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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

March 12, 1999

MEMORANDUM:

Subject: Efficacy Review for 42182-1/Microban Additive "B"
DP Barcode: D251051

From: Srinivas Gowda, MSc., M.A., Microbiologist *Srinivas Gowda*
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Applicant: Microban Products Company
Winston-Salem, NC

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
5-Chloro-2-(2,4 dichlorophenoxy)phenol.....	99.00
<u>Inert Ingredient(s):</u>	1.00
Total:	100.00

BACKGROUND: Product manager has requested review of Section IV, items 16 to 25 of Supplemental Literature & Data Packet (MRID No. 445145-01). Registrant requested PM to review these efficacy data. These data were not submitted by the registrant to support any label claims and therefore, no labeling was provided.

RECOMMENDATIONS:

- (16) AATCC Test Method 147 - Qualitative Antibacterial Assessment Test Results: Plastics, Fabrics, Multiple Washings

Claims for effectiveness at the bacteriostatic level (inhibition of growth) are not related to human health. Therefore the submitted zones of inhibition data were not reviewed or accepted. However, registrants are required to keep these data in their files. The Agency retains the right to call in such data any time.

- (17) AATCC Test Method 100 - Quantitative Antibacterial Assessment Test Results: Fabric

The submitted Screening or Presumptive Test data show 99.9% reduction of Staphylococcus aureus ATCC 6538 and Klebsiella pneumoniae ATCC 4352 at a contact time of 24 hours when treated Round Robin Sample #1 Acetate Wipe Fabric and Fabric Round Robin were tested by the AATCC Test Method 100-1993.

- (18) AATCC Test Method 30 - 1993 Fungal Resistance Test. Test Results: Part III Fabric, Part IV Fabric

The submitted mold/mildewstatic data against Aspergillus niger are considered to be not related to human health. Therefore, such data are not required to be submitted or reviewed. However, registrants are required to keep these data in their files. The Agency retains the right to call in such data any time.

- (19) AATCC Test Method 174 - Antimicrobial Activity Assessment of Carpets Test Results: Carpets.

AATCC Test Method 174, part I. Qualitative Assessment of Antibacterial Activity on Carpets: Single Streak Method.

Claims for effectiveness at the bacteriostatic level (inhibition of growth) are not related to human health. Therefore the submitted data were not reviewed or accepted. However, registrants are required to keep these data in their files. The Agency retains the right to call in such data any time.

AATCC Test Method 174, part II. Quantitative Assessment of Antibacterial Activity on Carpets.

The submitted Screening or Presumptive carpet sanitizing test data show 99.9% reduction of Staphylococcus aureus ATCC 6538 and Klebsiella pneumoniae ATCC 4352 at a contact time of 24 hours when treated Burlington-Lees carpet and Burlington carpet DK 166-4008, 286867 were tested by the

AATCC Test Method 174-1993.

AATCC Test Method 174, part III. Antifungal Activity Assessment of Carpet: Mildew and Rot Resistance.

The submitted mold/mildewstatic data against Aspergillus niger are considered to be not related to human health. Therefore, such data are not required to be submitted or reviewed. However, registrants are required to keep these data in their files. The Agency retains the right to call in such data any time.

(20) GSA Standards Test Results: Carpet

AATCC Test Method 100-1988 [GSA Test Requirements]

The submitted Screening or Presumptive carpet sanitizing test data show 99.9% reduction of Staphylococcus aureus ATCC 6538 and Klebsiella pneumoniae ATCC 4352 at a contact time of 24 hours when Microban Additive "B" treated Mohawk Carpet was tested by the AATCC Test Method 100-1988.

AATCC Test Method 30-1988, Part III [GSA Test Requirements]

The submitted mold/mildewstatic data against Aspergillus niger are considered to be not related to human health. Therefore, such data are not required to be submitted or reviewed. However, registrants are required to keep these data in their files. The Agency retains the right to call in such data any time.

(21) Kirby-Bauer Standard Antimicrobial Susceptibility Test. Test Results: Toys.

Claims for effectiveness at the bacteriostatic level (inhibition of growth) are not related to human health. Therefore the submitted data were not reviewed or accepted. However, registrants are required to keep these data in their files. The Agency retains the right to call in such data any time.

(22) Modified AATCC Test Method 100. Test Results: Tray Graphs.

The submitted Screening or Presumptive Test data show 99.9% reduction of Staphylococcus aureus ATCC 6538 and Klebsiella pneumoniae ATCC 4352 at a contact time of >4 hours when Hasbro treated polypropylene trays were tested by the AATCC Test Method 100-1993 (Modified).

The submitted Screening or Presumptive Test data show 99.9% reduction of Staphylococcus aureus ATCC 6538 and Klebsiella pneumoniae ATCC 4352 at a contact time of 24 hours when Hasbro treated springs were tested by the AATCC Test Method 100-1993 (Modified).

(23) ASTM Designation: G21-90 - Standard Practice for Determining Resistance of Synthetic Polymeric Materials to Fungi. Test Results: Toys.

The submitted mold/mildewstatic data against Aspergillus niger, Penicillium pinophilum, Chaetomium globosum, Trichoderma virens, and Aureobasidium pullulans are considered to be not related to human health. Therefore, such data are not required to be submitted or reviewed. However, registrants are required to keep these data in their files. The Agency retains the right to call in such data any time.

- (24) Modified AOAC Method 991.47 - Hard Surface Carrier Method. Test Results: Polyethylene Graph.

The submitted Screening or Presumptive Test data show significant reduction (57-86%) in the population of Staphylococcus aureus ATCC 6538 during the exposure period of 4-6 hours when Microban Additive "B" treated polyethylene square was tested by the Modified AOAC Hard Surface Carrier Test Method.

- (25) AOAC Official Method 960.09 - Germicidal and Detergent Sanitizing Action of Disinfectants. Test Results: Nonporous Food Contact Surfaces.

The submitted Screening or Presumptive Test data show significant reduction in the population of Staphylococcus aureus ATCC 6538 (99%), Escherichia coli (99.9%), Pseudomonas aeruginosa (98%) during the exposure period of 24 hours when Microban Additive "B" treated Absorbeeze All-Purpose Towels were tested by the Modified AOAC Germicidal and Detergent Sanitizer Test Method.

Also, the submitted Screening or Presumptive Test data show significant reduction in the population of Staphylococcus aureus ATCC 6538 (90%), Escherichia coli (94%), Pseudomonas aeruginosa (88%) during the exposure period of 24 hours when Microban Additive "B" treated White Plastic cutting Boards were tested by the Modified AOAC Germicidal and Detergent Sanitizer Test Method.

LABELING

No labeling was provided.

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