



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

63761-11

Date of Issuance:

9/2/22

NOTICE OF PESTICIDE:

Registration
 Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

ProvaStride

Name and Address of Registrant (include ZIP Code):

Levi Howell
Regulatory Affairs Manager
Sterilex LLC, D/B/A Sterilex
Electronic Transmittal: levi.howell@sterilex.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 (FIFRA).

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/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.
2. Be aware that proposed data requirements have been identified in a Work Plan. For more information on these proposed data requirements, you may contact the Reevaluation Team

Signature of Approving Official:

Jacqueline Hardy
Jacqueline Hardy, Branch Chief
Regulatory Management Branch 2
Antimicrobials Division (7510P)

Date:

9/2/22

Leader (Team 36): <http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division>

3. 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.
4. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, “EPA Reg. No. 63761-11.”
5. Submit one copy of the final printed label for the record before you release the product for shipment.

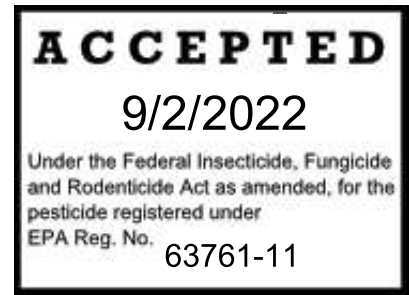
Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the Agency. See FIFRA section 2(p)(2). If the website is false or misleading, the product would be misbranded and unlawful to 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.

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 11/5/2021
- Alternate CSF #A dated 10/18/2021
- Alternate CSF #B dated 11/5/2021
- Alternate CSF #C dated 11/5/2021
-

If you have any questions, please contact Jamie Gobreski by phone at 202-566-0748 or via email at gobreski.jamie@epa.gov.

Enclosure Stamped Label



ProvaStride™

{Alternate Brand Names:}
[FortiStride™]

Active Ingredients:

Sodium Carbonate Peroxyhydrate..... 6.38%
Tetraacetythylenediamine..... 3.55%

Inert Ingredients..... 90.07%

TOTAL..... 100.0%

KEEP OUT OF THE REACH OF CHILDREN
CAUTION

FIRST AID

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. Call a poison control center or doctor for 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.

General Information: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For medical emergencies, call the poison control center at 1-800-222-1222. For general information on this product, call [800-511-1659] [may include hours of service], or contact the National Pesticides Information Center (NPIC) at 1-800-858-7378, Monday through Friday, 8 AM to 12 PM PST, or at <http://npic.orst.edu>.

[See back [side] [other] [panel] [box] label for [additional] [complete] directions for use [and] [precautionary statements]]

Manufactured for
STERILEX

111 Lake Front Drive
Hunt Valley, MD

Phone: (443) 541-8800

Phone (Toll-Free): 1-800-511-1659

Made in USA

EPA Reg. No. _____

EPA Est. No. _____

[NET CONTENTS: _____]

[Item Code: _____]

[LOT NUMBER: _____][BATCH NUMBER: _____] (*NOTE TO REVIEWER – this may be printed on container itself)

[NOT FOR SALE OR USE AFTER: _____] (*NOTE TO REVIEWER – this may be printed on container itself)

[Expiration Date][Exp. Date] [Expiry Date] (*NOTE TO REVIEWER – this may be printed on container itself)

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Harmful if swallowed.

Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

***DIRECTIONS FOR USE**

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

SANITIZING OF HARD, NON-POROUS, INANIMATE, NON-FOOD CONTACT SURFACES

Dry product not for direct application to food contact surfaces and equipment. ProvaStride eliminates 99.9% of the following bacteria in 5 minutes on hard, non-porous, inanimate, non-food contact surfaces according to the Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces:

Klebsiella aerogenes (ATCC 13048)

Staphylococcus aureus (ATCC 6538)

Escherichia coli (ATCC 11229)

Listeria monocytogenes (ATCC 15313)

Salmonella enterica (Salmonella) (ATCC 10708)

Salmonella enterica serovar Enteritidis (ATCC 13076)

Cronobacter sakazakii (ATCC 29004)

Campylobacter jejuni (ATCC 29428)

APPLICATION INSTRUCTIONS FOR USE AS A [FLOOR], [FLOOR SURFACE] [BOOT] SANITIZER

After cleaning and sanitizing equipment, [use a spreader to] apply [sprinkle] [spread] ProvaStride evenly to the floor [loading bay] [or] [doorway] surface at a minimum use rate of 2.0 oz [57 grams] per 100 square feet. Re-apply powder as needed to ensure the concentration maintains a minimum use rate of 2.0 oz [57 grams] per 100 square feet of [floor] surface. If moisture amount exceeds 0.97 fl. oz. per square foot, the minimum spread rate of ProvaStride must increase to support a minimum concentration of 2.8 oz. ProvaStride per gallon of water.

APPLICATION INSTRUCTIONS FOR USE AS A SANITIZER IN A FLOOR MAT, [FOOT PAN]

[Apply] [Sprinkle] [Spread] ProvaStride evenly to the foot pan [floor mat] [or] [containment device]. Ensure complete coverage of the bottom of the floor mat [foot pan] [or] [containment device] at a minimum use rate of 2.0 oz [57 grams] per 100 square feet. Re-apply powder as needed to ensure the concentration maintains a minimum use rate of 2.0 oz. [57 grams] per 100 square feet of surface containing no more than fl. oz. [29 ml] of moisture per square foot. If moisture amount exceeds 0.97 fl. oz. per square foot, the minimum spread rate of ProvaStride must increase to support a minimum concentration of 2.8 oz. ProvaStride per gallon of water.

APPLICATION INSTRUCTIONS FOR USE IN HIGH TRAFFIC AREAS/FORK LIFT ROUTES

After cleaning and sanitizing equipment, [use a spreader to] apply [sprinkle] [spread] ProvaStride evenly to the [floor] surface of high traffic areas [fork life route] [doorway] at a minimum use rate of 2.0 oz [57 grams] per 100 square feet. Re-apply powder as needed to ensure the concentration maintains a minimum use rate of 2.0 oz [57 grams] per 100 square feet of [floor] surface. If moisture amount exceeds 0.97 fl. oz. per square foot, the minimum spread rate of ProvaStride must increase to support a minimum concentration of 2.8 oz. ProvaStride per gallon of water.

APPLICATION INSTRUCTIONS FOR USE IN AND AROUND DRAINS

After cleaning and sanitizing equipment, apply [sprinkle] [spread] ProvaStride evenly to the [drain] surface at a minimum use rate of 2.0 oz [57 grams] per 100 square feet. Re-apply powder as needed to ensure the concentration maintains a minimum use rate of 2.0 oz [57 grams] per 100 square feet of [floor] surface. If moisture amount exceeds 0.97 fl. oz. per square foot, the minimum spread rate of ProvaStride must increase to support a minimum concentration of 2.8 oz. ProvaStride per gallon of water.

GENERAL DISINFECTION AND CLEANING DIRECTIONS FOR HARD NON-POROUS SURFACES

ProvaStride is a [broad spectrum] [hospital use] disinfectant when applied at a rate of 13.4 oz – 17.4 oz ProvaStride per gallon of water [100 – 130 grams ProvaStride per liter of water] (or equivalent use dilution). ProvaStride was tested according to the AOAC Use-Dilution Test Method modified in the presence of 400 ppm hard water and 5% soil contamination on the following organisms:

Pseudomonas aeruginosa (Pseudomonas) (ATCC# 15442)
Staphylococcus aureus (Staph) (ATCC# 6538)
Salmonella enterica (Salmonella) (ATCC# 10708)

APPLICATION INSTRUCTIONS

Remove visible soil from all areas, articles and surfaces to be disinfected using a pre-clean, pre-flush, or pre-scrape and, if necessary, presoak. Mix of 13.4 oz – 17.4 oz ProvaStride per gallon of water [100 – 130 grams ProvaStride per liter of water]. Thoroughly wet surfaces by pouring, wiping, brushing, scrubbing or spraying with a coarse trigger sprayer, sponging, pumping it through the system, drawing it through the system or mopping. Allow surfaces to remain visibly wet for at least 10 minutes. Do not breathe spray. Rinse all food contact surfaces thoroughly with a potable water rinse.

Viruses

ProvaStride is effective against the following viruses on hard, non-porous surfaces at a rate of 1.66 – 2.08 lbs per gallon of water [200 – 250 grams per liter of water], with a 90 second contact time in the presence of 400 ppm hard water:

Avian influenza A (H5N1) Virus, Strain NIBRG-14
Porcine Epidemic Diarrhea Virus, Source: Iowa State University
Feline calicivirus, Strain F-9

APPLICATION INSTRUCTIONS

Remove visible soil from all areas, articles and surfaces to be disinfected using a pre-clean, pre-flush, or pre-scrape and, if necessary, presoak. Mix of 1.66 lb – 2.08 lb ProvaStride per gallon of water [200 – 250 grams ProvaStride per liter of water]. Thoroughly wet surfaces by pouring, wiping, brushing, scrubbing or spraying with a coarse trigger sprayer, sponging, pumping it through the system, drawing it through the system or mopping. Allow surfaces to remain visibly wet for at least 1 minute and 30 seconds. Do not breathe spray. Rinse all surfaces thoroughly with a potable water rinse.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Keep out of children's reach. Store in a cool, dry location away from direct sunlight. Keep containers tightly sealed.

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 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:

(NOTE TO REVIEWER: The following language is for the nonrefillable pouches having a capacity of 10 pounds or less)

Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. Completely empty pouch into application equipment by shaking and tapping sides and bottom to loosen clinging particles. If not emptied in this manner, the pouch may be considered an acute hazardous waste and must be disposed in accordance with local, state and federal regulations. When completely empty discard packet in trash.

(NOTE TO REVIEWER: The following language is for nonrefillable fiber drum with plastic liner bag containers having a capacity greater than 5 pounds)

Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. Completely

empty bag into application equipment by shaking and tapping sides and bottom to loosen clinging particles. If not emptied in this manner, the bag may be considered an acute hazardous waste and must be disposed in accordance with local, state and federal regulations. When completely empty, offer for recycling if available or dispose of bag in a sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

(NOTE TO REVIEWER: The following language is for nonrefillable rigid plastic containers with plastic liner bag containers having a capacity of 10 pounds or less)

Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment by shaking and tapping sides and bottom to loosen clinging particles. If not emptied in this manner, the bag may be considered an acute hazardous waste and must be disposed in accordance with local, state and federal regulations. When completely empty, offer for recycling if available or dispose of bag in a sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

(NOTE TO REVIEWER: The following language is optional for nonrefillable rigid plastic containers having a capacity of 10 pounds or more when “or pressure rinse” appears in the Container Disposal statement)

Nonrefillable container. [Triple rinse] [or] [pressure rinse] container (or equivalent) promptly after emptying. [Pressure rinse as follows: 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 drip. Dispose of rinsate as pesticide waste. Do not reuse or refill this container. Offer for recycling, if available or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. If rinsate cannot be used, follow pesticide disposal instructions. If not triple rinsed these containers are acute hazardous wastes and must be disposed in accordance with local, state and federal regulations.]

[Triple rinse as follows: Fill the container ¼ full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Dispose of rinsate as pesticide waste. If rinsate cannot be used, follow pesticide disposal instructions. Offer for recycling, if available or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. If not triple rinsed these containers are acute hazardous wastes and must be disposed in accordance with local, state and federal regulations.]

Optional Marketing Claims

[*EFFECTIVE AGAINST][*KILLS]:

Klebsiella aerogenes

Staphylococcus aureus

Escherichia coli

Listeria monocytogenes

Salmonella enterica

Salmonella enterica serovar Enteritidis

Cronobacter sakazakii

Campylobacter jejuni

Pseudomonas aeruginosa

Staphylococcus aureus

Salmonella enterica

Avian influenza A

PED Virus

Feline calicivirus

[*KILLS]

Klebsiella aerogenes

Staphylococcus aureus

Escherichia coli

Listeria monocytogenes

Salmonella enterica

Cronobacter sakazakii

Campylobacter jejuni

Pseudomonas aeruginosa

Staphylococcus aureus

Salmonella enterica

Salmonella enterica serovar Enteritidis

[*INACTIVATES][*VIRICIDAL ACTIVITY AGAINST][*KILLS]

Avian influenza A Virus

PED Virus

Feline calicivirus

{*NOTE TO REVIEWER: Refer to Directions for Use for application information and instructions.}

- [ProvaStride is a powdered [dry] [floor][entryway] non food contact surface sanitizer specifically designed to improve sanitation on hard, nonporous surfaces where conditions favor microorganism growth and cause sanitation concern.]
- [[BASED OFF OF] [BASED ON] [INCLUDING] [INCLUDES] [USING] [POWERED BY] [PATENT PENDING] PurOxidate™ Technology]
- [ProvaStride is for use as a dry non-food contact surface sanitizer, or as a liquid disinfectant, on hard, nonporous surfaces in a variety of premises, including but not limited to, Federally Inspected Food Processing Facilities, Federally Inspected Meat And Poultry Plants, Dairies, Wineries, Breweries, Beverage Manufacturing Facilities, FDA Inspected Facilities USDA Inspected Facilities, Bakeries, Dairy Farms, Swine Farms, Poultry And Turkey Farms, Farm Premises, Hatcheries, Refrigerated Trucks¹, Kennels, Farrowing Rooms, Wean To Finish, Ante Rooms, Transportation Vehicles, Livestock Vehicle Entries, Live Production Offices, Feed Mills, Live Haul Facilities, Biosecurity Perimeters, Cattle Pens, Receiving Yards, Pet Animal Quarters, Zoos, Pet Shops, Animal Laboratories, Veterinary Facilities, Animal Care Facilities, Vivariums, Animal Research Facilities, Pet Shops, Veterinary Diagnostic Laboratories, Food Service Facilities, Kitchens, Grocery Stores, Deli Areas, Drains, Refrigerated Trucks¹, Coolers¹, Freezers¹, Trash Docks, Loading Bays, Facility Entryways, Doorways, High Traffic Passages, Oven Entrances, Wheels, Forklifts, Floor Scrubber, Warehouses, Dairy Brick, [and] Hemp Facilities.

¹Allow surfaces to come to room temperature prior to treatment

- [Dry [Powdered] Non-Food Contact Surface Sanitizer]
- [Floor [Footpan] [Boot] [Floormat] [Mat] [Drain surface] Dry Floor Sanitizer]
- [Powder [Dry Product] For Use in Non-Food Contact Areas of Dairy, Food, Meat, and Beverage Processing Facilities]
- [Dry [Powdered] Nonfood Hard Surface Animal Premise Sanitizer]
- [Dry floor sanitizing and deodorizing performance]
- [[Broad Spectrum] [Hospital use] Disinfectant]
- [Cleaner]
- [6 log reduction [of] [*Pseudomonas aeruginosa* (*Pseudomonas*) [(ATCC# 15442)]] [*Staphylococcus aureus* (*Staph*) [(ATCC# 6538)]] [*Salmonella enterica* (*Salmonella*) [(ATCC# 10708)]] when used as a liquid disinfectant on floor surfaces]
- [3 log reduction [of] [*Klebsiella aerogenes* [(ATCC 13048)]] [*Staphylococcus aureus* [(ATCC 6538)]] [*Escherichia coli* [(ATCC 11229)]] [*Listeria monocytogenes* [(ATCC 15313)]] [*Salmonella enterica* (*Salmonella*) [(ATCC 10708)]] [[*Salmonella enterica* serovar Enteritidis][S. Enteritidis][(ATCC 13076)]] [*Cronobacter sakazakii* [(ATCC 29004)]] [*Campylobacter jejuni* [(ATCC 29428)]] when used as dry powder on floor surfaces] {Note to reviewer: Genus for each organism may be written as first letter only on the market label}
- [The lowest required use rate of any dry floor sanitizer on the market]
- [Dry[powdered][solids][granular]floor[foot pan] sanitizer]
- [Demonstrated to provide [6-log] microbial reduction when used as a disinfectant]
- [Low moisture sanitization]
- [Controls microbial growth in areas where condensation forms]
- [Inhibition of mold growth]
- [Patent pending]
- [No pre-dilution necessary]
- [Formulated to kill up to 99.9% of bacteria when used as a dry nonfood contact sanitizer and [99.9999% of bacteria when used as a liquid disinfectant]]
- [For use in low moisture or dry processing plants]
- [For use in low moisture environments]
- [Support low-moisture sanitation efforts]
- [No need for external drain]
- [Apply as solid nonfood contact [powder] floor[foot pan][floor mat][boot][drain surface][surface][animal premise] sanitizer]
- [[Solid][floor][foot pan][floor mat][boot][drain surface][surface][animal premise] nonfood contact sanitizer[powder]]
- [Stain removal]
- [Non-staining]
- [Take your [biosecurity][sanitation] programs to the next level]

- [Controls odors]
- [Ideal for routinely[chronically] wet[moist] areas]
- [Helps remove sticky resins]
- [Clings to the surface of foot wear]
- [Clings to the surface of wheels]
- [Doorway intervention]
- [Replenish[daily][weekly][monthly]] as needed
- [Trusted by food processors world-wide]
- [Reduces environmental bacteria on hard, nonporous surfaces]

[Safety]

- [Aids in reduction of slips, trips and falls]
- [Non-Slip]
- [Enhances traction]
- [Does not off gas]
- [Non-flammable]
- [No fire hazard classification]
- [Does not produce [or contain] VOCs]
- [Non-irritating]
- [Low-dust]
- [Non-volatile]
- [Non-dusty formulation]
- [Non-flammable formulation [with < 10% Sodium Percarbonate]]]

[Sustainability]

- [Waste water friendly]
- [Compatible with wastewater systems]
- [Reduced water consumption]
- [Reduces the amount of water needed during cleaning]]

[Ease of Use]

- [Free-flowing powder]
- [Easy to dispense]
- [Product does not freeze]
- [Does not require titration]
- [Easy to measure/verify active ingredient levels]
- [Less frequent replacement]
- [Does not require drainage]]

[Compliance]

- [Aids in environmental control]
- [Aids in regulatory compliance]
- [Aids in risk based food safety programs]
- [Can be used as preventive control or corrective action (FSMA)]
- [Approved for inclusion in food safety plans]
- [Not regulated for transport]
- [Not regulated for DOT]
- [Formula designed to prevent drifting]
- [Easily distinguishable from food ingredients [due to color]]]
- [Product contains a [blue] color for easy identification]

[Compatibility]

- [Compatible with [common] floor surfaces]]

Emerging Viral Pathogen Claims

[ProvaStride][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.

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

- Large non-enveloped viruses
- Enveloped viruses

Emerging Viral Pathogen Claim – Terms of Registration

Emerging Viral Pathogen Claim	Supporting Virus(es)
Large, Non-Enveloped Virus Families	Feline calicivirus
Enveloped Virus Families	Feline calicivirus

- [ProvaStride][This product] has demonstrated effectiveness against viruses similar to [insert name of emerging virus(es)] on hard, non-porous surfaces. Therefore, [ProvaStride][This product] can be used against [insert name of emerging virus(es)] when used in accordance with the directions for use against [name of supporting virus(es)] on hard, non-porous surfaces. Refer to the [insert CDC or OIE] website at [insert pathogen-specific website address] for additional information.
- [Insert name of illness/outbreak] is caused by [insert name of emerging virus(es)]. [ProvaStride][This product] kills similar viruses and therefore can be used against [insert name of emerging virus(es)] when used in accordance with the directions for use against [name of supporting virus(es)] on hard, non-porous surfaces. Refer to [insert CDC or OIE] website at [insert pathogen-specific website address] for additional information.