



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 8, 2019

Dr. Priya Balachandran
VP Product Development and Marketing
Applied Silver, Inc.
26254 Eden Landing Road
Hayward, CA 94545

Subject: PRIA Label Amendment – Revised to Add Claims
Product Name: SilvaClean
EPA Registration Number: 90335-1
Application Date: 09/06/2018
Decision Number: 544121

Dear Dr. Balachandran:

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. 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) 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.

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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 Terria Northern by phone at 703-347-0265, or via email at northern.terria@epa.gov.

Sincerely,



Zeno Bain, Product Manager 33
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: Approved label

Mar 08, 2019

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 90335-1

SilvaClean®

Laundry additive for residual activity against post-laundry contamination. Antimicrobial textile treatment for commercial and industrial use on fibers or textiles.

SilvaClean will kill 99.9% of *Staphylococcus aureus* after 6 hours of contact and 99.9% of *Klebsiella pneumoniae* after 3 hours of contact with SilvaClean treated fabric (cotton, cotton/polyester blend or microfiber materials).

SilvaClean® will kill 99.9% of *Candida albicans* after 6 hours of contact; 99.9% of, Vancomycin-resistant *Enterococcus faecalis* (VRE), *Acinetobacter baumannii*, and Extended-spectrum beta-lactamase (ESBL) positive *Escherichia coli* after 3 hours of contact; and Methicillin-Resistant *Staphylococcus aureus* (MRSA) after 9 hours of contact with SilvaClean®-treated fabric (cotton or cotton/polyester blend materials)

SilvaClean® will kill 99.9% of the following organisms on different types of textiles after the hours of contact time listed below:

Microorganism	Hours of Contact	Textile
<i>Staphylococcus aureus</i>	6 hours	Cotton, cotton/polyester blend, or microfiber
<i>Klebsiella pneumoniae</i>	3 hours	
Vancomycin-resistant <i>Enterococcus faecalis</i> (VRE)	3 hours	Cotton or cotton/polyester blend
Extended-spectrum beta-lactamase (ESBL) positive	3 hours	
<i>Acinetobacter baumannii</i>	3 hours	
<i>Candida albicans</i> (yeast)	6 hours	
Methicillin-Resistant <i>Staphylococcus aureus</i> (MRSA)	9 hours	

SilvaClean® also is effective in inhibiting the growth of stain- and odor-causing bacteria and fungi (mold and mildew) in products to which it is applied.

{These claims may appear on any label panel}

SilvaClean® is composed of:

Active Ingredient:	
Silver*	22.5%
Other Ingredients	77.5%
Total	100.0%

* from silver nitrate.

KEEP OUT OF REACH OF CHILDREN

DANGER: Corrosive

See back panel for first aid and additional precautionary statements.

Net Contents: _____
EPA Reg. No. 90335-1
EPA Est. No. xxx-xx-x

Applied Silver, Inc.
26254 Eden Landing Road
Hayward, CA 94545

SilvaClean® is applied to or incorporated into industrial products listed below. For non-food contact uses only.

FOR COMMERCIAL AND INDUSTRIAL USE ONLY. Not for Residential Use.

Laundry additive with residual activity against *S. aureus* after 6 hours of contact and *K. pneumoniae* after 3 hours of contact on textiles made of cotton, cotton/polyester blend or microfiber materials. Examples include: pillow covers, sheets, blankets, bedspreads, apparel, uniforms, gowns, mops, cloths, and towels.

Laundry additive with residual activity against *C. albicans* after 6 hours of contact; Vancomycin-resistant *Enterococcus faecalis*, Extended-spectrum beta-lactamase positive *E. coli*, and *A. baumannii* after 3 hours of contact; and Methicillin-Resistant *S. aureus* after 9 hours of contact on textiles made of cotton or cotton/polyester blend. Examples include: pillow covers, sheets, blankets, bedspreads, apparel, uniforms, gowns, mops, cloths, and towels.

For material preservation against stain- and odor- causing bacteria and fungi (mold and mildew) of textiles made of: cotton or cotton/polyester blend, polyester, nylon, microfiber, spandex, and nylon/spandex blend. Example items include: pillow covers, sheets, blankets, bedspreads, apparel, uniforms, jerseys, active wear, scrubs, lab coats, quilts, liners, curtains, draperies, upholstery, towels, shower curtains, and carpets.

DIRECTIONS FOR USE

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

Laundry additive to reduce post-laundry contamination with residual activity against *S. aureus* (ATCC 6538) after 6 hours of contact and *K. pneumoniae* (ATCC 4352) after 3 hours of contact on textiles made of cotton, cotton/polyester blend or microfiber materials.

Laundry additive to reduce post-laundry contamination with residual activity against *C. albicans* (ATCC 10231) after 6 hours of contact; Vancomycin-resistant *E. faecalis*, (ATCC 51299) Extended-spectrum beta-lactamase positive *E. coli* (ATCC BAA-196), and *A. baumannii* (ATCC 19606), after 3 hours of contact; and Methicillin-Resistant *S. aureus* (ATCC 33591) after 9 hours of contact on cotton or cotton/polyester blend fabrics .

Laundry additive for preservation against stain- and odor-causing bacteria and fungi (mold and mildew).

Use as directed.

SilvaClean® is a concentrate that must be diluted with distilled or deionized water before use.

Following laundering and treatment with SilvaClean®, store clean, unused linens consistently with the facility's infection control practices. When linens are being used, SilvaClean® remaining in linens will reduce levels of *S. aureus* and *C. albicans* by 99.9% after 6 hours of contact; *K. pneumoniae*, Vancomycin-resistant *Enterococcus faecalis*, Extended-spectrum beta-lactamase positive *E. coli*, and *A. baumannii* by 99.9% after 3 hours of contact; and Methicillin-Resistant *S. aureus* by 99.9% after 9 hours of contact.

Dilute the following volumes of SilvaClean® concentrate volumes per 100 lbs of selected fabric type into 500 or 1000 mL distilled or deionized water and dose as part of the final rinse step in the laundry process to achieve residual post-laundry contamination reduction:

- 0.024 oz per 100 lbs cotton
- 0.032 oz per 100 lbs cotton/poly blend
- 0.048 oz per 100 lbs microfiber

Add the diluted solution into the final rinse cycle of a laundry process. Allow to soak with fabric at least 2 minutes.

Preservation against stain- and odor- causing bacteria and fungi (mold and mildew): Dilute SilvaClean® to provide 0.00016% to 0.0014% (1.6 ppm – 14 ppm) silver on fibers or textiles. The treatment level of SilvaClean® for a product will depend on the specific needs of the manufacturer, the textile being treated, and the level and type of performance desired.

Treat textile by soaking in dilute aqueous solution and agitating for at least 2 minutes.

Textile must be clean prior to the application of product. Retreat textile after each laundering.

Store and manage clean linens consistently with the facility's infection control program and best practices.

STORAGE and DISPOSAL

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

Storage: Store in a safe manner only in areas inaccessible to small children. Store in original container in dark location. Keep container tightly closed when not in use.

Pesticide Disposal: Pesticide wastes are toxic. Improper disposal of excess pesticide, intermediate mixtures, 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: RETURN THE CONTAINER TO APPLIED SILVER, INC. in the original outer packaging for appropriate disposal. Do not clean out, refill or dispose of this container.

PRECAUTIONARY STATEMENTS AND FIRST AID

DANGER

Corrosive

Causes irreversible eye damage and skin burns. Harmful if swallowed, inhaled or absorbed through skin. Do not get in eyes, on skin or on clothing. Avoid breathing spray or mist. Wear goggles, face shield or safety glasses. Wear chemical-resistant apron over coveralls with long-sleeved shirt and long pants, waterproof gloves covering hands, wrists and lower forearms. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using restroom. Remove and wash contaminated clothing before reuse.

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 on skin or clothing:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call 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 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.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

Have the product container or label with you when calling a Poison Control Center or doctor for treatment advice.

For emergency information on SilvaClean®, call the National Pesticides Information Center at 1-800-858-7378, 6:30 AM to 4:30 PM Pacific time (PT), seven days a week. During other times, call the Poison Control Center 1-800-222-1222.

Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

ENVIRONMENTAL HAZARDS

Do not contaminate water when disposing of equipment wash waters. This product is toxic to fish and aquatic invertebrates.

Optional Marketing Claims

Healthcare: As part of a diligent infection control program, experts recommend that a hospital should seek to reduce or eliminate exposure to pathogens to the greatest extent practical. One practical, inexpensive way to aid in this effort is to use SilvaClean® laundry additive. SilvaClean® provides residual post-laundry activity against the following pathogenic bacteria and yeast on cotton or cotton/polyester blend textiles: *S. aureus*, *C. albicans*, *K. pneumoniae*, *VRE*, *ESBL E. coli*, *A. baumannii* and *MRSA*. SilvaClean® provides residual post-laundry activity against the following pathogenic bacteria and yeast on microfiber textiles: *S. aureus* and *K. pneumoniae*. SilvaClean® has residual post-laundry activity against *S. aureus* and *C. albicans* after 6 hours of contact; *K. pneumoniae*, *VRE*, *ESBL E. coli*, and *A. baumannii* after 3 hours of contact; and *MRSA* after 9 hours of contact when textiles such as bed linens and patient gowns are laundered through the SilvaClean® program and properly stored. SilvaClean® may be a helpful addition to an Infection Control program. SilvaClean® is not a substitute for any existing component of a diligent Infection Control program. Practitioners should continue to implement fully all infection control measures.

Sports: As part of a diligent sports medicine Infection Control program, experts recommend that athletic programs should seek to reduce or eliminate exposure to pathogens to the greatest extent practical. One practical, inexpensive way to aid in this effort is to use SilvaClean® laundry additive. SilvaClean® provides residual post-laundry activity against the following pathogenic bacteria and yeast on cotton or cotton/polyester textiles: *S. aureus*, *C. albicans*, *K. pneumoniae*, *VRE*, *ESBL E. coli*, *A. baumannii* and *MRSA*.

SilvaClean® provides residual post-laundry activity against the following pathogenic bacteria and yeast on microfiber textiles: *S. aureus* and *K. pneumoniae*. SilvaClean® has residual post-laundry activity against *S. aureus* and *C. albicans* after 6 hours of contact; *K. pneumoniae*, VRE, ESBL *E. coli*, and *A. baumannii* after 3 hours of contact; and MRSA after 9 hours of contact when textiles such as uniforms, towels and practice apparel are laundered through the SilvaClean® program and properly stored. SilvaClean® may be a helpful addition to an Infection Control program. SilvaClean® is not a substitute for any existing component of a diligent Infection Control program. Practitioners should continue to implement fully all infection control measures.