



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

October 24, 2000

MEMORANDUM

Subject: Efficacy Review for 8383-3 Permacide Disinfectant and Sanitizer
DP Barcode: D267312

From: Ibrahim S. Barsoum, Ph.D., Microbiologist
Product Science Branch
Efficacy Evaluation Team
Antimicrobials Division (7510C)

Ibrahim S. Barsoum 10/24/00

To: Adam Heyward PM 34/Drusilla Copeland
Regulatory Management Branch II
Antimicrobials Division (7510C)

Thru: Emily Mitchell, M.S., Team Leader
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

Emily Mitchell 10/31/00

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

Applicant: Sporidicin International
Rockville, MD, USA

Formulation From Label:

<u>Active Ingredient(s)</u>	<u>% by wt</u>
Phenol.....	7.80%
Sodium Phenate.....	0.30%
<u>Inert Ingredient(s)</u>	<u>91.90%</u>
Total	100.000%

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BACKGROUND:

Product manager has requested to review the attached cover letter, label and efficacy data (MRID No.451504-01) submitted to support amendment by Sporocidin International to market the concentrate product of previously registered product "Sporocidin Disinfectant Solution" (EPA Registration No. 8383-3) under the product name "Permacide Disinfectant and Sanitizer." The marketed concentrate could be diluted 1part concentrate to 4 parts water to be used as a disinfectant or diluted 1 part concentrate to 14 parts water to be used as a sanitizer.

RECOMMENDATIONS: PSB findings are:

MRID # 451504-01

The submitted efficacy study was performed by Donna B. Suchmann of MicroBiotest Laboratories, 105B Carpenter Drive, Sterling, VA 20164 to determine the efficacy of Sporocidin Disinfectant Solution (EPA Registration No. 8383-3), lots no. 01393, 24381, and 16781 (60 days old) diluted 1 part to 2 parts of AOAC hard water as a sanitizer for non-food contact surfaces when tested against *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048) for 5 minutes contact time and in the presence of 5% horse serum.

Under the conditions of the experiment Sporocidin Disinfectant Solution (EPA Registration No. 8383-3), lots no. 01393, 24381, and 16781 (60 days old) diluted 1 part to 2 parts of AOAC hard water did demonstrate efficacy as a sanitizer for non-food contact surfaces ($> 5 \log_{10}$ reduction) when tested against *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048) for 5 minutes contact time in the presence of 5% organic soil.

LABEL CLAIMS:

The following label claims should be changed or removed from the label:

1. The word "New" must be removed from the label. This is not a new product.
2. Remove "Cleans air ducts" from the label.
3. Special Directions for HIV Claim should be added to the label.
4. Under the subtitle Disinfect and Deodorize: "Contains 1.62% active ingredients" should be changed to "Contains 1.56% active ingredients."
5. Under the subtitle Sanitize and Deodorize: "Contains 0.54% active ingredients" should be changed to "Contains 0.52% active ingredients."
6. Under the subtitle Disinfect and Deodorize: "Allow 1 to 10 minutes contact time" should be changed to "Allow 3 minutes contact time" which is the contact time accepted in previous label claims.
7. The word "non-porous" should be added to "hard, non-food surfaces such as....."

8. The label claim "Effective for cleaning, deodorizing, and decontaminating natural and synthetic fibers including carpets, textiles, mattressing and bedding" is not acceptable and should be removed from the label.

(C:\copies of reviews\Permacide Disinfectant and Sanitizer.wpd