UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

November 30, 2006

MEMORANDUM

Subject: Efficacy Review for Concrobium (EPA Reg. No. 82552-1); DP Barcode: D332319

From: Ibrahim Laniyan, Microbiologist
Product Science Branch
Antimicrobials Division (7510P)

Thru: Tajah Blackburn, Acting Team Leader
Product Science Branch
Antimicrobials Division (7510P)

11/30/06

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510P)

To: Renae Whitaker / Adam Heyward
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Siamons International, Inc.
36 Meteor Drive
Toronto, Ontario Canada M9W 1A4

Formulation from the Label:

Active Ingredient	% by wt.
Sodium Carbonate	0.95 %
Other Ingredients:	99.05 %
Total	100.00 %

I. BACKGROUND

The product, Concrobium (EPA Reg. No. 72372-1), is an EPA-approved fungistat/mildewstat for use on hard, non-porous surfaces in homes, businesses, and institutions. The applicant requested to amend the registration of this product to add fabric claims; to clarify the label Use Directions; and eliminate redundant statements throughout the label. Study was conducted at umedik Inc., located at 36 Meteor Drive, Toronto, Ontario Canada, M9W 1A4.

This data package contained a letter from the applicant's representative to the Agency (dated August 22, 2006), EPA Form 8570-1 (Application for Pesticide-Section I), EPA Form 8570-34 (Certification with Respect to Citation of Data), EPA Form 8570-4 (Confidential Statement of Formula), EPA Form 8570-35 (Data Matrix), one study (MRID Nos. 469204-01), Statements of No Data Confidentiality Claims for the study, and the proposed label (dated November 28, 2006).

II. USE DIRECTIONS

The product is designed to prevent mold and mildew on hard, non-porous surfaces such as appliance exteriors, bathtubs, bed frames and bed springs, cabinets, cat litter boxes, carts, counter tops, cuspidors, furniture, diaper changing tables and pails, garbage cans, lamps, laundry baskets, metal blinds, mirrors, recycling bins, sinks, sports equipment, toilets, toys, telephones, urinals, walls, windows.... The proposed label also indicated that the product can be used on surfaces such as ceramic tile, crystal, enamel, glass, glazed ceramic tile, glazed porcelain, laminate, linoleum, marble, Marlite, metal (e.g., brass, chrome, copper, stainless steel, tin), plastic, Plexiglas, sealed granite, and vinyl. Directions on the proposed label provided the following information regarding use of the product:

For cleaning and degreasing, apply Concrobium on area until evenly wet. Wipe. For tough stain, reapplication may be necessary.

For preventive treatment, apply Concrobium on area until evenly wet. To promote drying and to avoid residue marks, use a clean cloth or paper towel to wipe off excess wetness. Allow treated surfaces to dry completely.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Products for control of mold and mildew on surfaces (Mildewstats / Fungistats): The efficacy of products intended to prevent the growth of mold and mildew is greatly affected by the type of surface to which the products are applied. Test methods for representative surfaces are "Fabric Mildew Fungistatic Test Method", "Hard Surface Mildew Fungistatic Test Method", "Leather Mildew Fungistatic Test Method", and "Wood Block Mildew Fungistatic Test Method". If the surfaces to be treated, or the methods of application, or the organisms to be controlled by the product, are not the same as those indicated in the method, the method should be modified to reflect these differences. Modifications should also be made so that the method will more clearly reflect actual in-use conditions (including any specialized use situations). For example, tests for Products with funqistatic claims intended for use in shower stalls should include test data to indicate whether leaching will alter the efficacy of the product. Any modifications of test methods must be reported along with justification for the change submitted.

Mildewstats should also be tested to determine whether or not bleaching, staining, spotting or other undesirable effects occur on the surfaces, articles, and materials to be protected.

IV. BRIEF DESCRIPTION OF THE DATA

1. MRID 469204-01 "Fabric Mildew Fungistatic Test," Test Organism: *Aspergillus niger* (ATCC 6275) and *Penicillium variabile* (ATCC 32333) for Concrobium, by Peter Lea. Study conducted at umedik Inc.. Study completion date – May 19, 2005. Study Number 6353-Fabric.

This confirmatory study was conducted against *Aspergillus niger* (ATCC 6275) and *Penicillium variabile* (ATCC 32333). Three lots (Lot Nos. JJ040113-01/01/01, JJ040210-01/01/01, and JJ040628-01/01/02) of the product Siamons Mold Control were tested according to the test method as published in EPA's Pesticide Assessment Guidelines, Subdivision G: Product Performance, Section 93-15 (a) and 93-30 (I) (Item 1: Fabric Mildew Fungistatic Test Method, November 1982). Two lots (JJ040113-01/01/01 and JJ040210-01/01/01) were designated as the aged products (i.e., >60 days old). The product was received ready-to-use. The fungi were inoculated from stock cultures onto neopeptone agar plates and incubated at 25°C for eight days. Upon maturity, the spores were removed, and the suspensions were filtered through sterile cotton to remove the hyphae and hyphal fragments. Strips measuring 25 x 75 mm each were cut from unbleached cotton fabric. Each strip weighed ~ 0.27 grams (143.99 g/m^2) to conform to the EPA guidelines. All strips were autoclaved, with a subsequent soak in glycerol nutrient solution for 3 minutes. Each fabric strip was dried under sterile conditions before use. Ten dried, nutrient saturated fabric strips per lot were evaluated. Using a spray bottle, each lot of Siamons Mold Control was sprayed 4 to 5 times on both sides, from a distance of 6-8 inches, onto the fabric strips. The strips were hung in the sterile laminar air flow hood. Ten untreated fabric strips were sprayed with saline solution in place of the test agent for the untreated control. All samples were allowed to dry before inoculation. Equal volumes of 5 x 10^6 conidia/ml of *A. niger* and *P. variabile* were mixed together and agitated. Each side of each fabric strips was lightly sprayed to inoculate the mixed conidial suspension using a DeVilbiss atomizer. The fabric samples were suspended in individual 500 ml jars containing approximately 90 ml sterile water, and incubated at 28±2°C. Observations were made and recorded weekly for 4 weeks (minimally 7, 14, 21 and 28 days). The presence or absence of observable mold on the fabric strips was the criterion for determining the efficacy of the test agent. When no visible growth was evident at the end of the test period, the fabric strips were examined microscopically. Controls included those for purity and sterility. The reported growth percentages on **untreated control strips were 100%.**

Note: On my request, the applicant submitted, on November 27, 2006, first and fifth pages of the study report showing the study completion date of May 19, 2006.

Note: According to previous review, Siamons Mold Control is identical to Concrobium, the subject of the current efficacy review.

V. RESULTS

Siamons Mold Control, Lot JJ040113-01/01/01 (>60 days old)

MRID Number	Organisms	Carrier Number	Test Results – Visual/Microscopic Growth/Carrier				Control Inoculum (conidia/ml)
			Days				
			7	14	21	28	
469204-01	*A. niger* *P. variabile*	1-10	0%	0%	0%	0%	5.0×10^6 5.1×10^6

Note– Untreated controls 100% visual growth on each carrier.

Siamons Mold Control, Lot JJ040210-01/01/01 (>60 days old)

MRID Number	Organisms	Carrier Number	Test Results – Visual/Microscopic Growth/Carrier				Control Inoculum (conidia/ml)
			Days				
			7	14	21	28	
469204-01	*A. niger* *P. variabile*	1-10	0%	0%	0%	0%	5.0×10^6 5.1×10^6

Note– Untreated controls 100% visual growth on each carrier.

Siamons Mold Control, Lot JJ040628-01/01/02

MRID Number	Organisms	Carrier Number	Test Results – Visual/Microscopic Growth/Carrier				Control Inoculum (conidia/ml)
			Days				
			7	14	21	28	
469204-01	*A. niger* *P. variabile*	1-10	0%	0%	0%	0%	5.0×10^6 5.1×10^6

Note– Untreated controls 100% visual growth on each carrier.

VI. CONCLUSIONS

1. The submitted efficacy data (MRID # 469204-01) **support** the use of the product, Siamons Mold Control (ready-to-use), as a fungistat / mildewstat against *Aspergillus niger* and *Penicillium variabile* on surfaces composed of fabric in the absence of a soil load for a period of extended wetness. The study was not conducted according to GLP guidelines/recommendations (40 CFR 160), however the study deviation, in this case, was not significant.

VII. RECOMMENDATIONS

1. The proposed label claims that the product, Concrobium is an effective fungistat/mildewstat on fabrics when used as directed are **supported** by the applicant's data.

2. The proposed label claims that the product Concrobium is effective in preventing mold and mildew growth on wood, wallboard, concrete, and masonry (cinder) block, **are not supported** by any of the submitted data by the applicant. Acceptable efficacy data using "**Wood Block**

Mildew Fungistatic Test Method" must be submitted in order to keep those claims. **The applicant label claims for semi-porous and porous surfaces, wood, wallboard, concrete, and masonry (cinder) block, must be removed from the label.**

3. Mold remediation claims are not acceptable for the product Concrobium. **The applicant must remove mold remediation claims.**

4. The terms "**eliminates mold**", "**[stops]**", "**eliminates odor-causing particles**", "**[eliminating] [getting rid of]**", "**get[s] rid of mold**", and "**wipe[s] out mold**" (see pages 2 and 3 of the proposed label) are fund to be too strong for a fungistat/mildewstat product. **The applicant must remove those terms.**

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

- Remove "**all-in-one**" from the proposed label because it is used for **one-step** products.
- On page 4, remove **bed frames**, **chairs**, **desks**, and **slate** or **be more specific** on the surfaces.
- On page 5, remove "**most surfaces**".

Note to Product Manager: The recommendations were made after consultation with Michele Wingfield.