FINAL STUDY REPORT

STUDY TITLE

AOAC Use-Dilution Method

Test Organism:

Methicillin Resistant *Staphylococcus aureus* - MRSA (ATCC 33592)

PRODUCT IDENTITY

MonoFoil-D
Batch 100312001 and Batch 102512001

TEST GUIDELINE

OCSPP 810.2200

AUTHOR

Joshua Luedtke, M.S.
Study Director

STUDY COMPLETION DATE

November 19, 2012

PERFORMING LABORATORY

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

SPONSOR

Coeus Technology
2701 Enterprise Drive
Suite 230
Anderson, IN 46013

PROJECT NUMBER

A14225

QUALITY ASSURANCE UNIT SUMMARY

Study: AOAC Use-Dilution 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 of Phase Inspection	Date Reported to Study Director	Date Reported to Management
Critical Phase Audit	November 8, 2012	November 8, 2012	November 9, 2012
Final Report	November 16, 2012	November 16, 2012	November 19, 2012

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

Quality Assurance Auditor: _____ Date: 11/19/12

SUMMARY OF RESULTS

Test Substance:	MonoFoil-D (Batch 100312001 and Batch 102512001)
Dilution:	Ready to use (RTU)
Test Organism:	Methicillin Resistant *Staphylococcus aureus* - MRSA (ATCC 33592)
Exposure Time:	10 minutes
Exposure Temperature:	20 ± 1°C (20.0°C)
Organic Soil Load:	5% fetal bovine serum
Number of Carriers:	10 per batch
Efficacy Result:	MonoFoil-D demonstrated efficacy of two batches against Methicillin Resistant *Staphylococcus aureus* - MRSA, and therefore, meets the performance requirements set forth by the U.S. EPA following a 10 minute exposure time at 20 ± 1°C (20.0°C) in the presence of a 5% fetal bovine serum organic soil load.

STUDY MATERIALS

Test System/Growth Media

Test Organism	ATCC #	Growth Medium	Incubation Parameters
Methicillin Resistant *Staphylococcus aureus* - MRSA	33592	Nutrient Broth	35-37°C, aerobic

The test organism used in this study was obtained from the American Type Culture Collection (ATCC), Manassas, VA.

Recovery Media

Neutralizing Subculture Medium:
Letheen Broth + 0.07% Lecithin + 0.5% Tween 80 + 0.1% Sodium Thiosulfate (Primary and Secondary)

Agar Plate Medium:
Tryptic Soy Agar with 5% Sheep Blood (BAP)

Reagents

Organic Soil Load Description: 5% fetal bovine serum (FBS)

Carriers

Carriers were screened according to the AOAC Official Method of Analysis and all carriers positive for growth were discarded. Only penicylinders which demonstrated no growth during screening were used in this test. Stainless steel penicylinders were pre-soaked overnight in 1.0N NaOH, washed in water until neutral and autoclaved in deionized water.