67619-18

12/22/2006

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AND ALL PROTECTOR	U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Antimicrobials Division (7510P) 1200 Pennsylvania Avenue NW Washington, D.C. 20460	EPA Reg. Number: 67619-18	Date of Issuance: DEC 22 2006
		Term of Issuance: Conditional Name of Pesticide Product: SilviO	
	NOTICE OF PESTICIDE: Registration Reregistration		
(under FIFRA, a	as amended)		
		THE REPORT OF THE REPORT	
Registration is in no health and the envir accordance with the	le and Rodenticide Act. way to be construed as an endorsement or recommendation of the onment, the Administrator, on his motion, may at any time suspen	d or cancel the registra	· · ·
- v	Act. The acceptance of any name in connection with the registra the registrant a right to exclusive use of the name or to its use if it		
1. Sut	the registrant a right to exclusive use of the name or to its use if it oduct is conditionally registered in accordance with F omit and/or cite all data required for registration of yo on the Agency requires all registrants of similar produ	has been covered by IFRA sec 3(c)(7)(ur product under I acts to submit such	others. a) provided that you: FIFRA sec. 3(c)(5) a data; and submit
1. Sub wh acc	the registrant a right to exclusive use of the name or to its use if it oduct is conditionally registered in accordance with F omit and/or cite all data required for registration of your on the Agency requires all registrants of similar produ- eptable responses required for re-registration of your	has been covered by IFRA sec 3(c)(7)(ur product under 1 acts to submit such product under FIF	others. a) provided that you: FIFRA sec. 3(c)(5) a data; and submit FRA section 4.
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1. Sub who acc 2. Make a .	the registrant a right to exclusive use of the name or to its use if it oduct is conditionally registered in accordance with F omit and/or cite all data required for registration of you on the Agency requires all registrants of similar produ- eptable responses required for re-registration of your the labeling changes listed below before you release	has been covered by IFRA sec 3(c)(7)(our product under 1 nots to submit such product under FIF the product for sl	others. (a) provided that you: FIFRA sec. 3(c)(5) (a data; and submit (FRA section 4. (a) and submit) (b) a data; and submit) (c) a data; and submit) (c) a data; and submit) (c) a data; a da

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EPA Form 8570-6

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- **b.** On page 3 of 6, under the *Claims* section, in the bullet that states "Deodorizes by killing germs that cause odor", delete the word "germs" and insert the word "organism".
- c. On page 3 of 6, under the *Claims* section, in the bullet that states "Eliminates-or-Reduces odors [caused by germs or bacteria-and/or mildew]", delete the wording "germs or bacteria-and/or mildew" and insert in its place "odor causing organisms".
- **d.** On page 3 of 6, under the *Claims* section, in the bullet that states "Hospital grade disinfectant", delete the word "grade".
- e. On page 3 of 6, under the *Claims* section, in the bullet that states "Reduces the risk of infection and cross-contamination, delete the wording "the risk of infection and".
- f. On page 3 of 6, under the *Claims* section, in the bullet that states "[This product] controls the spread...", insert the word "treated" between the words "most" and "hard".
- g. On page 3 of 6, under the *Claims* section, in the bullet that states "This product meets AOAC...", insert the acronym "EPA" in front of the statement "standards for hospital disinfection".
- **h.** On page 3 of 6, under the *The Following is only for products with medical devices listed* on the label section, insert in this heading, after the word "*listed*" the wording "in tables 1 and 2".
- i. On page 4 of 6, under the *Table One Medical* section, under *Surfaces*, delete the bullet that states "patient chairs". Patient chairs can imply that it is used on porous surface chairs.
- j. On page 5 of 6, under the *Table Three Veterinary* section, under *Use Sites*, delete Equine Farms, Farms, Kennels, and Livestock-and/or-Swine-and/or-Poultry Facilities". In addition, under *Surfaces*, delete stalls and troughs. DISS/TSS-18 & 19 labeling requirements are necessary if you make claims for use on farm premises as disinfectants.
- k. On page 5 of 6, under the *Table Four Food Services* section, under *Surfaces*, in the first bullet that states 'any washable (food and non-food....)..."delete the word "food". In addition, under *Surfaces*, delete "food trays". In order to make food disinfectant claims for this product, the registrant needs to provide EPA clearance from the Food and Drug Administration.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 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. Submit one (1) copy of your final printed labeling prior to release of this product for shipment. If you have any questions concerning this letter, please contact Demson Fuller at (703) 308-8062.

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Sincerely,

Swindell

Marshall Swindell Product Manager Team-33 Regulatory Management Branch I Antimicrobials Division (7510P)

Enclosure: (Stamped Label)

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Note: Bold, italicized text and (ltalicized text within parentheses) is information for the reader and is not part of the label. [Bracketed] information and phrase sequence are optional unless specified in 40 CFR 156.10. Variables such as CAPITALIZATION, plurals or singular, bold and *italics* are optional unless specified in 40 CFR. The term "wipe(s)", is interchangeable with towel(s), towelete(s) and cloth(s) throughout except for the product brand name which can only be changed by notification or amendment. Listed uses and use sites can be used partially or in their entirety. <u>Underlined lext is new</u>. Strike-through (text) means removed.

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 Correr Customer Assistance 1-88-797-7225.
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NCGEPTED IN EPA Letter Dated

DEG 2 2 2006

Under the Pederal Insectation, Punglaide, and Rodenticide Act at amended, for the pesticide, registered under EPA Reg. No

67614-18

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PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS & DOMESTIC ANIMALS

FIRST AID: 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. For further information, call 1-888-797-7225. -or- Questions? Call 1-888-797-7225.

STORAGE AND DISPOSAL:

STORAGE: Store in a cool, dry place. Do not contaminate water, food or feed by storage or disposal.

DISPOSAL: Do not reuse empty container. Offer empty container for recycling. If recycling is not available, rinse thoroughly and discard container in trash.

DIRECTIONS FOR USE

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

DISINFECTION

TO [CLEAN AND] DISINFECT [AND DEODORIZE] HARD, NONPOROUS SURFACES: [Set trigger to spray [or foam]] Spray 6-8 inches from surface until [surface] is thoroughly wet for the contact time listed (below or on label). Wipe excess. (Rinse.) Allow to air dry. Rinse with potable water for food contact surfaces. (For all others, no mising is required.) Gross filth should be removed prior to disinfecting. [If streaking is observed, wipe with a clean, damp [cloth or] paper towel after appropriate contact time has expired.)

ORGANISMS:

Bacteria1: Enterococcus faecalis, vancomycin resistant (VRE) [ATCC 700221]*** Escherichia coli OH157 (E. coli) [ATCC 43888]*** Listeria monocytogenes [ATCC 19111]* Pseudomonas aeruginosa [ATCC 15442]* Salmonella [choleraesuis] [enterica] [ATCC 10708]* Staphylococcus aureus [ATCC 6538] Staphylococcus aureus, methicillin resistant (MRSA) [ATCC 700698]**

Viruses Non-enveloped²: Poliovirus type 1 [ATCC VR-1002] (Strain lansing))**** Rhinovirus type 37 [ATCC VR-1002] [(Strain lansing)]**** [(Strain 151-1)]**** [([leading] causative agent of the common cold)] Viruses Enveloped: Herpes simplex virus type 1 [ATCC VR-733] [(Strain F (1))]**2 [(causative agent of cold sores)] [(Causative agent or con sorces)] HIV type 1 [(Strain HTLV-IIIB)]*1 Influenza A [ATCC VR-544] [(Strain Hong Kong)]****2 [(representative of the common flu virus)]

Mold, Mildew, Fungi:

Trichophyton mentagrophytes [ATCC 9533]**** [athlete's foot fungus] 30 second contact time **1 minute contact time ****2 minute contact time ****10 minute contact time

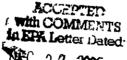
* Evaluated in the presence of a 5% organic soil load.

² Evaluated in the presence of a 1% organic soil load

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2 2 2006

Under the Federal insecticide, Pungicide, and Rodenticide Act as amended, for the pesticide, regimered under EPA Reg. No

67619-18

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Claims:

- · Broad spectrum no-rinse disinfectant for non-food contact surfaces
- [A] one-step cleaner/disinfectant
- · Aids in reducing -or- in the reduction of cross-contamination between treated surfaces
- Bactericide -or- Bactericidal
- Bleach Free
- · Broad spectrum disinfectant
- · [Cleans and] disinfects (insert use site(s) from table 1-5)
- · [Cleans and] disinfects [hard, nonporous surfaces]
- · Cleans, deodorizes and disinfects
- · Deodorizes by killing the second stat cause odors
- · Disinfectant, Fungicidal and Virucidal spray
- · DisInfecting formula
- · Disinfects [and deodorizes]
- · Disinfects and deodorizes by killing germs and their odors
- · Disinfects hard, nonporous surfaces [throughout the __ (insert use site(s) from table 1-5)]
- · Disinfects without bleaching
- Easy and convenient disinfecting [throughout the _____ (insert use site(s) from table 1-5)]
- · Easy, one-step cleaning and disinfecting
- · Effective against -or- Kills _ (insert any organism(s) from table above) [in the presence of organic soil]
- · Effective against -or- Kills a wide range of bacteria including Staphylococcus aureus, Salmonella choleraesuis, Pseudomonas aeruginosa [in the presence of organic soil]
- · [Effectively] disinfects [hard, nonporous] [environmental] surfaces
- · Eliminates odors at their source (caused by germs -or- bacteria -and/ormildew)
- Eliminates -or- Reduces odors (caused by geen

- · Exhibits effective virucidal activity
- · Fungicide -or- Fungicidal
- · Germicide -or- Germicidal
- · Hospital grattle disinfectant
- · Kills bacteria, viruses and mold Kills germs
- · Kills many common bacteria and viruses · Kills odor-causing bacteria -or- germs
- · Kills -or- Effective against bacteria
- . Kills -or- Effective against germs · Kills -or- Effective against viruses
- · Multi-purpose disinfectant One-step cleaner and disinfectant
- One-step cleaning and disinfecting [saves time]
- One-step disinfectant cleaner designed for general cleaning and disinfecting hard, nonporous environmental surfaces in health care facilities -or- (insert use site(s) from table 1)

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- · Prevents -or- controls mold growth
- Pseudomonocidal
- · [Ready-to-use] hospital [grade] disinfectant
- Reduces the r بأما أمعا Cross-contamination
- . The answer to your disinfecting needs
- . [The] quick -and/or- easy -and/or- convenient way to disinfect
- . [This product] controls the spread of germs on most hard, nonporous surfaces
- . This product meets AOAC efficacy testing requirements -or- standards for hospital disinfection
- · Use where control of the hazards of cross-contamination between treated surfaces is of prime importance
- · Virucide -or- Virucidal

Use Sites: See Tables 1-5.

The following is only for products with medical devices listed on the label:

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.

Special Instructions for Use Against HIV-1

ACCEPTED With COMMENTS In EPA Letter Dated

DEC 22 2006 Under the Poderal Insecticide, Fungicide, and Rodenticide amended, for the pesticide registered under EPA Reg. No.

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This product kills HIV-1 on precleaned environmental surfaces/objects previously soiled with blood/body fluids in health care settings or other 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 Human Immunodeficiency Virus (HIV-1) (associated with AIDS).

Special instructions for using this product to clean and decontaminate against HIV-1 on surfaces/objects soiled with blood/body fluids: Personal Protection: When handling items solled with blood or body fluids, use disposable impervious gloves, nowns, masks and eye coverings. Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces and other objects before applying this product.

Contact Time: Allow surfaces to remain wet for 30 seconds, [rinse and] let air dry. For all other organisms, see directions for contact times.

Disposal of Intectious Materials: Use disposable impervious gloves, gowns, masks and eye coverings. Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal. R0721-1

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GENERAL CLAIMS

- Convenient
- . Does not contain mercury
- Does not contain nonylphenol ethoxylates (NPEs) -and/or- alkylphenol ethoxylates (APEs)
- Does not contain VOCs
- Fasy
- · Easy and convenient to use
- · Easy to handle
- Effective
- Eliminates (daily) mixing and measuring
- Fast
- . [For] general use
- · For use on bathroom surfaces

- For use on nursery surfaces
 Mercury free
- No measuring
- No mixing
- · Nonyiphenol ethoxylate (NPE) -and/or- alkylphenol ethoxylate (APE) free
- Ready to use
- Shelf-stable formula
- · Specifically -or- Specially designed for the Medical/Dental/Veterinary/Health
- Care industry
- Suitable for hospital use
- VOC free
- VOC's below laboratory detection limits

SURFACE SAFETY CLAIMS

Safe for use on _____ (insert surface material(s) from table 5)
 Safe on hard, nonporous inanimate environmental surfaces

· Will not harm [titanium-coated] [medical grade] stainless steel

USE SITES

Ambulances -or- [Emergency Medical] Transport Vehicles Anesthesia Rooms -or- Areas [Assisted Living -or- Full Care] Nursing Homes CAT Lab[oratories] Central Service Areas Central Supply Rooms -or- Areas Critical Care Units -or- CCUs **Dialysis Clinics** Emergency Rooms -or- ERs Health Care Settings -or- Facilities Home Health Care [Settings] Hospitals [Hospital] Kitchens Intensive Care Units -or- ICUs Laboratories [Medical] Clinics **Medical Facilities**

TABLE ONE Medical:

Medical -or- Physician's -or- Doctor's Offices Newborn -or- Neonatal Nurseries Nursing -or- Nurses' Stations Orthopedics Outpatient Clinics Patient Restrooms Patient Restrooms Patient Rooms [Pediatric] Examination Rooms -or- Areas Pharmacies Physical Therapy Rooms -or- Areas Radiology -or- X-Ray Rooms -or- Areas Recovery Rooms Respiratory Therapy Rooms -or- Areas Surgery Rooms -or- Operating Rooms -or-ORs SURFACES bed pans

lexam -or- examination] tables [exam -or- examination] tables external surfaces of [medical] equipment -or-[medical] equipment surfaces external [surfaces of] ultrasound transducers gurneys hard, nonporous [environmental] hospital -or- medical surfaces [hospital -or- patient] bed railings -or- linings -or- frames IV poles plastic mattress covers

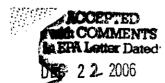
plastic mattress covers reception counters -or- desks -or- areas stretchers wash basins wheelchairs

B0721-1

USE SITES Dental Operatories Dental -or- Dentist's Offices

TABLE TWO Dental:

SURFACES dental countertops dental operatory surfaces dentist -or- dental chairs hard, nonporous [environmental] dental surfaces light lens covers reception counters -or- desks -or- areas



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

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TABLE THREE Voterinary:

USE SITES

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Animal Housing Facilities Animal Life Science Laboratories [Animal -or- Pet] Grooming Facilities

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Pet Areas Pet Shops -or- Stores Small Animal Facilities Veterinary Clinics -or- Facilities Veterinary Offices Veterinary -or- Animal Hospitals

SURFACES animal equipment automatic feeders cages external surfaces of [veterinary] equipment feed racks fountains hard, nonporous [environmental] veterinary surfaces pens reception counters -or- desks -or- areas

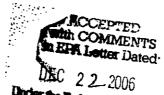
watering appliances

TABLE FOUR Food Service:

SURFACES any washable (Remaind non-food contact) surface where disinfection is required appliances dish racks drain boards food cases (See the see Second Se

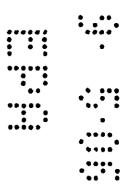
A potable water rinse is required for food contact surfaces. Do not use on glassware, utensils, or dishes.

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Uncler the Pederal Insecticide, Pungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No

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USE SITES Bars

Cafeterias Commercial -or- Institutional Kitchens Delis Fast Food Chains -ot- Restaurants Food Preparation and Processing Areas Food [Service -or- Processing] Establishments Food Serving Areas Other Food Service Establishments Restaurants School Kitchens . . .

TABLE FIVE Miscellaneous/General:

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USE SITES Airplanes **Blood Banks Bowling Alleys Butcher Shops** Churches Colleges **Correctional Facilities** Day Care Centers Dormitories Factories **Funeral Homes Grocery Stores** Gymnasiums -or- Gyms **Health Club Facilities** Hotels **Industrial Facilities** Laundromats Laundry Rooms Locker Rooms Manufacturing Plants -or- Facilities Military Installations Motels Produce Areas Public Areas **Recreational Centers -or- Facilities** Restrooms -or- Restroom Areas School Buses Schools Shelters Shower Rooms Storage Rooms -or- Areas Supermarkets Trains Universities

SURFACES [bathroom] fixtures [bath]tubs behind and under counters behind and under sinks booster chairs cabinets ceilings cell[ular] -or- wireless -or- mobile -or- digital ohones chairs (computer) keyboards [computer] monitors counters -or- countertops cribs desks [diaper -or- infant] changing tables diaper pails dictating equipment [surfaces] doorknobs exterior -or- external toilet surfaces exterior -or- external urinal surfaces faucets floors garbage -or- trash cans [grocery store -or- supermarket] carts hampers hand railings headsets highchairs lamos linoleum other telecommunications equipment [surfaces] playpens shelves showers -or- shower stails sinks stall doors tables telephones [tiled] walls toilet rims toilet seats towel dispensers toys vanity tops -or- vanities

SURFACE MATERIALS aluminum (baked) enamel . brass chipped enamel chrome clear plastic [common] hard, nonporous [household -or environmental] surfaces copper Formica glass glazed ceramic [tile] glazed porcelain laminated surfaces Marlite plastic [laminate] porcelain enamel sealed granite stainless steel synthetic marble vinyl [tile] similar hard, nonporous surfaces except for those excluded by the label

Not Recommended For Use On -or- Avoid contact with: acrylic plastics clothes fabric natural marble paper surfaces rubber silver unfinished wood wood

If unsure about compatibility with a surface, spot test a small area first.

R0721-1

- ACCEPTED With COMMENTS in EPA Letter Dated DEC 2 2 2006

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