

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

October 15, 2020

Lisa M. Amadio Principal Regulatory Consultant Agent for PureShield 5500 Military Trail, Suite 22-314 Jupiter, FL 33458

Subject: Label Amendment – To update label language Product Name: Bio-Protect DP EPA Registration Number: 87583-5 Application Date: February 28, 2020 Decision Number: 563236

Dear Ms. Amadio:

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. THE FOLLOWING HIGHLIGHTED SENTENCE IS ONLY TO BE USED FOR AMENDMENTS THAT ADDRESS RISK ISSUES, AS DISCUSSED WITH MANAGER OR PM: The next label printing of this product must use this labeling unless subsequent changes have been approved. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) 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. 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 Emilia Oiguenblik by phone at 703 347 0199, or via email at <u>Oiguenblik.emilia@epa.gov</u> or Eric Miederhoff by phone at 703 347 8028, or via email at <u>Miederhoff.eric@epa.gov</u>

E. Michelaff.

Eric Miederhoff Product Manager 31 Regulatory Management Branch I Antimicrobials Division (7510P) Office of Pesticide Programs

Enclosure; Stamped label

BIO-PROTECT DP

DISINFECTANT and ANTIMICROBIAL AGENT A Silicone Quaternary Ammonium Salt **A C C E P T E D** 10/15/2020

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No.

^{9. NO.} 87583-5

CTIVE INGREDIENTS: 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride	35.60%			
n-alkyl (50% C14, 40% C12, 10% C16) dimethyl benzyl ammonium chloride.	6.40%			
Octyl decyl dimethyl ammonium chloride	4.80%			
Didecyl dimethyl ammonium chloride	2.88%			
Dioctyl dimethyl ammonium chloride	1.92%			
THER INGREDIENTS:	48.40%			
DTAL:	100.00			
Contains over 6% mathematic				

Contains over 6% methanol

KEEP OUT OF REACH OF CHILDREN

FIRST AID

In case of emergency, call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15 - 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

IF ON SKIN: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 - 20 minutes.

IF SWALLOWED: 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. Call a poison control center or doctor immediately 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.

PureShield, Inc. 230 S. Broad St., Suite 1201 Philadelphia, PA 19102

EPA Reg. No. 87583-5 EPA Est. No.

Lot No.:

Net Contents:

(Note to Reviewer: Parenthesis () indicates optional language.)

MARKETING CLAIMS (Optional):

BIO-PROTECT DP is an effective disinfectant against Salmonella choleraesuis, Staphylococcus aureus, and Pseudomonas aeruginosa.

BIO-PROTECT DP is effective against odor causing bacteria, bacteria that cause staining and discoloration, fungi (mold and mildew), and algae.

BIO-PROTECT DP controls odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew), *Salmonella choleraesuis, Staphylococcus aureus,* and *Pseudomonas aeruginosa* (spray application only).

BIO-PROTECT DP may be used for treatment of the following hard nonporous surfaces to impart disinfection (*Salmonella choleraesuis, Staphylococcus aureus, and Pseudomonas aeruginosa*), bacteriostatic/ fungistatic/algaestatic, and deodorizing activity: Tubs, glazed tiles, vanity tops, shower stalls (areas), sinks, washable walls, vinyl wall paper for non-food contact, floors, window sills, cabinets, garbage cans, exterior surfaces of appliances and refrigerators.

BIO-PROTECT DP, an antimicrobial agent, disinfects hard, non-porous surfaces and kills Salmonella choleraesuis, Staphylococcus aureus, and Pseudomonas aeruginosa in hospitals and other medical facilities.

Controls Mold (and) (Mildew) Odor Protector Odor Inhibitor Concentrate (Concentrated) Bactericidal Deodorizes (Deodorizer) Disinfects (Disinfectant) For Hospital, Institutional, Industrial and Home Use A Disinfectant for use in Hospitals Hospital Disinfectant

For use in homes, offices, and institutions (schools, daycare centers, churches, correctional facilities)

For use in homes, offices, institutions (schools, universities, daycare centers, churches, correctional facilities), medical related facilities (laundries, clinics, dental offices, health care facilities, hospitals, medical offices, nursing homes), public facilities (airports, transportation terminals, bars, convenience stores, athletic facilities, locker rooms, barber shops, salons, hotels, public restrooms, playgrounds), transportation (airplanes, ambulances, boats, buses, campers, cars, emergency vehicles, ships, taxis, trains, trucks) and animal facilities (animal laboratories, farms, kennels, pet shops, zoos).

BIO-PROTECT DP can be used on:

- coils and drain pans of air conditioning and refrigeration equipment and heat pumps. as a broad-spectrum disinfectant in Ultrasonic Baths (Ultrasonic cleaning units).
- for cleaning and disinfecting of ultrasound transducers, probes, mammography compressor plates and other hard nonporous surfaces. Will not cause swelling of transducer membrane or harm compressor plates.
- Veterinary Practices, Animal Care, Animal Laboratory and Farm Premise applications.
- for swine premise sanitation on/in hauling equipment, loading equipment, farrowing barns and areas, nursery, blocks, creep areas.
- for farm premise sanitations on floors, walls, forks, shovels, scrapers and other hard, non-porous surfaces in barns, pens, stalls, and other facilities and fixtures occupied or traversed by animals.
- to clean and disinfect (manicure)(nail)(salon)(barber) tools and instruments: combs, brushes, scissors, blades, and manicure instruments.
- on (to clean and disinfect) nonporous athletic mates, wrestling mats, gymnastic mats, exercise equipment and training tables.
- on (to clean and disinfect) wrestling headgear, boxing headgear, protective headgear, athletic helmets, hard hats, half mask respirators, full face breathing apparatus, gas masks, goggles, spectacles, face shields, hearing protectors, and earmuffs. Rinse all equipment that comes in prolonged contact with skin with warm water and allow to air dry before reuse.

BIO-PROTECT DP is an antimicrobial agent effective against microorganisms that cause offensive odors on hard, non-porous surfaces.

BIO-PROTECT DP is an antimicrobial agent effective against odor-causing bacteria in the kitchen and bathroom.

BIO-PROTECT DP is an antimicrobial agent that disinfects hard, non-porous surfaces and kills Salmonella enterica and Staphylococcus aureus.

BIO-PROTECT DP provides an invisible barrier to inhibit the growth of odor-causing bacteria.

BIO-PROTECT DP provides an invisible barrier to inhibit the growth of bacteria which cause staining and discoloration.

BIO-PROTECT DP prevents deterioration caused by bacteria.

BIO-PROTECT DP resists development of microbial odors.

BIO-PROTECT DP resists development of stains and discoloration due to bacteria.

DIRECTIONS FOR USE

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

Allow treated areas and surfaces to dry before use. Remove children and pets from treated area until completely dry. Clean surfaces prior to application.

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 can be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection. OR

This product is not for use on medical device surfaces.

Do not use on food contact surfaces.

	Pest Controlled	Dilution Rate	Method of Application
Tubs, glazed tiles, vanity	Odor-causing bacteria,	0.5 oz./gallon	SPRAY: Dilute BIO-
tops, shower stalls (areas),	bacteria which cause		PROTECT DP in water; mix
sinks, washable walls, vinyl	staining and discoloration,		well. Using a trigger pump
wallpaper for non-food	mold and mildew		sprayer, spray the
contact, floors, window	Salmonella enterica and		entire surface area 4"-6"
sills, cabinets, garbage	Staphylococcus aureus		from the surface making
cans, exterior surfaces of			sure the surface is
appliances and			completely covered.
refrigerators			For Disinfecting: Let stand
			for 10 minutes, then wipe
			surface dry.

Application Instructions:

Dilute 2.0 fl. oz. in one gallon of water (1 gallon of BIO-PROTECT DP per 64 gallons of water).

For spray application, dilute BIO-PROTECT DP in water and mix well. Using a trigger pump sprayer, spray the entire surface area 4"- 6" from the surface making sure the surface is completely covered. The surface should remain visibly wet for 10 minutes then wipe surface dry.

For mop and bucket application, dilute BIO-PROTECT DP in a bucket and mix well. Mop area thoroughly.

For soaking application, dilute BIO-PROTECT DP in a container and mix well. Soak item for 10 minutes then wipe dry.

Laundry Bacteriostat: (Not for use in the state of California) Soiled and contaminated fabrics are of major housekeeping concern in hospitals, institutions, hotels, restaurants and schools. BIO-PROTECT DP provides cleaning properties against odor-causing bacteria for laundered items such as diapers, hospital and institutional linens, and athletic clothing. Use 0.6 ounces BIO-PROTECT DP per 100 pounds of dry fabric. Dilute the product in one to two gallons of water and add to the wash wheel in the final rinse. Retreat fabric after each washing. Dry fabric prior to use.

STORAGE AND DISPOSAL

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

For Household/residential use packages:

Pesticide Storage: Store in original, tightly-closed containers in an area inaccessible to children or persons unfamiliar with its use. Keep tightly closed until ready to use. Reclose tightly after each use. Store in original containers at or below 25 C (77F) and above 0 C (32F). Non-refillable container. Do not reuse or refill this container. Wrap container and put in trash or offer for recycling if available.

For Industrial and Commercial Use Packages:

Small Packages (1 gallon or less):

Pesticide Storage: Store in original, tightly-closed container in an area inaccessible to children or persons unfamiliar with its use and away from food or feed. Keep tightly closed until ready to use. Store in original, unopened containers at or below 25 C (77F). This product has a minimum shelf life of 12 months after date of shipment.

Pesticide Disposal: Pesticide wastes are acutely 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 the 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: Non-refillable container. Do not reuse or refill this container. Triple rinse container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

Pails, Drums and IBC's (containers greater than one gallon)

Pesticide Storage: Store in original, tightly-closed container in an area inaccessible to children or persons unfamiliar with its use and away from food or feed. Keep tightly closed until ready to use. Store in original, unopened containers at or below 25 C (77F). This product has a minimum shelf life of 12 months after date of shipment.

Pesticide Disposal: Pesticide wastes are acutely 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 the label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Containers Handling: REFILLABLE CONTAINER. Refill this container with this product only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents into application equipment or a mix tank. Fill container ¼ full with water. Replace and tighten closure. Tip container in its side and roll it back and forth, ensuring at least one complete revolutions, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Turn the container or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or mix tank or collect rinsate for later use of disposal. Insert pressure rinsing nozzle in the side of the container and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to the flow begins to drip.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive: Causes skin burns. Methanol may cause blindness. Causes irreversible eye damage. Fatal if swallowed. Harmful if inhaled. Do not get in eyes, on skin, or on clothing. Avoid contact with skin. Avoid breathing spray mist. Wear protective eyewear (goggles or face shield) and protective clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing and wash before reuse.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE. Do not use or store near heat or open flame. De-activation of BIO-PROTECT DP can be achieved by the addition of anionic surfactant (such as soap, sulfonates, sulfates) in quantity equivalent to that of BIO-PROTECT DP.

ENVIRONMENTAL HAZARDS

(If container is equal to or greater than 5 gal., the following statement must appear on the label.)

This pesticide is toxic to fish, aquatic invertebrates, oysters, and shrimp. 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.

(If container is less than 5 gal., use the following as an alternate to the above statement.) This pesticide is toxic to fish, aquatic invertebrates, oysters, and shrimp.

De-activation may be required during clean up if a spill occurs. De-activation of BIO-PROTECT DP can be achieved by the addition of anionic surfactant (such as soap, sulfonates, sulfates) in quantity equivalent to that of BIO-PROTECT DP.