



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

December 14, 2006

OPP Decision Number: D-366369

Olivia D. Laird
Laird's Regulatory Consultants, Inc.
The Agent for
Sporicidin International
17804 Braemar Place
Leesburg, Virginia 20175-7046

Subject: Application for Amended Registration
Product Name: Sporicidin Brand Disinfectant Towelettes
EPA Registration Number: 8383-7
Application Date: 28-Mar-2006
EPA Receipt Date: 31-Mar-2006

The following amendment, submitted in connection with registration under section 3(c) (7) (A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with the following comments.

Proposed amendment:

- Add claim for use against Avian A virus

Acceptable data:

The submitted efficacy data (MRID No. 469037-01) support the use of the liquid, non-towelette product, Sporicidin Disinfectant Solution, as a disinfectant with virucidal activity against Avian influenza (H9N2) virus on hard, non-porous surfaces in the presence of a 5% organic soil load for a contact time of 10 minutes at full strength.

Labeling comments:

1. The proposed label claims that the towelette product, Sporicidin Brand Disinfectant Towelettes, is an effective disinfectant against Avian influenza A virus on hard, non-porous surfaces for a contact time of 10 minutes is acceptable.

2. The file for the product "Sporicidin Brand disinfectant Towelettes" indicates that claims for all organisms were transferred from the liquid product "Sporicidin Brand disinfectant Solution" to the towelette product without confirmatory data or supplemental data to bridge the claims. This agreement was made prior to establishment of guidance for demonstrating the effectiveness of towelette products and requirements for confirmatory/bridging data. This being the case, claims against Avian influenza A on the towelette product is currently acceptable (provided the labeling revisions listed in #2 below are made).

Please Note: the Agency is revising its guidelines for towelette testing, and substantial data may be required in the future to bridge claims for Avian influenza and other organisms to the towelette product.

2. The proposed label now includes claims that the product, Sporicidin Brand Disinfectant Towelettes, is an effective disinfectant against Methicillin resistant *Staphylococcus aureus* (MRSA), Vancomycin resistant *Enterococcus faecium* (VRE), *Pellicularia filamentosa*, and *Penicillium variable* on hard, non-porous surfaces. Sporicidin International did not provide data to support these claims. References to Methicillin resistant *Staphylococcus aureus* (MRSA), Vancomycin resistant *Enterococcus faecium* (VRE), *Pellicularia filamentosa*, and *Penicillium variable* are currently acceptable, however additional data will be required in the future or during the time of reregistration to bridge these, and other bacterial claims to the towelette product.

3. The proposed label now claims that the product, Sporicidin Brand Disinfectant Towelettes, is effective against *Stachybotrys chartarum*. The Agency has not yet accepted a protocol for determining efficacy of a product against *Stachybotrys chartarum* on porous surfaces where it is likely found, nor has Sporicidin International submitted any such efficacy data; therefore, the reference to *Stachybotrys chartarum* must be deleted from the product label.

4. The proposed label now includes claims that the product, Sporicidin Brand Disinfectant Towelettes, is effective against *Chaetomium globosum*, and *Aspergillus niger*. Sporicidin International did not provide towelette data to support these claims, however they are currently acceptable, as data was conducted on the concentrate product. Note that additional data will be required in the future or during the time of reregistration to bridge these, fungicidal claims to the towelette product.

5. The proposed label now includes directions for use on farm premises and food processing plants based on Avian influenza A claims. It is unlikely that a towelette product would be adequate to disinfect large items such as farm equipment, animal and poultry housing, barns, kennels, breeding pens, hatcheries, trucks and other vehicles, and large items and areas in food processing plants. The label must be made clear that the product's use is only for surfaces which are not conducive to treatment by immersion or excess liquid (e.g. electrical panels, cash registers, door knobs and similar "high touch" surfaces) that cannot be immersed or saturated by other means, or those which are not safe for treatment with an excess of liquid. For uses in hospital/medical/health facilities, the directions for use in hospital disinfection must be followed. For all other use sites, general disinfection directions for must be followed.

6. Featured statements/phrases emphasized/enlarged lettering, special graphics, or any product name that employs the terms "Avian influenza A" or "Bird Flu", are unacceptable. Featured statements/phrases, emphasized/enlarged lettering or special graphics that are employed for the primary purpose of especially promoting or drawing attention to product efficacy against Avian influenza A, are also unacceptable. For example, a featured, incomplete phrase such as 'Kills Avian influenza A' will not be permitted, but the phrase "Kills Avian influenza A on pre-cleaned environmental surfaces" is acceptable.

7. The proposed label, page 2 (center panel) now lists directions "To Spot Clean, Deodorize, and Decontaminate Carpets." The term "Decontaminate" must be removed. This is an unwarranted public health claim and is not recognized for product label use by the Agency. This matter was previously addressed in an August 25, 2003 letter from the Agency to Sporidicin International's representative and in a June 25, 2002 efficacy DER regarding the liquid product, yet the claim remains on the product label.

8. Under the heading "To Disinfect and Deodorize" on Page 2 (center panel) of the proposed label, the Sporidicin International must add the statement: "Use as many towelettes as necessary for the treated area to remain wet for the entire contact time," or similar.

9. The proposed label, page 2 (left and center panels), lists 3 different contact times for different groups of organisms (i.e. 1 minute, 3 minutes, 10 minutes, and no contact time in the case of mold and mildew associated organisms). This is unacceptable. The user will not know which microorganisms are present on a surface to be treated, and therefore will not be able to determine which contact time to follow. Under the Directions for Use/To Disinfect and Deodorize section in the center panel, Sporidicin International must list a general contact time for disinfection of 10 minutes.

10. Per PR Notice 94-4, the following statement must be added to the label:

"This product is not to be used as a terminal sterilant/high level disinfectant on any surfaces 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."

11. Sporidicin International must make the following changes to the proposed label:

- On page 2 of the proposed label (left panel), change "manikins" to read "mannequins."
- On page 2 of the proposed label (left panel), change "wood" to read "treated wood," change "porcelain" to read "glazed porcelain," and change "tile" to read "glazed tile."
- On page 2 of the proposed label (left panel), change "differs in composition" to read "differ in composition."
- On page 2 of the proposed label (left panel), change "*Salmonella choleraesuis*" to read

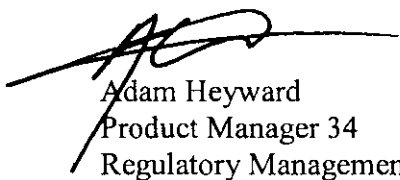
"*Salmonella enterica*." The nomenclature of this organism has changed and this should be noted on the proposed label and in all future submissions.

- On page 2 of the proposed label (center and right panels), change "Avian influenza A virus" to read "Avian influenza A (H9N2) virus."
- On page 2 of the proposed label (middle panel), under the "To Kill, Clean and Prevent Mold and Mildew" section, change "Thoroughly wet pre-cleaned surface Sporidicin towelettes" to read "Thoroughly wet pre-cleaned surface with Sporidicin Disinfectant Towelettes."
- On page 2 of the proposed label (right panel; last paragraph), change "or (2) contact" to read "or (2) contacts."

Submit three (3) copies of the labeling bearing the revisions stated above. A copy will be stamped and returned for your records.

If you have questions concerning this letter, please contact Stacey Grigsby by telephone at 703-305-6440 or by email at grigsby.stacey@epa.gov or me by telephone at 703-308-6422 or by e-mail at heyward.adam@epa.gov.

Sincerely,



Adam Heyward
 Product Manager 34
 Regulatory Management Branch II
 Antimicrobials Division



DISINFECTANT TOWELETTES

An effective disinfectant and active deodorant for hospitals, clinics, medical, dental and veterinary offices, laboratories, industrial clean rooms, homes, nursing homes, ambulances, hotels, restaurants, schools, airplanes, trains, boats, autos, buses, health spas and toilets.

Active Ingredients

Phenol	1.56%
Sodium Phenate	0.06%
Inert Ingredients	98.38%
Total	100.00%

Keep Out of Reach of Children

CAUTION

Contents: 120 Towelettes 5" x 8" saturated with disinfectant

- BACTERICIDAL
- FUNGICIDAL
- VIRUCIDAL**
- TUBERCULOCIDAL
- PREVENTS MOLD AND MILDEW
- ELIMINATES ODORS*

EPA REG. NO. 8383-7
EPA Est. No. 047178-IL-001

ACCEPTED
with COMMENTS
EPA Letter Dated:

DEC 14 2006

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. *8383-7*

Insert
UPC code here

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AN EFFECTIVE CLEANER, DISINFECTANT AND ACTIVE DEODORANT for hospitals, clinics, medical and veterinary offices, laboratories, industrial clean rooms, homes, nursing homes, ambulances, hotels, restaurants, schools, airplanes, trains, boats, autos, buses, health spas and toilets.

DISINFECTANT AND DEODORIZER FOR HARD, NON-POROUS SURFACES in medical treatment and patient rooms, operating rooms, emergency rooms, recovery rooms and bathrooms. Use on medical and dental equipment such as beds, surgical carts, counter tops, manikins, telephones, furniture, wheelchairs, walkers, sinks, floors, walls, light switches, linen hampers, shower stalls, toilet seats, trash containers and damp and musty areas, including animal enclosures. Reduces the hazards of cross-contamination.

ACTIVE DEODORIZER*: Provides continuous residual bacteriostatic activity against odor-causing organisms for up to 6 months, if not removed from the surfaces including plastics, latex, vinyl, glass, wood, metal, porcelain, tile and paint.

- Kills Trichophyton Mentagrophytes (Fungus that causes Athlete's Foot) on bathroom, shower and pool surfaces • Penetrates cracks • Non-staining • Contains no harmful abrasives • Self-sanitizes against odor-causing bacteria.

SPORICIDIN Brand DISINFECTANT TOWELETTES are germicidal when used as directed for disinfection but differs in composition from other Sporidicin products.

PASSES AOAC EFFICACY STANDARDS FOR INSTITUTIONAL AND HOSPITAL DISINFECTION

- Kills HIV-1 (AIDS Virus) in *one minute*. (See Sporidicin Bulletin No. 303)
- Kills Staphylococcus aureus, Salmonella choleraesuis, Pseudomonas aeruginosa, Methicillin resistant Staphylococcus aureus (MRSA), Vancomycin resistant Enterococcus faecium (VRE) and Trichophyton Mentagrophytes (Athlete's Foot fungus) in *three minutes*.
- Kills vegetative organisms including Streptococcus pyogenes, Streptococcus salivarius, Escherichia coli, Herpes simplex types 1/F and 2/G (oral, ocular and genital), Influenza A₂ (Japan 305/57 Asian

strain) and Avian Influenza A virus, Pellicularia filamentosa, Penicillium variable, Vaccinia, Canine parvovirus, Cytomegalovirus, Coronavirus, Polio Type 1 virus, and Mycobacterium tuberculosis in *ten minutes* at 20°C/68°F or above.

DIRECTIONS FOR USE: It is a violation of U.S. Federal Law to use this product in a manner inconsistent with its labeling.

DO NOT DILUTE OR MIX WITH OTHER CHEMICALS

PRECLEAN surfaces using Sporidicin Brand Disinfectant Towelettes to remove soil and filth. Wipe dry.

PREPARATION OF DISPENSER: Remove safety seal and pull up tab. Remove lid and discard inner seal. Insert approximately 1 inch of towelette from center of roll through tab opening in lid. Replace lid. Pull each sheet up at a sharp angle and snap off. Keep container closed between uses.

TO DISINFECT AND DEODORIZE: Thoroughly wet pre-cleaned surface with Sporidicin Disinfectant Towelette. Allow contact times as stated above at room temperature (20°C/68°F or above) to kill listed organisms. NOTE: See Sporidicin Bulletin No. 303 for HIV (AIDS virus) instructions.

*****TO KILL, CLEAN AND PREVENT MOLD AND MILDEW:** Thoroughly wet pre-cleaned surface Sporidicin towelettes. Repeat application if new growth appears. Effective against Stachybotrys chartarum, Chaetomium globosum and Aspergillus niger.

TO CLEAN AIR DUCTS: Apply to hard, non-porous surfaces.

TO SPOT CLEAN, DEODORIZE AND DECONTAMINATE CARPETS: Apply to spot or area to be treated with Sporidicin Towelette. Wipe dry with clean towel or cloth.

FOR FARM EQUIPMENT, ANIMAL AND POULTRY HOUSING, BARNs, KENNELS, BREEDING PENS, HATCHERIES, TRUCKS AND OTHER VEHICLES:
Pre-Clean - Remove poultry, animals, feed and water from premises. Remove litter, feces and gross filth from areas to be treated. Pre-clean all surfaces thoroughly with Sporidicin Enzymatic Cleaner, soap or detergent and rinse with potable water. To **Disinfect**

- Apply Sporidicin Towelettes to pre-cleaned area. Allow to remain wet for 10 minutes, and then air dry. Rinse all feed and water containers with potable water before use.

FOR FOOD PROCESSING PLANTS: Follow pre-cleaning and disinfecting instructions outlined above to disinfect hard, non-porous surfaces and materials in food handling areas, including poultry and meat packing facilities, slaughter houses, etc. All surfaces and materials that come in contact with food must be rinsed with potable water prior to use.

NOTE: Kills Avian Influenza A Virus on environmental surfaces in 10 minutes.

OTHER APPLICATIONS: Recommended for use in food and sewage cleanups, blood spills, respirators, personal protective equipment and restoration equipment.

PRECAUTIONARY STATEMENTS: Hazard to Humans and Domestic Animals.

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

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 eye. Call a poison control center or doctor for treatment advice. Have product container or label with you when calling a poison control center or doctor, or going for treatment.

STORAGE AND DISPOSAL: Store at room temperature. Discard empty container in regular trash.

NOTE: 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) contact 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 pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

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