UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

May 13, 2009

MEMORANDUM

Subject: Efficacy Review for EPA Reg. No. 9009-16, SoWhite Ultra Brand and Disinfectant, DP Barcode: 364048

From: Tajah L. Blackburn, Ph.D., Microbiologist
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Product Science Branch
Antimicrobials Division (7510P)
5/15/09

Thru: Michele Wingfield, Chief
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To: Emily Mitchell PM 32/ Wanda Henson
Regulatory Management Branch II
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Applicant: OnLine Packaging, Inc.
4311 Plover Road
Plover, WI 544467

Formulation from the Label:

Active Ingredient(s)	% by wt.
Sodium Hypochlorite	6.0%
Other Ingredients	94.0%
Total	100.0%

I BACKGROUND

The product, SoWhite Brand Ultra Bleach and Disinfectant, (EPA Reg. No. 9009-16) is a registered disinfectant, non-food contact sanitizer, sanitizing rinse, and virucide. Two efficacy studies were provided to provide the registration to add claims for effectiveness as a non-food contact sanitizer and fungicide. Efficacy studies were conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, in Eagan, MN 55121.

The data package contained a letter from the registrant's representative (dated March 30, 2009), EPA Form 8570-34, EPA 8570-35, two efficacy studies (MRID Nos. 477191-01 and -02), and the proposed label.

II USE DIRECTIONS

Directions on the proposed label provided the following instructions for the preparation and use of the product as a non-food contact sanitizer and fungicide:

Non-food contact sanitizer

Rinse Method: Prepare sanitizing solution by thoroughly mixing 4 oz of this product with 10 gallons of water to provide approximately 200 ppm available chlorine by weight. Clean equipment surfaces in the normal manner. Prior to use, rinse all surfaces thoroughly with the sanitizing solution, maintaining contact with the sanitizer for at least 2 minutes. Do not rinse equipment with water after treatment and do not soak equipment overnight.

Immersion Method: Prepare sanitizing solution by thoroughly mixing in an immersion tank, 4 oz of this product with 10 gallons of water to provide approximately 200 ppm available chlorine by weight. Clean equipment in the normal manner. Prior to use, immerse equipment in the sanitizing solution for at least 2 minutes and allow the sanitizer to drain. Do not rinse equipment after treatment.

Spray/Fog Method: Pre-clean all surfaces after use. Prepare a 200 ppm available chlorine sanitizing solution of sufficient size by thoroughly mixing the product in a ratio of 4 oz product with 10 gallons of water. Use spray or fogging equipment, which can resist hypochlorite solutions. Prior to using equipment, thoroughly spray or fog all surfaces until wet, allowing excess sanitizer to drain. Vacate area for at least 2 hours.

Fungicidal directions were not included on the proposed label.

III AGENCY STANDARDS FOR PROPOSED CLAIMS

Sanitizers (For Non-Food Contact Surfaces)

The effectiveness of sanitizers for non-food contact surfaces must be supported by data that show that the product will substantially reduce the numbers of test bacteria on a treated surface. Testing requirements in EPA DIS/TSS-10 may be used. The test surface(s) should represent the types(s) of surfaces recommended for treatment on the label, i.e., porous or nonporous. Tests should be performed with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old against *Staphylococcus aureus* (ATCC 6538) and either *Klebsiella pneumoniae* (aberrant, ATCC 4352) or *Enterobacter aerogenes* (ATCC 13048 or 15038). Results must show a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes.

Disinfectants for Use as Fungicides (Against Pathogenic Fungi, Using the AOAC Germicidal Spray Products as Disinfectants Method)

The effectiveness of liquid disinfectants against specific pathogenic fungi must be supported by efficacy data using an appropriate test. The AOAC Germicidal Spray Products as Disinfectants Method contains procedures for testing fungicidal activity. Ten carriers on each of 2 product samples representing 2 different product lots must be employed in the test. Killing of the specific pathogenic fungi on all carriers is required.

Note: As an interim policy, the Agency is accepting studies with dried carrier counts that are at least 10^4 for *Trichophyton mentagrophytes*, *Aspergillus niger*, and *Candida albicans*. The Agency recognizes laboratories are experiencing problems in maintaining dried carrier counts at the 10^6 level. This interim policy will be in effect until the Agency determines that the laboratories are able to achieve consistent carrier counts at the 10^6 level.

IV SYNOPSIS OF SUBMITTED EFFICACY STUDIES

1. MRID No. 477191-01, "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces" Against *Staphylococcus aureus* and *Enterobacter aerogenes* using SoWhite 5.25% Bleach, by Amy Jeske. Study Completion Date—March 17, 2009. Project# A07428.

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048). Three lots (Lot Nos. 1, 2, and 3) of the product SoWhite 5.25% Bleach were tested according to the Standard Test Method for Efficacy of Sanitizers recommended for Inanimate Non-Food Contac Surfaces (ASTM E1153). One lot was ≥ 60 days old. The test substance was received ready-to-use. Organic soil (5%) was added to the test system. Each sterile glass carrier was inoculated with 0.02 ml of culture. The inoculated carriers were dried 35-37°C in the constant humidity chamber of 40±2% relative humidity with lids slightly open. The carriers were dried at this temperature and humidity for 20 minutes. Following the completion of drying, all

carriers were removed from the constant humidity chamber and transferred to individual sterile vessels using sterile forceps. Each teat carrier was medicated with 5.0 ml of the test substance using identical staggered intervals. The treated carriers were held at 20°C for a five minute exposure time. Following the contact time, 20 ml of the appropriate neutralizer solution was transferred to each vessel. The vessel was rotated vigorously on an even plane approximately 50 rotations to suspend the surviving organisms in the neutralizer solution. Each carrier was neutralized using identical staggered intervals, agitating each in turn. Within 30 minutes after neutralizing the carriers, 1 ml of the 10^0 and 10^{-1} dilutions of the neutralized solution was plated from each vessel in duplicate, using the standard spread plate technique and BAP plates for both organisms. The *S. aureus* plates were incubated at 35-37°C for 46 hours and the *E. aerogenes* plates at 25-30°C for 46 hours prior to observation for number of colonies. Controls included those for carrier quantitation, purity, sterility, neutralization confirmation, and inoculum count.

2. MRID No. 477191-02, "Fungicidal Use Dilution Method" Against *Trichophyton mentagrophytes* using SoWhite 5.25% Bleach, by Amy Jeske. Study completion date—March 17, 2009. Project# A077429.

This study was conducted against *Trichophyton mentagrophytes* (ATCC 9533). Two lots (Lot Nos. 1 and 2) of the products, SoWhite 5.25% Bleach, were testing using AOAC Use Dilution Method (modified for fungi). Organic soil load (5%) was added to the test system. The test substance was received ready-to-use. A culture of Trichophyton mentagrophytes was prepared by inoculating the appropriate number of Potato Dextrose agar plates and incubating the plates at 25-30°C for 10-15 days. The mycelia were removed from all plates using a sterile swab. The mycelia were transferred to a glass bottle containing approximately 20 sterile glass beads and saline/triton Solution (0.85% saline + 0.05% triton X-100), and hand swirled. The culture was filtered through sterile gauze to remove hyphal fragments. The conidial concentration was estimated by counting in a hemacytometer. Sterile penicylinders were immersed for 15 minutes in the conidial suspension at a ratio of 1 carrier per 1 ml suspension. The penicylinder were then dried on filter paper in a sterile Petri dish at 35-37°C for 40 minutes at a 41% relative humidity. For each test substance, 10 contaminated and dried carriers were individually transferred by hook needle at staggered intervals to individual tubes containing 10 ml of the test substance, and exposed for 5 minutes at 20°C. Following exposure, each exposed carrier was then transferred by hook needle at identical staggered intervals to 10 ml of neutralizing broth. Carriers were transferred from primary subculture tubes into individual secondary subculture tubes containing 10 ml of Sabouraud Dextrose broth, lecithin, and Tween 80 for ≥ 30 minutes following the first transfer. The neutralized subculture tubes were incubated for 10 days at 25-30°C. The agar subculture plates were incubated for 44-76 hours at 25-30°C. Following incubation, the subcultures were visually examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

V RESULTS

MRID Number	Organism	Lot No.	Average No. Surviving (CFU/carrier)	Parallel Control (CFU/carrier)	Percent Reduction
477191-01	*Staphylococcus aureus*	1	$<2.51 \times 10^1$	5.01×10^6	>99.9
		2	$<2.51 \times 10^1$	5.01×10^6	>99.9
		3	$<2.51 \times 10^1$	5.01×10^6	>99.9
	Enterobacter aerogenes	1	2.51×10^1	4.47×10^6	>99.9
		2	2.51×10^1	4.47×10^6	>99.9
		3	2.51×10^1	4.47×10^6	>99.9

MRID # 472415-16	Contact Time	No. Exhibiting Growth/Total No. Tested		Dried Carrier Count (CFU/ carrier)
		Lot 1	Lot 2	
Trichophyton mentagrophytes	**5 min**	**1°=0/10** **2°=0/10**	**1°=0/10** **2°=0/10**	1.92×10^6

VI CONCLUSIONS

1. The submitted efficacy study (MRID No. 477191-01) is acceptable regarding the use of the product, SoWhite 5.25% Bleach, as a non-food contact sanitizer against *Staphylococcus aureus* and *Enterobacter aerogenes* in presence of 5% organic soil load for a contact time of 5 minutes at the ready-to-use preparation. At least a 99.9% reduction in population was observed. At least one of the product lots tested was at least 60 days old at the time of testing. The carrier quantitation counts for the tested microorganisms met the laboratory acceptance criterion. Neutralization confirmation testing met the acceptance criterion of growth within 1 $\log_{10}$ of the numbers control. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth.

2. The submitted efficacy data (MRID 477191-02) is acceptable regarding the use of the product, SoWhite 5.25% Bleach, as a disinfectant with fungicidal activity against *Trichophyton mentagrophytes* in 5 minutes, at the ready-to-use preparation, on hard, non-porous surfaces in the presence of a 5% organic soil load at room temperature. Carrier counts for the tested microorganisms met the laboratory acceptance criterion.

VII RECOMMENDATIONS

1. The proposed label claims are unacceptable regarding the use of the product, SoWhite Brand Ultra Bleach and Disinfectant, as a non-food contact sanitizer on hard, non-porous surfaces for a contact time of 5 minutes in the presence of 5% organic soil load. Data was generated using SoWhite Bleach 5.25% Bleach (EPA Reg. No. 9006-15?). No additional information was provided to describe the tested product. The registrant must provide clarity regarding the tested product, and the product for which the claims are sought. Additionally, the proposed contact time for sanitization is 2 minutes. The submitted efficacy data was demonstrated a 5 minute contact time. Once the registrant provides the requested clarification, the label must be revised to reflect the data-supported contact time.

2. The proposed label was silent for fungicidal use directions against *Trichophyton mentagrophytes*. Consistent with the statements above data was generated using SoWhite Bleach 5.25% Bleach (EPA Reg. No. 9006-15?). No additional information was provided to describe the tested product. The registrant must provide clarity regarding the tested product, and the product for which the claims are sought. Once the registrant provides the requested clarification, the label must be revised to include data-supported use directions.

3. ATCC designation numbers are required in one of the following locations:

- on the data matrix;
- on the master label (as optional text) with the listing of the organisms claimed; or
- as the final page of the master label (as optional text).