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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

November 22, 2006

MEMORANDUM

Subject: Efficacy Review for Sporidicin Brand Disinfectant Solution;
EPA Reg. No. 8383-3; DP Barcode: D331848

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Applicant: Sporidicin International
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Formulation from the Label:

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Phenol.....	1.56%
Sodium Phenate.....	0.06%
<u>Other Ingredients</u>	<u>98.38%</u>
Total.....	100.00%

I. BACKGROUND

The product, Sporidicin Brand Disinfectant Solution (Reg. No. 8383-3), is an Agency-approved disinfectant (bactericide, virucide, fungicide, tuberculocide) and deodorizer for use on hard, non-porous surfaces in household, institutional, industrial, commercial, food processing, animal care, and hospital or medical environments. The applicant requested to amend the registration of this product to add a claim for effectiveness as a disinfectant against Avian influenza A virus. The study was conducted at MicroBioTest, Inc., located at 105 Carpenter Drive in Sterling, VA 20164.

This data package contained a transmittal document from the applicant's representative to the Agency (dated August 3, 2006), one study (MRID No. 469037-01), a Statement of No Data Confidentiality Claims for the study, and the proposed label.

II. USE DIRECTIONS

The product is designed for disinfecting hard, non-porous surfaces such as counter tops, floors, furniture, light switches, linen hampers, manikins, shower stalls, sinks, surgical carts, telephones, toilet seats, trash containers, walkers, walls, and wheelchairs. The proposed label indicates that the product may be used on hard, non-porous surfaces including: glass, metal, painted surfaces, plastic, porcelain, tile, vinyl, and wood. Directions on the proposed label provided the following information regarding preparation and use of the product as a disinfectant against Avian influenza A virus: Pre-clean surfaces with the product to remove soil and filth. Wipe dry with paper towel, cloth, or sponge. Thoroughly wet pre-cleaned surfaces with the product. Allow surfaces to remain wet for 10 minutes.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Virucides

The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level. These Agency standards are presented in DIS/TSS-7.

IV. SUMMARY OF SUBMITTED STUDIES

1. MRID 469037-01 “Virucidal Efficacy Test, Avian Influenza virus” for Sporicidin Disinfectant Solution, by Tien V. Mai. Study conducted at MicroBioTest, Inc. Study completion date – July 17, 2006. Laboratory Project Identification Number 184-206.

This study was conducted against Avian influenza virus type A (H9N2) (Strain Turkey/Wis/66; obtained from SPAFAS), using embryonated chicken eggs (obtained from BE Eggs) as the host system. Three lots (Lot Nos. A6007, B6028 and A6006) of the product, Sporicidin Disinfectant Solution, were tested according to MicroBioTest Protocol “Virucidal Efficacy Test, Avian Influenza virus,” dated June 7, 2006 (copy provided). The product was received ready-to-use. The stock virus culture contained at least a 5% organic soil load (type not specified). Films of virus were prepared by spreading 0.2 mL of virus inoculum over the bottoms of separate sterile glass Petri dishes. The virus films were dried at ambient temperature. For each lot of product, separate dried virus films were exposed to 2.0 mL of the product for 10 minutes at 23°C. After the contact period, the virus-disinfectant mixture was neutralized with 2.0 mL of newborn calf serum containing 1% Polysorbate 80. The plates were scraped with a cell scraper to re-suspend the contents. Ten-fold serial dilutions were prepared, using RPMI 1640 supplemented with 5% newborn calf serum. Embryonated chicken eggs were inoculated intra-allantoically in quadruplicate with 0.2 mL of the dilutions. The eggs were incubated for 2-4 days at 36±2°C, candled to determine embryo viability, and then kept at 2-8°C for at least 8 hours. Afterwards, samples were collected, stored at ≤-10°C, and assayed for the presence of replicating virus using a hemagglutination assay. Controls included those for plate recovery, toxicity, toxicity-related viral interference, host viability/sterility, and neutralizer effectiveness. The 50% embryo lethal dose/embryo infectious dose per mL (ELD/EID₅₀/mL) was determined by the method of Reed and Muench.

Note: The laboratory report contains a “Confidentiality” clause on page 23, which states that no reference to the work or data may be made public without written consent.

V. RESULTS

MRID Number	Organism	Results			Dried Virus Control (ELD/EID ₅₀ /mL)
			Lot No. A6007	Lot No. B6028	
469037-01	Avian influenza (H9N2) virus	10 ⁻² to 10 ⁻⁷ dilutions	Complete inactivation	Complete inactivation	≥10 ^{7.50}
		ELD/EID ₅₀ /mL	≤10 ^{1.50}	≤10 ^{1.50}	

VI. CONCLUSIONS

1. The submitted efficacy data (MRID No. 469037-01) support the use of the product, Sporidicin 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. A recoverable virus titer of at least 10^4 was achieved. Cytotoxicity was not observed. Complete inactivation (no growth) was indicated in all dilutions tested.

VII. RECOMMENDATIONS

1. The proposed label claims that the product, Sporidicin Brand Disinfectant Solution, is an effective disinfectant against Avian influenza A virus on hard, non-porous surfaces for a contact time of 10 minutes at full strength. Avian influenza A label claims are accepted for this product as a Ready-to-Use Spray product for Commercial, Industrial, Institutional, Agricultural and Residential Use Surfaces. It should 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., cages, equipment tables, lab benches, faucet handles, door knobs, and similar "high touch" surfaces). For uses in hospital/medical/health facilities, the directions for use in hospital disinfection should be followed. For all other use sites, general disinfection directions for use should be followed.

2. If the applicant intends to market their product in **larger packaging sizes** (e.g., ≥ 55 gallons) for use on poultry premises, as shown on page 2 of the proposed label, the following label directions are required to permit their classification as non-food products:

- (a) Remove all poultry and feeds from premises, trucks, coops, and crates.
- (b) Remove all litter droppings from floors, walls, and surfaces of facilities occupied or traversed by poultry.
- (c) Empty all troughs, racks, and other feeding and watering appliances
- (d) Thoroughly clean all surfaces with soap and detergent rinse with water.
- (e) Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes.
- (f) Ventilate buildings, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set, or dried.
- (g) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

Current packaging sizes and site/pest relationships do not warrant the directions listed about for farm and poultry premises.

3. 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.

4. 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, the applicant must list a general contact time for disinfection of 10 minutes. Furthermore, the applicant must also list that contact time under the "To Kill, Clean, and Prevent Mold and Mildew" section.

5. The proposed label and last accepted label claim that the product, Sporidicin Brand Disinfectant Solution, 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 the applicant submitted any such efficacy data; therefore, the reference to *Stachybotrys chartarum* must be deleted from the product label.

6. The proposed label, page 2 (center panel) lists directions "To 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 the applicant's representative and in a June 25, 2002 efficacy DER, yet the claim remains on the product label.

7. The applicant must make the following changes to the proposed label:

- On page 2 of the proposed label (left panel), change "cross-infection" to read "cross-contamination."
- 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 "*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 (left panel and right panel), change "Avian influenza A virus" to read "Avian influenza A (H9N2) virus."