FINAL STUDY REPORT

STUDY TITLE

Fungicidal Germicidal Spray Method

Test Organism:

Stachybotrys chartarum (ATCC 66239)

PRODUCT IDENTITY

MDF-200 Batch No: AWC03-806 Part A-Lot 1 + MDF-200 Batch No: BWC04-806 Part B-Lot 1
and
MDF-200 Batch No: AWC03-706 Part A-Lot 2 + MDF-200 Batch No: BWC04-709 Part B-Lot 2

DATA REQUIREMENTS

U.S. EPA 40 CFR Part 158
"Data Requirements for Registration"
Pesticide Assessment Guidelines - Subdivision G, Section 91-2 (e)

AUTHOR

Anne Stemper, B.S.
Study Director

STUDY COMPLETION DATE

October 3, 2006

PERFORMING LABORATORY

ATS Labs
1285 Corporate Center Drive, Suite 110
Eagan, MN 55121

SPONSOR

Modec, Inc.
4725 Oakland Street
Denver, CO 80239

PROJECT NUMBER

A04221

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA Section 10 (d) (1) (A), (B), or (C).

Company: Modec, Inc.

Company Agent: BRIAN J. KALAMANKA

PRESIDENT & CEO
Title

Signature

Date: 04 OCT 2006

GOOD LABORATORY PRACTICE STATEMENT

The study referenced in this report was conducted in compliance with U.S. Environmental Protection Agency Good Laboratory Practice (GLP) regulations set forth in 40 CFR Part 160.

The studies not performed by or under the direction of ATS Labs are exempt from this Good Laboratory Practice Statement and include: characterization and stability of the compound(s).

Submitter: MODEC, INC. Date: 04-OCT-2006

Sponsor: Date: 04-OCT-2006

Study Director: Date: 10-3-06
Anne Stemper, B.S.

QUALITY ASSURANCE UNIT SUMMARY

Study: Fungicidal Germicidal Spray Method

The objective of the Quality Assurance Unit is to monitor the conduct and reporting of non-clinical laboratory studies. These studies have been performed under Good Laboratory Practice regulations (40 CFR Part 160) and in accordance to standard operating procedures and standard protocols. The Quality Assurance Unit maintains copies of study protocols and standard operating procedures and has inspected this study on the dates listed below. Studies are inspected at time intervals to assure the integrity of the study.

Phase Inspected	Date	Study Director	Management
Critical Phase	September 13, 2006	September 13, 2006	October 3, 2006
Final Report	October 2, 2006	October 2, 2006	

The findings of these inspections have been reported to management and the Study Director.

Quality Assurance Auditor: K. Igdal Date: 10-03-06

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STUDY PERSONNEL

STUDY DIRECTOR: Anne Stemper, B.S.

Professional personnel involved:

David Rottjakob, M.T.	- Director, Microbiology Services
Scott R. Steinagel, B.S.	- Microbiology Laboratory Supervisor
Adam W. Pitt, B.S.	- Research Assistant II
Matthew Sathe, B.S.	- Research Assistant I
Peter Toll, B.S.	- Research Assistant I
Lisa Slusser, B.S.	- Research Assistant I
Katherine C. Sager, B.S.	- Research Assistant I

STUDY REPORT

GENERAL STUDY INFORMATION

Study Title: Fungicidal Germicidal Spray Method

Project Number: A04221

Protocol Number: MOD02080206.FGS

Sponsor: Modec, Inc.
4725 Oakland Street
Denver, CO 80239

Test Facility: ATS Labs
1285 Corporate Center Drive, Suite 110
Eagan, MN 55121

TEST SUBSTANCE IDENTITY

Test Substance Name: MDF-200

Lot/Batch(s): MDF-200 Batch No: AWC03-806 Part A-Lot 1 + MDF-200 Batch No: BWC04-806 Part B-Lot 1
and
MDF-200 Batch No: AWC03-706 Part A-Lot 2 + MDF-200 Batch No: BWC04-709 Part B-Lot 2

Test Substance Characterization
Test substance characterization as to content, stability, etc., (40 CFR, Part 160, Subpart F [160.105]) is the responsibility of the Sponsor.

STUDY DATES

Date Sample Received: August 15, 2006
Study Initiation Date: August 22, 2006
Experimental Start Date: September 13, 2006
Experimental End Date: September 25, 2006
Study Completion Date: October 3, 2006

OBJECTIVE

The objective of this assay was to determine the effectiveness of spray products as disinfectants for contaminated surfaces in compliance with the U.S. Environmental Protection Agency requirements set forth in the Pesticide Assessment Guidelines.

SUMMARY OF RESULTS

Test Substance:	MDF-200 Batch No: AWC03-806 Part A-Lot 1 + MDF-200 Batch No: BWC04-806 Part B-Lot 1 and MDF-200 Batch No: AWC03-706 Part A-Lot 2 + MDF-200 Batch No: BWC04-709 Part B-Lot 2
Dilution:	Equal parts (50%) of each lot of Part A and Part B
Test Organism:	*Stachybotrys chartarum* (ATCC 66239)
Exposure Time:	Ten minutes
Exposure Temperature:	Room Temperature (24.7°C)
Efficacy Result:	MDF-200 demonstrated efficacy of two batches against *Stachybotrys chartarum*, and therefore, meets the requirements set forth by the U.S. EPA for disinfectant label claims following a ten minute exposure period.

STUDY MATERIALS

Test System/Growth Media

Test Organism	ATCC #	Growth Medium
Stachybotrys chartarum	66239	Potato Dextrose Agar

The microorganism used in this study was obtained from the American Type Culture Collection, Manassas, Virginia.

Recovery Media

Neutralizing Subculture Medium:	Primary Neutralizer: Tryptic Soy Broth + 0.14% Lecithin + 1.0% Tween 80 + 0.05% Catalase Secondary Neutralizer: Tryptic Soy Broth
Agar Plate Medium:	Potato Dextrose Agar

Carriers

Glass slides (18 mm x 36 mm) were utilized as the carrier for this assay. The carriers were placed into a vessel and sterilized in an air oven for two hours at approximately 180°C. Using a biological safety hood, individual sterile plastic petri dishes were matted with two pieces of filter paper. One sterile glass slide was transferred into each of the matted petri dishes.

TEST METHOD

Preparation of the Test Substance

A 50% A + 50% B dilution was made for each lot of test substance using 50.0 mL of Part A and 50.0 mL of Part B. Each prepared test substance was homogenous as determined by visual observation and was used within three hours of preparation.

Preparation of the Conidial Suspension

Sterile filter paper was placed on the surface of the potato dextrose agar prior to inoculation. The exposed surface of the filter paper was inoculated with a culture of *Stachybotrys chartarum* and incubated 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 beads and sterile saline/Triton Solution (0.85% Saline + 0.05% Triton X-100) and shaken thoroughly. The culture was filtered through sterile gauze to remove hyphal fragments. The conidial concentration was estimated by counting in a hemacytometer.

Contamination of the Carriers

The conidial suspension was thoroughly mixed. Individual glass slide carriers were each inoculated with 0.01 mL conidial suspension using a calibrated pipettor. The inoculum was uniformly spread over the test surface of the slide contained in the petri dish. The dish was covered immediately and the procedure repeated until all slides were individually inoculated. The slides were allowed to dry for 30 minutes at 35-37°C and 40% humidity.

Exposure Conditions

Dried fungal films were sprayed individually at staggered intervals with the test substance until wet, at a distance of 6 inches above the carrier. Each carrier remained in contact with the prepared test substance for ten minutes at room temperature (24.7°C).

Test System Recovery

Following the exposure period, the remaining liquid was drained off. Each medicated carrier was then transferred using sterile forceps at identical staggered intervals to 20 mL aliquots of Tryptic Soy Broth + 0.14% Lecithin + 1.0% Tween 80 + 0.05% Catalase. The carriers were transferred from the primary subcultures into individual secondary subcultures containing 20 mL aliquots of Tryptic Soy Broth ≥30 minutes following the subculture of first carrier.

Incubation and Observation

The neutralized subcultures broths were incubated for 10 days at 25-30°C. The agar plate subcultures were incubated for 68 hours at 25-30°C. The subcultures were refrigerated at 2-8°C for two days prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth.

STUDY CONTROLS

Purity Control

A "streak plate for isolation" was performed on the organism culture and following incubation examined in order to confirm the presence of a pure culture. The acceptance criterion for this study control is a pure culture demonstrating colony morphology typical of the test organism.

Carrier Sterility Control

A representative uninoculated carrier was added to the neutralizing subculture medium. The subculture medium containing the carrier was incubated and examined for growth. The acceptance criterion for this study control is lack of growth.

Neutralizing Subculture Medium Sterility Control

A representative sample of uninoculated neutralizing subculture medium was incubated and visually examined. The acceptance criterion for this study control is lack of growth.

Viability Control

A representative inoculated carrier was added to the subculture medium. The subculture medium containing the carrier was incubated and visually examined for growth. The acceptance criterion for this study control is growth.

Neutralization Confirmation Control

The neutralization of the test substance was confirmed by exposing sterile carriers (representing not less than 10% of the total number of test carriers) to the test substance and transferring them to primary subcultures containing 20 mL of neutralizing subculture medium. Carriers were then transferred from primary subcultures into individual secondary subcultures ≥30 minutes following the primary transfer. The secondary subcultures were inoculated with ≤100 colony forming units (CFU) of each test organism, incubated under test conditions and visually examined for the presence of growth. This control was performed with multiple replicates using different dilutions of the test organism. A standardized spread plate procedure was run concurrently in order to enumerate the number of CFU actually added. The control result was reported using data from the most appropriate dilution.

The acceptance criterion for this study control is growth of subcultures containing the carrier following inoculation with ≤100 CFU.

Carrier Population Control

Inoculated carriers were added at a ratio of 1 carrier to 10 mL neutralizing broth and vortex mixed. Appropriate serial ten-fold dilutions were prepared and the aliquots were spread plated on agar plate medium, and incubated. Following incubation, the resulting colonies were enumerated and the CFU/carrier calculated. The acceptance criterion for this study control is a minimum of 1.0×10^4 CFU/carrier.

STUDY ACCEPTANCE CRITERIA

Test Substance Performance Criteria
The EPA efficacy performance requirements for label claims state that the disinfectant must kill the microorganism on 10 out of the 10 inoculated carriers.

Control Acceptance Criteria
The study controls must perform according to the criteria detailed in the study controls description section.

PROTOCOL CHANGES

Protocol Amendments:
No protocol amendments were required for this study.

Protocol Deviations:
The protocol specified that the test substance was to be sprayed until the test carriers appeared thoroughly wet and the amount of time for this to occur was to be recorded. During testing, the carriers appeared thoroughly wet after three pumps from the spray bottle, however, the amount of time (seconds) to achieve thorough wetness was not recorded, thus resulting in a protocol deviation. This deviation did not have an impact on the outcome of the study because the carriers were treated until thoroughly wet per the protocol.

DATA ANALYSIS

Calculations

Carrier Population Control Calculation:

$$\text{carrier population, CFU/carrier} = \frac{\text{(average number colonies/plate @ dilution) x (dilution factor) x (volume neutralizer)}}{\text{(number of carriers tested) x (volume plated)}}$$

The carrier population was calculated and reported using data from the most appropriate dilution(s).

Statistical Analysis
None used.

STUDY RETENTION

Record Retention
All of the original raw data developed exclusively for this study shall be archived at ATS Labs, 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121. These original data include, but are not limited to, the following:

1. All handwritten raw data for control and test substances including, but not limited to, notebooks, data forms and calculations.
2. Any protocol amendments/deviation notifications.
3. All measured data used in formulating the final report.
4. Memoranda, specifications, and other study specific correspondence relating to interpretation and evaluation of data, other than those documents contained in the final study report.
5. Original signed protocol.
6. Certified copy of final study report.
7. Study-specific SOP deviations made during the study.

Test Substance Retention
The test substance will be discarded following study completion per Sponsor approved protocol. It is the responsibility of the Sponsor to retain a sample of the test material.

REFERENCES

1. Association of Official Analytical Chemists (AOAC), 2000. Germicidal Spray Products as Disinfectants, 961.02. *In* Official Methods of Analysis of the AOAC, Chapter 6, Seventeenth Edition.

2. Association of Official Analytical Chemists (AOAC), 1990. Germicidal and Detergent Sanitizing Action of Disinfectants, p. 139 [Preparation of Synthetic Hard Water]. *In* Official Methods of Analysis of the AOAC, Fifteenth Edition.

3. Association of Official Analytical Chemists (AOAC), 1995. Fungicidal Activity of Disinfectants, 955.17. *In* Official Methods of Analysis of the AOAC, Chapter 6, Sixteenth Edition.

4. U.S. Environmental Protection Agency, Registration Division, Office of Pesticide Programs, 1982. Efficacy Data Requirements, Disinfectants for Use on Hard Surfaces, DIS/TSS-1.

5. U.S. Environmental Protection Agency, Registration Division, Office of Pesticide Programs, 1979. Efficacy Data Requirements, Supplemental Recommendations, DIS/TSS-2.

6. U.S. Environmental Protection Agency, Registration Division, Office of Pesticide Programs, 1982. Subseries 91A: Public Health Uses. *In* Pesticide Assessment Guidelines – Subdivision G (Product Performance).

RESULTS

For Control and Neutralization Results, see Tables 1-3
All data measurements including the culture purity, viability, neutralizing subculture medium sterility, carrier sterility, neutralization confirmation, and carrier population controls were within acceptance criteria.

For Test Results, see Table 4.

ANALYSIS

MDF-200 Batch No: AWC03-806 Part A-Lot 1 + MDF-200 Batch No: BWC04-806 Part B-Lot 1 and MDF-200 Batch No: AWC03-706 Part A-Lot 2 + MDF-200 Batch No: BWC04-709 Part B-Lot 2, a pump spray product, demonstrated no growth of *Stachybotrys chartarum* (ATCC 66239) in any of the 10 primary subcultures and no growth in any of the 10 secondary subcultures following a ten minute exposure period.

STUDY CONCLUSION

Under the conditions of this investigation, MDF-200 Batch No: AWC03-806 Part A-Lot 1 + MDF-200 Batch No: BWC04-806 Part B-Lot 1 and MDF-200 Batch No: AWC03-706 Part A-Lot 2 + MDF-200 Batch No: BWC04-709 Part B-Lot 2, a pump spray product, demonstrated efficacy against *Stachybotrys chartarum* as required by the U.S. EPA for disinfectant label claims following a ten minute exposure period.

In the opinion of the Study Director, there were no circumstances that may have adversely affected the quality or integrity of the data.

TABLE 1: CONTROL RESULTS

The following results from controls confirmed study validity:

Type of Control		Results
		***Stachybotrys chartarum* (ATCC 66239)**
Purity Control		Pure
Viability Control		Growth
Carrier Sterility Control		No Growth
Neutralizing Subculture Medium Sterility Control	Primary	No Growth
	Secondary	No Growth

TABLE 2: CARRIER POPULATION CONTROL RESULTS

Test Organism	Date Performed	Result
Stachybotrys chartarum (ATCC 66239)	9-13-06	1.0×10^4 CFU/carrier

TABLE 3: NEUTRALIZATION CONFIRMATION CONTROL RESULTS

Test Substance	Test Organism	Date Performed	Inoculum (CFU)	Number Subcultures	
				Tested	Positive
MDF-200 Batch No.: AWC03-806 Part A-Lot 1 + MDF-200 Batch No.:BWC04-806 Part B-Lot 1	*Stachybotrys chartarum* (ATCC 66239)	9-13-06	20	1	1
MDF-200 Batch No.: AWC03-706 Part A-Lot 2 + MDF-200 Batch No.:BWC04-709 Part B-Lot 2				1	1

CFU = Colony Forming Unit

TABLE 4: TEST RESULTS

Test Substance	Test Organism	Date Performed	Sample Dilution*	Number of Carriers	
				Exposed	Showing Growth**
MDF-200 Batch No.: AWC03-806 Part A-Lot 1 + MDF-200 Batch No.:BWC04-806 Part B-Lot 1	*Stahcybotrys chartarum* (ATCC 66239)	9-13-06	Equal parts (50%) of each lot of Part A and Part B	1°=10 2°=10	1°=0 2°=0
MDF-200 Batch No.: AWC03-706 Part A-Lot 2 + MDF-200 Batch No.:BWC04-709 Part B-Lot 2				1°=10 2°=10	1°=0 2°=0

* Sample mixed in equal parts
** Number of carriers showing growth of the test organism
1° Primary subculture
2° Secondary subculture