fragrance-free option. (Product Name) (at (2.0 or 2) fluid ounces per gallon dilution), is cost-effective and reduces restocking intervals for routine high touch surface cleaning (of [insert/select sites from use sites and surfaces table]). Use (Product Name) as part of a simple and effective cleaning and disinfection program¹ for your entire facility.

(Product Name or this product) is ideal for [Insert use sites and/or on types of surfaces]. Available in a (insert fragrance description) fragrance (or fragrance-free option), (Product Name or this product) is suitable for use in [insert use sites]. Use (product name or this product) daily as part of a simple and effective cleaning and disinfection program⁸ for your entire facility. (Product Name is infection prevention made simpleTM.)

[This product or Product name] is a(n) (effective) soft surface^{2,3} sanitizer.

[Product name] is a soft surface^{2,3} sanitizer against Staphylococcus aureus and Enterobacter aerogenes.

[Product Name] is for use in healthcare facilities as a hard surface disinfectant that delivers effective performance. With a fantastic fresh scent, [Product Name] leaves the room clean and disinfected! [Product name or this product] economically disinfects and deodorizes.

This product [or product name] is designed to disinfect, sanitize⁹, clean and deodorize¹ [insert surfaces] [and] [insert surfaces]. This product (or product name) is for use on hard, non-porous surfaces (throughout) (the) (in) (and) [Insert use sites].

When used as directed, [this product or product name] is a one-step¹ hospital disinfectant cleaner and deodorant (or odor-counteractant, or odor neutralizer) designed for general cleaning, (and) disinfecting (and deodorizing) hard, nonporous surfaces. Quickly removes dirt, grime, food residue, blood and other organic matter commonly found in hospitals (and/or health care facilities). It (also) eliminates odors leaving (restroom(s) or bathroom(s)) surfaces smelling clean and fresh. Use where odors are a problem.

[This product or product name] is used to clean, disinfect, sanitize⁹, and deodorize [Insert Surfaces] on hard, non-porous surfaces (throughout) (the) (in) (and) [Insert use sites].

[This produce or product name] is a one-step¹ pH neutral formulation disinfectant that is effective against gram-negative and gram-positive bacteria, is virucidal* (including HIV-1, HBV, HCV, and Influenza A virus) and controls the growth of mold and mildew when used as directed on hard, non-porous surfaces.

(This product or product name) is a hospital disinfectant that can be used as a Bactericide and Virucide* at 2 fluid ounce per gallon (or equivalent use dilution) of 400 ppm hard water (as CaCO3) in the presence of organic soil (5% blood serum).

[Types of Surfaces:]

Use this product [or product name] on washable hard, nonporous surfaces of: countertops, counters, floors, walls, glazed ceramic tile, glazed porcelain, 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, showers, shower stalls, shower handles, sinks, bed railings, bed frames, exam tables, examination tables, examination rooms, mattress covers³, high touch surfaces, critical touch points, high touch points, light switches, elevator buttons, remote controls, carts, bed pans, tables, bed rails, bedside tables, door handles, door knobs (and pulls), trash cans, waste receptacles, garbage cans, dumpsters, cages,

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crates, veterinary surfaces, food cases, reusable restraints, exercise equipment, weights and sports equipment, wrestling and gymnastic mats, athletic mats, athletic training tables, physical therapy tables, wheelchairs, shared work equipment, telephones, shared work stations, fiberglass, synthetic marble, stainless steel, glass, vinyl, hard plastic, desks, folding tables, tables, racks, nonporous flooring material, sealed stone and concrete, hard nonporous bathroom surfaces, all (other) hard nonporous environmental surfaces.

Use this product [or product name] on soft surfaces³ of: upholstery, fabric, drapes, window treatment(s), curtain(s), draperies, shower curtain(s), cushions, fabric barriers, fabric or upholstered seats and couches, and upholstered furniture.

[Use Sites:]

Hospitals, nursing homes, healthcare settings, healthcare facilities, doctor's offices, patient care rooms, patient care areas, Emergency Rooms, recovery rooms, rest homes, long term healthcare facilities, acute healthcare facilities, hospice facilities, surgery rooms, operating rooms, dental offices and clinics, home healthcare institutions, classrooms, daycare centers, nurseries, schools, offices, athletic facilities, public buildings, public facilities, recreational facilities, office buildings, lodging/hospitality establishments, restaurants, bars, cafeterias, cafes, kitchens, quick serve restaurants, transportation terminals, train stations, bus stations, airline terminals, airports, travel rest areas, hotels, motels, churches, factories, manufacturing sites/facilities, food processing plants, food preparation areas, federally inspected meat and poultry plants, supermarkets, convenience stores, shopping malls, veterinarian offices, veterinary clinics, kennels, animal hospitals, animal hospital facilities, animal care facilities, pet care areas, cruise ships, jails, prisons, correctional facilities, correction facilities, detention centers, apartment buildings, homes, home, public restrooms, bathroom, bathrooms, restrooms.

Claim qualifiers:

¹when used according to disinfection directions for all listed organisms.

²100% cotton and 100% polyester

³when used according to the soft surface sanitizer directions for spot treatment of precleaned soft surfaces.

⁶verify dilution prior to use

⁸On hard, non-porous surfaces

⁹When used as directed for Sanitizing Hard, Non-Porous, Non-food contact surfaces

¹⁰Pseudomonas aeruginosa, Staphylococcus aureus, Salmonella enterica

^{*}Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), HIV-1 (AIDS Virus), Influenza A Virus, and Influenza B Virus

^{**}Staphylococcus aureus-MRSA, Enterococcus faecalis-VRE and Acinetobacter baumannii

^{***}Staphylococcus aureus (ATCC 13048) and Enterobacter aerogenes (ATCC 6538)

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EMERGING VIRAL PATHOGENS:

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 makes claims against certain emerging viral pathogens from the following viral category:

-Enveloped Viruses

-Large Non-Enveloped Viruses

follow the direction for use for the following organisms on the label:
Human Rotavirus
Feline Picornavirus
Feline Picornavirus

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

Efficacy Table:

BACTERICIDAL ACTIVITY (BACTERIA): (Using AOAC test methods (under Good Laboratory Practices, [GLPs], in the presence of 5% blood serum, when diluted at 2 fl. oz./gal, and a 10-minute contact time, unless otherwise noted, (this product or product name) kills the following organisms on hard nonporous inanimate surfaces:)

Organism:	ATCC Number:	Contact Time:
Pseudomonas aeruginosa	ATCC 15442	10 minutes
Staphylococcus aureus	ATCC 6538	10 minutes
Bordetella bronchiseptica	ATCC 10580	10 minutes
Enterobacter aerogenes	ATCC 13048	10 minutes
Escherichia coli O157:H7	ATCC 35150	10 minutes
Extended-Spectrum beta-lactamase (ESBL) Escherichia coli	ATCC BAA-196	10 minutes
Extended-Spectrum beta-lactamase (ESBL) producing <i>Klebsiella pneumoniae</i>	ATCC 700603	10 minutes
Klebsiella pneumoniae (NDM-1)	CDC 1000527	10 minutes
Listeria monocytogenes	ATCC 19117	10 minutes
Methicillin Resistant Staphylococcus aureus (MRSA)	ATCC 33592	10 minutes
Multi-drug Resistant (MDR) Acinetobacter baumannii	ATCC 19606	10 minutes
Neisseria gonorrhoeae	ATCC 43069	10 minutes
Proteus mirabilis	ATCC 9240	10 minutes
Proteus vulgaris	ATCC 9920	10 minutes
Salmonella enterica	ATCC 10708	10 minutes
Salmonella enterica subspecies enterica serovar Pullorum	ATCC 19945	10 minutes
Salmonella enterica subspecies enterica serovar Typhimurium	ATCC 23564	10 minutes
Serratia marcescens	ATCC 14756	10 minutes
Shigella flexneri serotype 2B	ATCC 12022	10 minutes
Shigella sonnei	ATCC 25931	10 minutes
Streptococcus pneumoniae	ATCC 6305	10 minutes
Streptococcus pyogenes	ATCC 19615	10 minutes
Vancomycin Resistant <i>Enterococcus faecalis</i> (VRE)	ATCC 51575	10 minutes
Vibrio cholerae	ATCC 14035	10 minutes
Yersinia enterocolitica	ATCC 23715	10 minutes

VIRUCIDAL ACTIVITY (VIRUSES): (Under Good Laboratory Practices, [GLPs], in the presence of 5% blood serum, when diluted at 2 fl. oz./gal, and a 10-minute contact time, unless otherwise noted, (this product or product name) kills the following organisms on hard nonporous inanimate surfaces:)

Virus:	ATCC Number/Strain:	Contact Time:
Hepatitis C Virus (HCV)	Bovine Viral Diarrhea virus as a	10 minutes
	surrogate	
Hepatitis B Virus (HBV)	Duck Hepatitis B virus as a surrogate	10 minutes
HIV-1 (AIDS Virus)	Strain HTLV-III _B	10 minutes
Herpes Simplex Virus Type 1	ATCC VR-733, Strain F (1)	10 minutes
Herpes Simplex Virus Type 2	ATCC VR-734, Strain G	10 minutes
Human Coronavirus	ATCC VR-740, Strain 229E	10 minutes
Human Rotavirus	ATCC VR-2018, Strain WA	10 minutes
Influenza A Virus	ATCC VR-544, Strain A	10 minutes
Influenza B Virus	ATCC VR-823, Strain B	10 minutes
Vaccinia virus	ATCC VR-119, Strain WR	10 minutes
Animal Premise Virucidal Activity	ATCC Number/Strain:	Contact Time
Avian Influenza A (H3N2) Reassortant virus	ATCC VR-2072, Strain	10 minutes
	A/Washington/897/80 x	
	A/Mallard/NewYork/6750/78	
Avian Infectious Bronchitis	Strain Beaudette IB42	10 minutes
Canine Coronavirus	ATCC VR-809, Strain 1-71	10 minutes
Canine Distemper virus	ATCC VR-128, Strain Lederle	10 minutes

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

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List statements may be reduced to allow for reference to a single claim or type of microorganism found on this label

Master Label for PROFECT Neutral 64

Spartan Chemical Company, Inc.

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Feline Picornavirus	ATCC VR-649, Strain FRV	10 minutes
	(17FRV)	
Infectious Bovine Rhinotracheitis	ATCC VR-188, Strain LA	10 minutes
Porcine Respiratory and Reproductive	Strain NVSL	10 minutes
Syndrome (PRRS) virus		
Pseudorabies virus	ATCC VR-135, Strain Aujeszky	10 minutes
Transmissible Gastroenteritis virus (TGE)	obtained from the University of	10 minutes
	Minnesota	
MILDEW-FUNGISTAT ACTIVITY: (Und	er Good Laboratory Practices, [GLPs], in	the presence of 5% blood serum, when
diluted at 2 fl. oz./gal, and a 10-minute contact		
organisms on hard nonporous inanimate surface		1 /
Organism:	ATCC Number:	Contact Time:
Aspergillus niger	ATCC 6275	After initial application, reapply once
. 0		per week or when growth reappears.
		111 / 1 / 2 / 1 1/1 2 1 /
Non-Food Contact Surface Sanitizers: (Und	er Good Laboratory Practices, [GLPs], w	nen diluted at 2 fl. oz./gal with a 2-minute
<u>Non-Food Contact Surface Sanitizers:</u> (Und contact time, unless otherwise noted, (this prosurfaces:)		
contact time, unless otherwise noted, (this procurfaces:)		
contact time, unless otherwise noted, (this pro-	duct or product name) kills the following	organisms on hard nonporous inanimate
contact time, unless otherwise noted, (this procure surfaces:) Organisms:	duct or product name) kills the following ATCC Number:	organisms on hard nonporous inanimate Contact Time:
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Directions for Use:

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

Preliminary cleaning is required for visibly soiled areas.

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-Step¹ Disinfectant, Deodorizer, and Cleaner on Hard, Non-Porous Surfaces:

For one-step disinfecting, deodorizing, and cleaning in the presence of 5% organic soil use (Product Name) at 2 fl. oz. per gallon of water (1020 ppm active). Apply with a mop, cloth, trigger sprayer, or other coarse spray device. Treated surface must remain visibly wet for 10 minutes. Wipe off with a clean cloth or allow to air dry. Do not breathe spray or mist. Visibly soiled surfaces must be precleaned prior to the disinfection. When used as directed, this product is effective against {insert selected pathogens from the efficacy table} or {Pseudomonas aeruginosa (ATCC 15442), Staphylococcus aureus (ATCC 6538), Bordetella bronchiseptica (ATCC 10580), Enterobacter aerogenes (ATCC 13048), Escherichia coli O157:H7 (ATCC 35150), Extended-Spectrum beta-lactamase (ESBL) producing Escherichia coli (ATCC BAA-196), Klebsiella pneumoniae (ESBL)(ATCC 700603), Klebsiella pneumoniae (NDM-1)(CDC 1000527), Listeria monocytogenes (ATCC 19117), Methicillin Resistant Staphylococcus aureus (MRSA)(ATCC 33592), Multi-drug Resistant (MDR) Acinetobacter baumannii (ATCC 19606), Neisseria gonorrhoeae (ATCC 43069), Proteus mirabilis (ATCC 9240), Proteus vulgaris (ATCC 9920), Salmonella enterica (ATCC 10708), Salmonella enterica subspecies enterica serovar Pullorum (ATCC 19945), Salmonella enterica subspecies enterica serovar Typhimurium (ATCC 23564), Serratia marcescens (ATCC 14756), Shigella flexneri serotype 2B (ATCC 12022), Shigella sonnei (ATCC 25931), Streptococcus pneumoniae (ATCC 6305), Streptococcus pyogenes (ATCC 19615), Vancomycin Resistant Enterococcus faecalis (VRE) (ATCC 51575), Vibrio cholerae (ATCC 14035), and Yersinia enterocolitica (ATCC 23715).}

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.

*Virucidal Activity on Hard, Non-Porous Surfaces:

Use (Product) (Product Name) at 2 fl. oz. per gallon of water (1020 ppm active). Apply with a mop, cloth, trigger sprayer, or other coarse spray device. Treated surfaces must remain visibly wet for 10 minutes. Wipe off with a clean cloth or allow to air dry. Do not breathe spray or mist. When used as directed, this product is effective against Hepatitis C Virus (HCV)(Bovine Viral Diarrhea as a surrogate), Hepatitis B Virus (HBV)(Duck Hepatitis B virus as a surrogate), HIV-1 (AIDS Virus)(Strain HTLV-III_B), Herpes Simplex Virus Type 1 (ATCC VR-733, Strain F(1)), Herpes Simplex Virus Type 2 (ATCC VR-734, Strain G), Human Coronavirus (ATCC VR-740, Strain 299E), Human Rotavirus (ATCC VR-2018, Strain WA), Influenza A Virus (ATCC VR-544, Strain A), Influenza B Virus (ATCC VR-823, Strain B) and Vaccinia virus (ATCC VR-119, Strain WR).

*Animal Premise Virucidal Activity on Hard, Non-Porous Surfaces:

Remove all animals and feeds from areas to be treated, including animal transportation vehicles, and enclosures. Remove all litter, droppings, and manure from floors, walls and surfaces of barns, pens, stalls, chutes, and other surfaces of facilities and fixtures occupied or traversed by poultry or other animals.

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Empty (or cover) all troughs, racks, and other feeding and watering appliances. Thoroughly clean surfaces with soap or detergent and rinse with water.

Use (Product) (Product Name) at 2 fl. oz. per gallon of water (1020 ppm active). Apply with a mop, cloth, trigger sprayer, or other coarse spray device. Treated surfaces must remain visibly wet for 10 minutes. Wipe off with a clean cloth or allow to air dry. Do not breathe spray or mist. When used as directed, this product is effective against {insert selected pathogens from the efficacy table} or {Avian Influenza A (H3N2) Reassortant virus (ATCC VR-2072, Strain A/Washington/897/80 x A/Mallard/NewYork/6750/78), Canine Coronavirus (ATCC VR-809, Strain 1-71), Canine Distemper virus (ATCC VR-128, Strain Lederle), Feline Picornavirus (ATCC VR-649, Strain FRV (17FRV)), Infectious Bovine Rhinotracheitis (ATCC VR-188, Strain LA), Porcine Respiratory and Reproductive Syndrome (PRRS) virus (Strain NVSL), Pseudorabies virus (ATCC VR-135, Strain Aujeszky), and Transmissible Gastroenteritis virus (TGE)(obtained from the University of Minnesota).} Ventilate buildings, coops, and other closed spaces. Do not house animals, poultry, livestock or employ equipment until treatment has been absorbed, set, or dried. Thoroughly scrub all treated feed racks, troughs, automatic feeders, fountains and waters, which can contact food or water with soap or detergent, and rinse with potable water before reuse.

*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 visibly wet for 10 minutes.

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 Control Mildew:

Use (Product) (Product Name) at 2 fl. oz. per gallon of water (1020 ppm active). Apply with a mop, cloth, trigger sprayer, or other coarse spray device. Allow to air dry. Do not breathe spray or mist. Repeat application once a week or when mildew growth reappears. When used as directed this product is an effective mildewstat against Aspergillus niger.

Non-Food Contact Sanitizing on Hard, Non-Porous Surfaces:

Use (Product) (Product Name) at 2 fl. oz. per gallon of water. Apply with a mop, cloth, trigger sprayer, or other coarse spray device. Treated surface must remain visibly wet for (2 minutes or 120 seconds). Visibly soiled surfaces must be precleaned prior to sanitizing. Wipe off with a clean cloth or allow to air dry. Do not breathe spray or mist. When used as directed for sanitization this product is effective against Enterobacter aerogenes and Staphylococcus aureus.

Prepare fresh solution daily or more often if solution becomes visibly dirty, diluted, or soiled.

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To Sanitize Soft Surfaces:

When used according to these directions, (Product) (Product Name) is an effective soft surface sanitizer for spot treatment of precleaned soft surfaces. Use (Product) (Product Name) at 2 fl. oz. per gallon of water. Apply with a trigger sprayer, or other coarse spray device. Precleaning is required prior to sanitizing soft, porous surfaces². Hold sprayer 6" – 8" from surface and spray until fabric is wet. Fabric must remain visibly wet for 10 minutes. Allow fabric to air dry. Reapply, as necessary. When used as directed this product is effective against Enterobacter aerogenes⁴ and Staphylococcus aureus⁵.

Cleaning and Deodorizing Hard, Non-Porous Surfaces:

Use (Product) (Product Name) at 2 fl. oz. per gallon of water. Apply with a mop, cloth, trigger sprayer, or other coarse spray device. Wipe off with a clean cloth or allow to air dry. Do not breathe spray or mist.

One-Step¹ Cleaning and Disinfecting Toilet Bowls and Urinals

- 1. Remove any visible soil prior to treatment.
- 2. Apply 2 fl. oz. of (Product Name) (Product) to the toilet bowl water.
- 3. Swab the exposed surfaces including under the rim.
- 4. Allow to remain visibly wet on surfaces for 10 minutes.
- 5. Flush toilet or urinal and rinse swab mop thoroughly.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

DANGER. Corrosive. Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through the skin. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Wear protective eye wear (goggles/face shield), rubber gloves and protective clothing (coveralls over long-sleeved shirt and long pants; socks and chemical resistant footwear; chemical resistant gloves.), and a NIOSH-approved particulate filtering facepiece respirator with any N, R or P filter; OR a NIOSH-approved elastomeric particulate respirator with any N, R, or P filter; OR a NIOSH-approved powdered air purifying respirator with HE filters. Do not breathe spray or mist. Wash thoroughly with soap and water after handling and before eating, drinking, smoking tobacco, chewing gum, or using the toilet. Remove contaminated clothing and wash clothing before reuse.

(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.

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(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 Disposal: Nonrefillable container. Do not reuse or refill container. Triple rinse as follows: Fill container ¼ 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 Disposal: Nonrefillable container. Do not reuse or refill container. Triple rinse as follows: Fill container ½ 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 this 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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Secondary Container Label for Diluted Product

[PROFECT Neutral 64] [Product Name] [Daily Cleaner Disinfectant]

User Prepared Ready-To-Use Solution

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

ACTIVE INGREDIENTS IN CONCENTRATED PRODUCT:

The product in this container is diluted as directed on the pesticide product label.

Follow the directions for use on the pesticide label when applying this product. The product in this container with pesticide is not for sale and is for storage and use.

(Optional phrases)

Read the safety data sheet before using.

See first aid statement on pesticide product label.

(*Note to Reviewer:* In accordance with 40 CFR 156.68(d), all first aid statements, as prescribed, will appear on the front panel of the product label)

KEEP OUT OF REACH OF CHILDREN

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PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

DANGER. Corrosive. Causes irreversible eye damage and skin burns. May be fatal if inhaled. Harmful if absorbed through the skin. Harmful if swallowed. Do not get in eyes, on skin or on clothing Wear protective eye wear (goggles/face shield), rubber gloves and protective clothing (coveralls over long-sleeved shirt and long pants; socks and chemical resistant footwear; chemical resistant gloves.), and a NIOSH-approved particulate filtering facepiece respirator with any N, R or P filter; OR a NIOSH-approved elastomeric particulate respirator with any N, R, or P filter; OR a NIOSH-approved powdered air purifying respirator with HE filters. Do not breathe spray or mist. Wash thoroughly with soap and water after handling and before eating, drinking, smoking tobacco, chewing gum, or using the toilet. Remove contaminated clothing and wash clothing before reuse.

FIRST AID				
If in eyes:	-Hold eye open and rinse slowly and gently with water for 15-20 minutesRemove contact lenses, if present, after the first 5 minutes, then continue rinsing eyeCall a poison control center or doctor for treatment advice.			
If on skin:	-Take off contaminated clothingRinse skin immediately with plenty of water for 15-20 minutesCall a poison control center or doctor for treatment advice.			
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 -Call a poison control center or doctor for further treatment advice. 			
If swallowed:	Call a poison control center or doctor immediately for treatment advice. -Have person sip a glass of water if able to swallow. -Do not induce vomiting unless told to do so by a poison control center or doctor. -Do not give anything by mouth to an unconscious person.			
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.

NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage.

MEDICAL EMERGENCY: 888-314-6171

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