

NON-GLP STUDY REPORT

STUDY TITLE

Custom Microbiology

Test Organisms:

Staphylococcus aureus (ATCC 6538)

Escherichia coli (ATCC 11229)

PRODUCT IDENTITY

80% 20% Microfiber Material

AUTHOR

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STUDY COMPLETION DATE

March 15, 2010

PERFORMING LABORATORY

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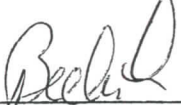
PROJECT NUMBER

A09033

This study was not performed under
EPA Good Laboratory Practice Regulations
(40 CFR Part 160)


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STUDY REPORT

GENERAL STUDY INFORMATION

Study Title: Custom Microbiology
Project Number: A09033
TRF Number: ACA01011910.CUST

TEST SUBSTANCE IDENTITY

Test Substance Name: 80% 20% Microfiber Material

STUDY DATES

Date Sample Received: February 2, 2010
Study Initiation Date: February 8, 2010
Experimental Start Date: February 15, 2010
Experimental End Date: March 1, 2010
Study Completion Date: March 15, 2010

Test Organisms	ATCC #	Growth Medium	Incubation Paramaters
<i>Staphylococcus aureus</i>	6538	Synthetic Broth	35-37°C, aerobic
<i>Escherichia coli</i>	11229	Synthetic Broth	35-37°C, aerobic

The microorganisms used in this study were obtained from the American Type Culture Collection (ATCC), Manassas, Virginia.

Neutralizing Subculture Medium: Lethen Broth + 0.1% Sodium Thiosulfate
Exposure Temperature: Room temperature (21.39-21.8°C)
Number of Carriers Tested/Lot: Duplicate carriers
Soil Load Description: 5% fetal bovine serum (FBS)
Agar: Tryptic Soy Agar + 5% Sheep's Blood (BAP)

EXPERIMENTAL DESIGN

A film of bacterial cells was dried onto the 1" x 1" end of duplicate 1" x 3" glass carriers. The 80% 20% Microfiber Material was saturated using filter sterilized deionized water. The 80% 20% Microfiber Material was used to wipe each carrier by wiping the inoculated portion of the carrier (left to right, then right to left, and repeat). Immediately following wiping, the glass carriers were transferred to individual vessels containing neutralizer and were assayed for survivors. Appropriate culture purity, organic soil sterility, carrier sterility, neutralizer sterility, neutralization confirmation and carrier population controls were performed. Percent and log₁₀ reductions were determined for the treated carriers by comparison to the carrier population control results.

STUDY RESULTS

TABLE 1: CONTROL RESULTS

The following results from controls confirmed study validity:

Type of Control	Results	
	<i>Staphylococcus aureus</i> (ATCC 6538)	<i>Escherichia coli</i> (ATCC 11229)
Purity Control	Pure	Pure
Organic Soil Sterility Control	No Growth	No Growth
Neutralizing Subculture Medium Sterility Control	No Growth	No Growth
Carrier Sterility Control	No Growth	No Growth

TABLE 2: CARRIER POPULATION CONTROL RESULTS

Test Organism	Carrier #	CFU/Carrier	Log ₁₀	Average Log ₁₀	Geometric Mean
<i>Staphylococcus aureus</i> (ATCC 6538)	1	2.6 x 10 ⁶	6.41	6.36	2.29 x 10 ⁶
	2	2.0 x 10 ⁶	6.30		
<i>Escherichia coli</i> (ATCC 11229)	1	4 x 10 ⁴	4.6	4.6	4.0 x 10 ⁴
	2	3 x 10 ⁴	4.5		

CFU = Colony Forming Unit

TABLE 3: NEUTRALIZATION CONFIRMATION CONTROL RESULTS

Test Substance	Test Organism	Dilution	Numbers Control (CFU)	Results (CFU)	Log ₁₀ Difference	Pass/Fail (±1 Log ₁₀)
80% 20% Microfiber Material	<i>Staphylococcus aureus</i> (ATCC 6538)	10 ⁻⁵	84, 80	68, 74	0.06	Pass
	<i>Escherichia coli</i> (ATCC 11229)	10 ⁻⁶	15, 22	10, 17	0.13	Pass

CFU = Colony Forming Unit

TABLE 4: TEST RESULTS

Test Substance: 80% 20% Microfiber Material with Filter sterilized deionized water				
Dilution	Test Organism: <i>Staphylococcus aureus</i> (ATCC 6538)		Test Organism: <i>Escherichia coli</i> (ATCC 11229)	
	Carrier 1	Carrier 2	Carrier 1	Carrier 2
	Number of Survivors			
10 ⁰	TNTC, TNTC	144, 162	18, 12	1, 1
10 ⁻¹	49, 44	29, 21	0, 1	0, 0
10 ⁻²	6, 11	3, 5	0, 1	0, 0
10 ⁻³	1, 1	0, 0	0, 0	0, 0
Filtration of ~36 mL of 10 ⁰ dilution	TNTC	TNTC	288	35

TNTC= Too Numerous to Count (>300 Colonies)

TABLE 5: CALCULATED VALUES

Test Organism	Test Substance	Percent Reduction	Log ₁₀ Reduction
<i>Staphylococcus aureus</i> (ATCC 6538)	80% 20% Microfiber Material	99.5%	2.33
<i>Escherichia coli</i> (ATCC 11229)		99.7%	2.6

CONTROL RESULTS

The results of controls run for culture purity, carrier sterility, neutralizer sterility, organic soil sterility, neutralization confirmation and carrier population controls were all acceptable.

ANALYSIS

Carriers wiped with 80% 20% Microfiber Material, immersed in filter sterilized deionized water, demonstrated a 99.5% (2.33 Log₁₀) reduction of *Staphylococcus aureus* (ATCC 6538) survivors when tested in the presence of 5% fetal bovine serum organic soil load at room temperature (21.39°C).

Carriers wiped with 80% 20% Microfiber Material, immersed in filter sterilized deionized water, demonstrated a 99.7% (2.6 Log₁₀) reduction of *Escherichia coli* (ATCC 11229) survivors when tested in the presence of 5% fetal bovine serum organic soil load at room temperature (21.8°C).

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