

US EPA ARCHIVE DOCUMENT

## MEMORANDUM

DATE: March 14, 2006

SUBJECT: Efficacy Review for MoldWash, EPA File Symbol 72468-G,  
DP Barcode: D325923

FROM: CSC Systems & Solutions LLC

THRU: Wallace Powell  
Antimicrobials Division

TO: Nancy Whyte  
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APPLICANT: Mold Free, Inc.  
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### **I BACKGROUND**

The product, MoldWash (EPA File Symbol 72468-G), is new product. The applicant seeks to have the product approved for use as a fungicide and fungistat on wood and gypsum facing. The product is a "100% repackaging" of the registered product, Betanix Plus (EPA Reg. No. 72468-2). The study was conducted at SGS U.S. Testing Company, Inc., located at 75 Passaic Avenue in Fairfield, NJ 07004.

This data package contained a letter from the applicant to EPA (dated December 5, 2005), EPA Form 8570-1 (Application for Pesticide), EPA Form 8570-27 (Formulator's Exemption Statement), one study (MRID No. 467361-01), a Statement of No Data Confidentiality Claims for the study, and the proposed label. This data package also contains EPA Form 8570-4 (Confidential Statement of Formula) for the product, Betanix Plus.

Note: EPA Form 8570-4 (Confidential Statement of Formula) contains Confidential Business Information. Data or information claimed by the applicant to be FIFRA confidential has not been included in this report.

Note: CSS downloaded the last accepted label for the product, Betanix Plus (dated March 30, 2005) from the Internet.

### **II USE DIRECTIONS**

The product is designed to be used to control and prevent mold infestation of wood surfaces, such as bare siding, ceiling joists, decks, flooring, logs, rafters, trim, and trusses. The

label indicates that the product may be used on bare wood, plywood, particle board, and gypsum. Directions on the proposed label provided the following information regarding use of the product: Apply full-strength by brush or by spray until wood surfaces are thoroughly wet. Spray evenly using a medium or coarse sprayer at low pressure (20-30 psi). The product may also be applied as a foam or by injection.

### 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 type(s) of surfaces recommended for treatment on the label, i.e., porous or non-porous. Products that are represented as "one-step sanitizers" should be tested with an appropriate organic soil load, such as 5 percent serum. 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. These Agency standards are presented in DIS/TSS-10.

There are cases where an applicant requests to make claims of effectiveness against additional microorganisms for a product that is to be used as a sanitizer for non-food contact surfaces. The DIS/TSS standards are silent on this matter. Confirmatory test standards would apply. Therefore, 2 product samples, representing 2 different product lots, should be tested against each additional microorganism. Results must show a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes.

#### Products Controlling Microorganisms of Economic or Aesthetic Significance

Algaecides, slimicides, preservatives, deodorizers, and other products expressly claiming control of microorganisms of economic or aesthetic significance not directly related to human health do not require efficacy data. However, adequate dosage recommendations and complete directions for use must be provided in labeling. These Agency standards are presented in DIS/TSS-16.

### IV COMMENTS ON THE SUBMITTED EFFICACY STUDY

**1. MRID 467361-01 "Testing of MoldWash for the Evaluation of Fungicidal or Fungistatic Properties," by Lee Lam. Study conducted at SGS U.S. Testing Company, Inc. Study completion date – November 8, 2004. Report No. 001:008697/4.**

This study was conducted against *Aspergillus niger* (ATCC 6275) and *Stachybotrys chartarum* (ATCC 16026). Two lots (Lot Nos. 302111 and 403192) of the product, MoldWash,

were tested. The product was received ready-to-use. The laboratory report referenced the Sanitizer Test from DIS/TSS-10 and the Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-food Contact Surfaces (ASTM Method E1153). This method was used to assess the effectiveness of the product to reduce existing mold on glass, wood, and wallboard surfaces. A parallel test was performed using a method designed to determine the residual fungistatic effectiveness of the product on glass and wood surfaces. Controls included an untreated control and those for initial inoculum confirmation, viability, neutralizer effectiveness, and sterility.

For the fungicidal test, duplicate sterile carriers of glass, birch, and card stock (wallboard facing) per product lot per organism were inoculated with approximately  $1 \times 10^5$  spores of the test organism. The carriers, approximately 1x1 inch in size, were dried at 35°C for 30-45 minutes. The carriers were sprayed with the product at a distance of 6-8 inches until completely wet. Carriers were allowed to remain exposed to the product for 5, 10, 20, and 60 minutes. Carriers were then plate counted to determine the number of surviving organisms.

For the residual fungistatic test, ten (10) sterile carriers of glass and birch per product lot per organism were sprayed with the product at a distance of 6-8 inches until completely wet. The carriers, approximately 1x1 inch in size, were dried at 35-37°C for 45 minutes. After drying, each carrier was inoculated with approximately  $1 \times 10^5$  spores of the test organism and placed in a Petri dish over water agar. Carriers were incubated at 25-30°C and a relative humidity of 85-95%, and scored weekly on a scale of 0 (no growth) to 4 (heavy growth). If no growth was observed, carriers were re-inoculated and placed in new Petri dishes for a second and third week. Certain carriers were re-inoculated and placed in new Petri dishes for a fourth week.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

## V RESULTS

### A. Results from Fungicidal Testing

MRID Number	Organism	Lot No.	Time Period	Average No. Surviving	Microbes Initially Present	Percent Reduction *
				(CFU/carrier)		
467361-01	<i>Aspergillus niger</i> Glass slide carriers	302111	0 min	<20	$9.8 \times 10^5$	>99.9
			5 min	<20	$1.2 \times 10^5$	>99.9
			10 min	<20	$5.0 \times 10^4$	>99.9
			20 min	<20	$1.1 \times 10^4$	>99.8
			60 min	<20	$8.2 \times 10^3$	>99.8
467361-01	<i>Aspergillus niger</i> Glass slide carriers	403192	0 min	<20	$9.8 \times 10^5$	>99.9
			5 min	<20	$1.2 \times 10^5$	>99.9
			10 min	<20	$5.0 \times 10^4$	>99.9
			20 min	<20	$1.1 \times 10^4$	>99.8
			60 min	<20	$8.2 \times 10^3$	>99.8

MRID Number	Organism	Lot No.	Time Period	Average No. Surviving	Microbes Initially Present	Percent Reduction *
			(CFU/carrier)			
467361-01	<i>Aspergillus niger</i> Wood carriers	302111	0 min	<20	$3.0 \times 10^5$	>99.9
			5 min	<20	$3.0 \times 10^5$	>99.9
			10 min	<20	$2.8 \times 10^5$	>99.9
			20 min	<20	$3.2 \times 10^5$	>99.9
			60 min	<20	$3.0 \times 10^5$	>99.9
467361-01	<i>Aspergillus niger</i> Wood carriers	403192	0 min	<20	$3.0 \times 10^5$	>99.9
			5 min	<20	$3.0 \times 10^5$	>99.9
			10 min	<20	$2.8 \times 10^5$	>99.9
			20 min	<20	$3.2 \times 10^5$	>99.9
			60 min	<20	$3.0 \times 10^5$	>99.9
467361-01	<i>Aspergillus niger</i> Card stock carriers	302111	0 min	<20	$3.4 \times 10^5$	>99.9
			5 min	<20	$1.4 \times 10^5$	>99.9
			10 min	<20	$7.4 \times 10^6$	>99.9
			20 min	<20	$1.8 \times 10^5$	>99.9
			60 min	<20	$5.4 \times 10^4$	>99.9
467361-01	<i>Aspergillus niger</i> Card stock carriers	403192	0 min	<20	$3.4 \times 10^5$	>99.9
			5 min	<20	$1.4 \times 10^5$	>99.9
			10 min	<20	$7.4 \times 10^6$	>99.9
			20 min	<20	$1.8 \times 10^5$	>99.9
			60 min	<20	$5.4 \times 10^4$	>99.9
467361-01	<i>Stachybotrys chartarum</i> Glass slide carriers	302111	0 min	<20	$1.3 \times 10^5$	>99.9
			5 min	<20	$1.1 \times 10^5$	>99.9
			10 min	<20	$1.2 \times 10^5$	>99.9
			20 min	<20	$1.4 \times 10^5$	>99.9
			60 min	<20	$1.1 \times 10^5$	>99.9
467361-01	<i>Stachybotrys chartarum</i> Glass slide carriers	403192	0 min	<20	$1.3 \times 10^5$	>99.9
			5 min	<20	$1.1 \times 10^5$	>99.9
			10 min	<20	$1.2 \times 10^5$	>99.9
			20 min	<20	$1.4 \times 10^5$	>99.9
			60 min	<20	$1.1 \times 10^5$	>99.9
467361-01	<i>Stachybotrys chartarum</i> Wood carriers	302111	0 min	<20	$8.1 \times 10^5$	>99.9
			5 min	<20	$9.8 \times 10^5$	>99.9
			10 min	<20	$1.1 \times 10^6$	>99.9
			20 min	<20	$5.3 \times 10^5$	>99.9
			60 min	<20	$9.3 \times 10^4$	>99.9
467361-01	<i>Stachybotrys chartarum</i> Wood carriers	403192	0 min	<20	$8.1 \times 10^5$	>99.9
			5 min	<20	$9.8 \times 10^5$	>99.9
			10 min	<20	$1.1 \times 10^6$	>99.9
			20 min	<20	$5.3 \times 10^5$	>99.9
			60 min	<20	$9.3 \times 10^4$	>99.9

MRID Number	Organism	Lot No.	Time Period	Average No. Surviving	Microbes Initially Present	Percent Reduction *
			(CFU/carrier)			
467361-01	<i>Stachybotrys chartarum</i> Card stock carriers	302111	0 min	<20	$7.2 \times 10^4$	>99.9
			5 min	<20	$9.6 \times 10^4$	>99.9
			10 min	<20	$1.1 \times 10^5$	>99.9
			20 min	<20	$9.2 \times 10^4$	>99.9
			60 min	<20	$7.3 \times 10^4$	>99.9
467361-01	<i>Stachybotrys chartarum</i> Card stock carriers	403192	0 min	<20	$7.2 \times 10^4$	>99.9
			5 min	<20	$9.6 \times 10^4$	>99.9
			10 min	<20	$1.1 \times 10^5$	>99.9
			20 min	<20	$9.2 \times 10^4$	>99.9
			60 min	<20	$7.3 \times 10^4$	>99.9

\* Percent reductions reported in the laboratory report (assigned MRID No. 467361-01) were calculated using the mean untreated control count, 0-60 minutes. Percent reductions reported in this table were calculated using the untreated control count and organism count for a given time period (i.e., untreated control count for 10 minute-time period and organism count for 10-minute time period).

#### B. Results from Residual Fungistatic Testing

In the tables below, no growth is rated as (0) and heavy growth is rated as (4).

MRID Number	Organism	% Growth											
		Lot No. 302111						Lot No. 403192					
		Day 14		Day 21		Day 28		Day 14		Day 21		Day 28	
Carrier (Wood or Glass)		W	G	W	G	W	G	W	G	W	G	W	G
467361-01	<i>Aspergillus niger</i>	1	0	0	1	0	4	1	0	0	1	0	1
		0	0	0	1	3	2	0	0	0	1	0	0
		0	0	0	1	0	1	0	0	0	1	0	0
		0	0	0	1	0	0	0	0	0	1	0	0
		0	0	0	1	0	0	0	0	0	1	0	0
		0	0	0	1	0	1	0	0	0	1	0	0
		0	0	0	1	0	0	0	0	0	1	0	1
		0	0	0	1	0	2	0	0	0	1	0	0
		1	0	0	1	1	2	1	0	0	1	1	2
		1	0	0	1	0	3	1	0	0	1	1	0

Note: Data for studies against *Aspergillus niger* for Day 7 were also reported in the laboratory report (assigned MRID No. 467361-01), but have not been reported here. Untreated control carriers showed heavy growth.

MRID Number	Organism	% Growth											
		Lot No. 302111						Lot No. 403192					
		Day 14		Day 21		Day 28		Day 14		Day 21		Day 28	
Carrier (Wood or Glass)		W	G	W	G	W	G	W	G	W	G	W	G
467361-01	<i>Stachybotrys chartarum</i>	0	1	2	2	2	2	0	0	1	0	1	0
		0	1	1	2	1	2	0	0	0	1	1	1
		0	1	1	2	2	2	0	0	0	0	0	0
		0	1	1	3	1	3	0	0	0	1	0	1
		0	1	1	3	2	3	0	1	0	1	0	1
		0	1	1	2	2	2	0	1	0	3	0	0
		0	1	0	1	1	2	0	1	0	1	0	0
		0	1	0	3	1	3	0	0	1	0	1	1
		0	1	1	1	1	2	0	0	1	0	1	1
		0	1	0	2	0	2	0	1	1	2	1	2

Note: Data for studies against *Stachybotrys chartarum* for Day 7 were also reported in the laboratory report (assigned MRID No. 467361-01), but have not been reported here. Untreated control carriers showed heavier growth than the treated carriers.

## VI CONCLUSIONS

1. The submitted efficacy data (MRID No. 467361-01) appear to support the use of the product, MoldWash, as a sanitizer on non-food contact, glass, wood, and wallboard surfaces against *Aspergillus niger* and *Stachybotrys chartarum* for a contact time of 5 minutes at full strength. A 99.9% reduction in population was observed for a 5-minute contact time. There are two concerns regarding the laboratory report, which cause the validity of the results to be questioned. First, the laboratory report does not confirm whether a neutralizer was added to the carriers after the exposure time. The protocol mentions the use of a neutralizer to recover organisms from the tested carriers; however, the laboratory report does not describe a product neutralization step. Second, test results provided for the exposure period of 0 minutes are unexpected. These results show the number of surviving organisms to be <20 CFU/carrier (i.e., a 99.9% reduction), which implies immediate kill.

Neutralization test results indicated a satisfactory recovery of low-level inoculum. Viability controls were positive for growth. Sterility testing was conducted.

2. The submitted efficacy data (MRID No. 467361-01) support the use of the product MoldWash, as a residual fungistat against *Aspergillus niger* and *Stachybotrys chartarum* on glass and wood surfaces. Relatively no growth of *Aspergillus niger* was observed 21 days after glass and wood surfaces had been treated with the product. Relatively no growth of *Stachybotrys chartarum* was observed 14 days after glass and wood surfaces had been treated with the product. Untreated control carriers exhibited growth of *Aspergillus niger* and *Stachybotrys chartarum* on treated carriers.

## VII RECOMMENDATIONS

1. The proposed label claims that the product, MoldWash, can be used for the remedial control of mold, fungi, and black molds. No contact time is specified. Dosage recommendations are provided. Data provided by the applicant appear to support these claims. As discussed in the Conclusions Section of this report, the validity of the efficacy data is questionable. The applicant needs to confirm whether fungicidal testing of the product included a step to neutralize the product, and needs to discuss the results of testing conducted at a 0-minute time period.
2. The proposed label claims that the product, MoldWash, can protect treated wood and gypsum facing against mold infestation. Data provided by the applicant support this claim.