FINAL STUDY REPORT

STUDY TITLE

AOAC Fungicidal Activity Method

Test Organism:

Penicillium variabile (ATCC 52262)

PRODUCT IDENTITY

MDF-500 Parts A & B
Lot 1: Batch AZA-30 + Batch BZB-30 and Lot 2: Batch AXA-02 + Batch BXB-02

DATA REQUIREMENTS

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

AUTHOR

Amy S. Jeske, B.S.
Study Director

STUDY COMPLETION DATE

March 22, 2007

PERFORMING LABORATORY

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

SPONSOR

Modec, Inc.
4725 Oakland Street
Denver, CO 80239

SPONSOR REPRESENTATIVE

Ag-Chem Consulting
12208 Quinque Lane
Clifton, VA 20124

PROJECT NUMBER

A04727

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: James E. Tellman

CFO

Title

Signature

Date: 3/25/07

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: James E. Tellman Date: 3/25/07

Sponsor: _____ Date: _____

Study Director: Amy S. Jeske, B.S. Date: 3/22/07

QUALITY ASSURANCE UNIT SUMMARY

Study: AOAC Fungicidal Activity 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	March 7, 2007	March 7, 2007	March 22, 2007
Final Report	March 22, 2007	March 22, 2007	

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

Quality Assurance Auditor: Brenda Sr Date: 3/22/07

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STUDY PERSONNEL

STUDY DIRECTOR: Amy S. Jeske, B.S.

Professional personnel involved:

David Rottjakob, M.T.	- Director, Microbiology Services
Scott R. Steinagel, B.S.	- Microbiology Laboratory Supervisor
Jill Ruhme, B.S.	- Research Scientist I
Matthew Sathe, B.S.	- Research Assistant I
Peter Toll, B.S.	- Research Assistant I
Katherine C. Sager, B.S.	- Research Assistant I

STUDY REPORT

GENERAL STUDY INFORMATION

Study Title: AOAC Fungicidal Activity Method

Project Number: A04727

Protocol Number: MOD02012507.FACT.2

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

Sponsor Representative:
Ag-Chem Consulting
12208 Quinque Lane
Clifton, VA 20124

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

TEST SUBSTANCE IDENTITY

Test Substance Name: MDF-500 Parts A & B

Lot/Batch(s): Lot 1: Batch AZA-30 + Batch BZB-30 and Lot 2: Batch AXA-02 + Batch BXB-02

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: February 12, 2007
Study Initiation Date: February 16, 2007
Experimental Start Date: March 7, 2007
Experimental End Date: March 19, 2007
Study Completion Date: March 22, 2007

OBJECTIVE

The objective of this study was to determine the efficacy of the Sponsor's product for fungicidal disinfection of inanimate objects.

SUMMARY OF RESULTS

Test Substance:	MDF-500 Parts A & B (Lot 1: Batch AZA-30 + Batch BZB-30 and Lot 2: Batch AXA-02 + Batch BXB-02)
Dilution:	Combine equal parts of Part A with Part B and mix well
Test Organism:	*Penicillium variabile* (ATCC 52262)
Exposure Temperature:	20±2°C
Organic Soil Load:	None required
Efficacy Result:	MDF-500 Parts A & B demonstrated efficacy of two lots against *Penicillium variabile* as required by the U.S. EPA for fungicidal label claims following the 5 and 10 minute exposure times.

STUDY MATERIALS

Test System/Growth Media

Test Organism	ATCC #	Growth Medium
Penicillium variabile	52262	Sabouraud Dextrose Agar

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

Recovery Media

Neutralizing Subculture Medium:	Sabouraud Dextrose Broth with 0.14% Lecithin, 1.0% Tween 80 and 0.05% Catalase
Agar Plate Medium:	Sabouraud Dextrose Agar

TEST METHOD

Preparation of Test Organism

A culture of *Penicillium variabile* was prepared by inoculating multiple plates of Sabouraud Dextrose Agar at center and incubating at 25-30°C for 10-15 days. The mycelia were removed from all plates by adding approximately 1-3 mL of sterile saline/Triton solution (0.85% Saline + 0.05% Triton X-100) and swabbing with a sterile swab. The liquid was collected from the plate using a pipet and transferred to a glass bottle containing beads and sterile saline/Triton Solution (0.85% Saline + 0.05% Triton X-100) and thoroughly mixed. The culture was filtered through sterile gauze to remove hyphal fragments. The conidial concentration was estimated by counting in a hemacytometer. The count was 2×10^8 conidia/mL. The suspension was standardized by dilution to achieve $\geq 5 \times 10^6$ conidia/mL.

Preparation of Test Substance
The test substance was prepared by mixing 3.0 mL of Part A with 3.0 mL of Part B for each lot. The test substance was homogenous as determined by visual observation.

Five (5.0) mL aliquots of the test substance at the concentration under test were transferred to sterile 25 x 150 mm tubes, placed in a 20±2°C water bath and allowed to equilibrate for ≥10 minutes.

Inoculation of Test Substance
A volume of 0.50 mL of the test organism suspension was added to the tubes containing 5.0 mL of each lot of test substance at 20±2°C (20.0°C). To inoculate the test substance, the tube was removed from the water bath and slanted slightly. The pipette was then inserted into the tube and the suspension was added without touching pipette into the fluid. The tube was agitated gently after adding the suspension and replaced into the water bath.

Subculture of Test Substance
Exactly 5 minutes after transfer of organism suspension to each test substance, a 4 mm loop was inserted into the slanted tube (60° angle) and sample was withdrawn without touching tube walls or lip. One loopful was transferred to an appropriately labeled subculture tube containing 10 mL of broth media. Subcultures were repeated beginning at exactly 10 minutes and once again at exactly 15 minutes after transfer of culture to the test substance.

Incubation and Observation
Subculture plates were incubated for 44-76 hours at 25-30°C. Subculture tubes were incubated for 10 days at 25-30°C. The subculture tubes were stored at 2-8°C for two days prior to examination Following incubation, or incubation and storage the subculture tubes were visually examined for growth.

STUDY CONTROLS

Purity Control
A "streak plate for isolation" was performed on the organism culture and following incubation it was 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.

Viability Control
One loopful of the conidial suspension was transferred to a tube of subculture broth to demonstrate culture viability. The acceptance criterion for this study control is growth.

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

Initial Suspension
This suspension was serially diluted and plated using standard microbiological techniques. Following incubation at 25-30°C for 44-76 hours, the organism plates were observed to enumerate the concentration of the test organism present at the time of testing. The acceptance criterion for this study is growth of ≥5 x 10^6 conidia/mL.

Neutralization Confirmation
The neutralization of the test substance was confirmed by transferring 0.01 mL of the test substance to subculture tubes containing 10 mL of subculture media. The transfer tubes were challenged with low levels of the organism (neutralization control), incubated as in test and observed for the presence of growth. Dilutions of the organism used for inoculation were plated on subculture agar to enumerate the number of organisms added to the subculture tubes. The acceptance criterion for this control is growth after inoculation with low levels of the test organism.

STUDY ACCEPTANCE CRITERIA

Test Substance Performance Criteria

From all subculture tubes, growth (+) or no growth (0) was recorded.

The EPA efficacy performance requirements for label claims state that the test substance must kill conidial spores in all subculture tubes within 10 minutes to be an effective fungicide.

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

PROTOCOL CHANGES

Protocol Amendments:
1. This protocol is being amended to clarify the preparation of the conidial suspension used to inoculate the test substance. Multiple plates of Sabouraud Dextrose Agar or Potato Dextrose Agar will be inoculated at center and incubating at 25-30°C for 10-15 days. The mycelia will be removed from the plate by adding approximately 1-3 mL of sterile saline or saline/Triton solution and swabbing or scraping with a sterile cell scraper or swab. The liquid will be collected from the plate using a pipet and transferred to a glass bottle containing beads and sterile saline or saline/Triton solution. Any residual colony clumps may also be added to the bottle at the discretion of the technician. The bottle will be shaken thoroughly and then the liquid will be filtered through sterile gauze to remove the hyphal fragments. The conidial concentration will be estimated by counting in a hemacytometer. The suspension will be standardized in order to achieve $\geq 5 \times 10^6$ conidia/mL. This standardization may include any of the following means i.e. comparison to a turbidity standard, counting in a hemacytomer, dilution, and concentration through centrifugation.

2. In order to report the test substance name in the clearest possible manner in the report, this protocol is amended to clarify the test substance name. The test substance will be reported as MDF-500 Parts A & B, Lot 1: Batch AZA-30 + Batch BZB-30 and Lot 2: Batch AXA-02 + Batch BXB-02.

Protocol Deviations:
No protocol deviations occurred during this study.

DATA ANALYSIS

Calculations: Conidia/mL = $\frac{\text{(average CFU @ dilution used) x (dilution factor)}}{\text{(volume plated)}}$

Statistical Methods: 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. The original data includes, but is 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. Fungicidal Activity of Disinfectants, (955.17), 2000. Official Methods of Analysis of the AOAC, Seventeenth Edition.
2. U.S. Environmental Protection Agency, Registration Division, Office of Pesticide Programs, DIS/TSS-6, August 12, 1981.

RESULTS

For Control and Neutralization Results, see Tables 1-3.

All data measurements/controls including the culture purity, viability, neutralizing subculture medium sterility, neutralization confirmation, and initial suspension were within acceptance criteria.

For Test Results, see Table 4.

ANALYSIS

MDF-500 Parts A & B (Lot 1: Batch AZA-30 + Batch BZB-30 and Lot 2: Batch AXA-02 + Batch BXB-02), prepared by mixing parts A & B equally, demonstrated no growth of *Penicillium variabile* in the subculture tubes following 5, 10 and 15 minute exposure times.

The highest dilution that kills spores within 10 minutes is considered as the highest dilution that could be expected to disinfect inanimate surfaces contaminated with pathogenic fungi.

STUDY CONCLUSION

Under the conditions of this investigation, MDF-500 Parts A & B (Lot 1: Batch AZA-30 + Batch BZB-30 and Lot 2: Batch AXA-02 + Batch BXB-02), prepared by mixing together equal parts A & B, demonstrated efficacy against *Penicillium variabile* as required by the U.S. EPA for fungicidal label claims following 5 and 10 minute exposure times.

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
	Penicillium variabile
Culture Purity	Pure
Viability Control	Growth
Neutralizing Subculture Sterility Control	No Growth

TABLE 2: NEUTRALIZATION CONFIRMATION RESULTS

Test Substance	Test Organism	Neutralization Confirmation			
		Date Performed	Inoculum CFU	Number Subculture Tubes Tested	Number Subculture Tubes Positive
MDF-500 Lot 1: Batch AZA-30 + Batch BZB-30	*Penicillium variabile*	3/7/07	85	1	1
MDF-500 Lot 2: Batch AXA-02 + Batch BXB-02				1	1

CFU = Colony Forming Unit

The neutralization controls showed growth, eliminating fungistasis as a cause of lack of growth in the test system.

TABLE 3: INITIAL SUSPENSION

Test Organism	Date Performed	Result
		CFU/mL
Penicillium variabile	3/7/07	8.5×10^7

CFU = Colony Forming Unit

TABLE 4: EVALUATION OF GROWTH IN SUBCULTURES

Test Substance	Test Organism	Sample Dilution	Exposure Time		
			5 Minutes	10 Minutes	15 Minutes
MDF-500 Lot 1: Batch AZA-30 + Batch BZB-30	*Penicillium variabile*	Combine equal parts A & B	0	0	0
MDF-500 Lot 2: Batch AXA-02 + Batch BXB-02			0	0	0

+ = Growth of test organism in subculture tubes.
0 = No growth in subculture tubes.

ATS LABS

AMENDMENT TO GLP TEST PROTOCOL

Amendment No.:	2
Effective Date:	March 21, 2007
Sponsor:	Modec, Inc. 4725 Oakland Street Denver, CO 80239
Sponsor Representative:	Ag-Chem Consulting 12208 Quinque Lane Clifton, VA 20124
Test Facility:	ATS Labs 1285 Corporate Center Drive, Suite 110 Eagan, MN 55121
Protocol Title:	AOAC Fungicidal Activity Method
ATS Labs Protocol Number:	MOD02012507.FACT.2
ATS Labs Project Number:	A04727

Modifications to Protocol:

In order to report the test substance name in the clearest possible manner in the report, this protocol is amended to clarify the test substance name. The test substance will be reported as MDF-500 Parts A & B, Lot 1: Batch AZA-30 + Batch BZB-30 and Lot 2: Batch AXA-02 + Batch BXB-02.

Changes to the protocol are acceptable as noted.

Study Director _____ Date 3/21/07

EXACT COPY
ASJ DATE 3/22/07

ATS LABS

AMENDMENT TO GLP TEST PROTOCOL

Amendment No.:	1
Effective Date:	February 26, 2007
Sponsor:	Modec, Inc. 4725 Oakland Street Denver, CO 80239
Sponsor Representative:	Ag-Chem Consulting 12208 Quinque Lane Clifton, VA 20124
Test Facility:	ATS Labs 1285 Corporate Center Drive, Suite 110 Eagan, MN 55121
Protocol Title:	AOAC Fungicidal Activity Method
ATS Labs Protocol Number:	MOD02012507.FACT.2
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Changes to the protocol are acceptable as noted.

Amy S Jeske
Study Director

2/26/07
Date

EXACT COPY
INITIALS [illegible] DATE 3/22/07