



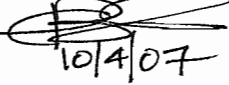
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

September 24, 2007

MEMORANDUM

Subject: Efficacy Review for EPA Reg. No. 72468-3, Moldwash Wood Preservative/ Mold Control; DP Barcode: 341642

From: Tajah L. Blackburn, Ph.D., Microbiologist 
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Michele Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510P)

To: Adam Heyward PM 34/ Stacey Grisby
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Mold Free, Inc.
9601 Wilshire Boulevard, Suite 620
Beverly Hills, CA 90210

Formulations from Label

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Disodium Octaborate Tetrahydrate (Na ₂ B ₈ O ₁₃ ·4H ₂ O).....	10% (12% BAE)*
<u>Other Ingredients</u>	90%
Total	100%

* 10% Disodium Octaborate Tetrahydrate—active ingredient is equivalent to 12% Boric Acid, Acid Equivalents-BAE

I BACKGROUND

The product, Moldwash Wood Preservative/ Mold Control (EPA Reg. No. 72468-3), is registered for "the preservation, protection and preventative treatment of wood against decay fungi mold and wood-destroying insects and for remedial control of such pests in infested wood" (per last accepted label, stamped May 3, 2007). This current data package is in response to the Agency letter (dated June 11, 2007). The registrant references a letter, in the current data package, detailing the purpose for this submission; however no such letter was located. Adam Heyward recalled that the purpose of this submission was to include the claim "Moldwash wet-wipes pre-moistened with MoldWash solution may be used to wipe clean mold and mildew stains on hard, non-porous surfaces."

The current data package includes a letter from the registrant (dated June 20, 2007), one efficacy study (MRID No. 471642-01), Attachment 2- Sponsor's Product Representation (dated November 8, 2004), the last accepted label (MAY 2, 2007), and the proposed label.

II USE DIRECTIONS

This product is used for preventative treatment of wood in existing structures (before the signs of infestation), for pre-treatment of wood during construction and for remedial treatment of wood infected with mold and fungus. This product is recommended for use on wood and cellulose materials in the form of bare wood, plywood, and particle where in intact water repellent barrier such as paint, stain or sealer is not present. Directions on the proposed label provided the following instructions for use of the ready-to-use preparation:

Remedial Application: Apply solutions by brush or spray until the wood surface is thoroughly wet, at the rate of approximately 1 gallon per 200 square feet of wood surface area. Spray evenly using a medium or coarse spray at low pressure (20-30 psi). Best results and penetration will be obtained when ambient temperatures are above 55°F. Do not spray frozen wood, painted or waterproofed surfaces.

Preventative Application: Apply solution to all accessible surfaces of bare wood at a rate of approximately 1 gallon per 200 square feet of wood surface area. Application should be performed after framing and roofing are in place and before drywall and insulation are installed. Protect wood from excessive rain.

III AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Use as Fungicides (Against Pathogenic Fungi, Using a Modified AOAC Use-Dilution Method)

The effectiveness of liquid disinfectants against specific pathogenic fungi must be supported by efficacy data using an appropriate test. The AOAC Use-Dilution Method may be modified to conform to the appropriate elements in the AOAC Fungicidal Test. The inoculum in the test must be modified to provide a concentration of at least 10^6 conidia per carrier. 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. These Agency standards are presented in DIS/TSS-6. As an interim policy, the Agency is accepting studies with dried carrier counts that are at least 10^4 for *Trichophyton mentagrophytes* and *Aspergillus niger*. 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.

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IV RESULTS

Efficacy data was not required to support claims. The efficacy study MRID No. 471642-01 was previously submitted (utilizing MRID No. 467361-01, January 20, 2006) to support claims for mold control.

V CONCLUSIONS/RECOMMENDATIONS

The proposed label addition is not acceptable. The currently registered public-health product is applied by brushing or spraying until the wood surface is thoroughly wet, at a rate of approximately 1 gallon per square feet using a medium or coarse spray. The addition of label directions for cleaning, to remove mold and mildew stains using pre-moistened wipes, require a separate Agency application/registration complete, as this is a non-public health claim and different application method.