ATS LABS

NON-GLP STUDY REPORT

STUDY TITLE

Antimicrobial Activity of Surface Bound Agents (JIS 2801)

Test Organism:

Staphylococcus aureus (ATCC 6538)

PRODUCT IDENTITY

Richlite, Richlite/AFM, Richlite/AFM/M-1, and Richlite/AFM/M-1x2

AUTHOR

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STUDY COMPLETION DATE

August 25, 2009

PERFORMING LABORATORY

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

SPONSOR

Richlite Company
624 E. 15th Street
Tacoma, WA 98421

PROJECT NUMBER

A08063

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

STUDY REPORT

GENERAL STUDY INFORMATION

Study Title: Antimicrobial Activity of Surface Bound Agents (JIS 2801)

Project Number: A08063

TRF Number: RHL01071609.J2801

TEST SUBSTANCE IDENTITY

Test Substance Name: Richlite, Richlite/AFM, Richlite/AFM/M-1, and Richlite/AFM/M-1x2

STUDY DATES

Date Sample Received: July 31, 2009
Study Initiation Date: August 4, 2009
Experimental Start Date: August 20, 2009
Experimental End Date: August 24, 2009
Study Completion Date: August 25, 2009

Test Organism	ATCC #	Culture Medium
Staphylococcus aureus	6538	Nutrient Broth

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

Exposure Time: 24 Hours
Dilution: Ready to use (RTU)
Exposure Temperature: 35-37°C
Number of Carriers Tested: Duplicate carriers/material
Soil Load Description: No organic soil load required
Neutralizer: Letheen Broth + 0.07% Lecithin + 0.5% Tween 80

EXPERIMENTAL DESIGN

Duplicate, Sponsor-provided approximate 2" x 2" test carriers were inoculated with the test organism. A sterile 40 mm x 40 mm carrier film was placed over each carrier. The carriers were allowed to expose at 35-37°C and ≥ 90% relative humidity for 24 hours. Following exposure, each carrier was neutralized and assayed for survivors. Appropriate 1" x 1" stainless steel squares were similarly evaluated at time zero and following 24 hours of exposure. Appropriate culture purity, inoculum count, neutralization confirmation and stainless steel (quantitation) controls were performed. Percent reductions were determined for the test carriers based on the 24 hour stainless steel control carriers.

STUDY RESULTS

TABLE 1: CONTROL RESULTS

The following results from controls confirmed study validity:

Type of Control	Results
	Staphylococcus aureus **(ATCC 6538)**
Purity Control	Pure
Inoculum Count Control	7.7×10^6 CFU/mL

CFU = Colony Forming Unit

TABLE 2: NEUTRALIZATION CONFIRMATION RESULTS

Test Substance	Test Organism	Dilution Plated	Numbers Control (Survivors/mL)	Results (Survivors/mL)	Log Difference Pass / Fail (± 1.0 $\log_{10}$)
Richlite	*Staphylococcus aureus* (ATCC 6538)	10^{-4}	19,14	12,12	0.15 Pass
Richlite/AFM				11,12	0.15 Pass
Richlite/AFM/ M-1				24,11	-0.03 Pass
Richlite/AFM/ M-1x2				19,18	-0.05 Pass

TABLE 3: STAINLESS STEEL CONTROL RESULTS

Test Organism	Exposure Time (hours)	Carrier #	Number of Survivors/ Carrier	Log_{10}
Staphylococcus aureus (ATCC 6538)	Time zero	1	3.1×10^5	5.49
	24 hours	1	1.00×10^5	5.000

TABLE 4: EVALUATION OF TEST CARRIER DATA

Test Substance: Richlite

Test Organism	Exposure Time	Carrier #	Number of Survivors (Neutralized Solution)			
			Dilution	CFU/plate	CFU/Carrier	Log_{10}
Staphylococcus aureus (ATCC 6538)	24 hours	1	10^0	5,3	2×10^2	2.3
			10^{-1}	1,1		
			10^{-2}	0, 0		
			10^{-3}	0, 0		
			10^{-4}	0, 0		
		2	10^0	1,1	5×10^1	1.7
			10^{-1}	0,0		
			10^{-2}	0,0		
			10^{-3}	0,0		
			10^{-4}	0,0		

Test Substance: Richlite/AFM

Test Organism	Exposure Time	Carrier #	Number of Survivors (Neutralized Solution)			
			Dilution	CFU/plate	CFU/Carrier	Log_{10}
Staphylococcus aureus (ATCC 6538)	24 hours	1	10^0	0,0	$<5 \times 10^1$	<1.7
			10^{-1}	0,0		
			10^{-2}	0, 0		
			10^{-3}	0, 0		
			10^{-4}	0, 0		
		2	10^0	0,0	$<5 \times 10^1$	<1.7
			10^{-1}	0,0		
			10^{-2}	0,0		
			10^{-3}	0,0		
			10^{-4}	0,0		

A value of <1 was used in place of zero for calculation purposes.
CFU = colony forming unit

TABLE 4: EVALUATION OF TEST CARRIER DATA (continued)

Test Substance: Richlite/AFM/M-1

Test Organism	Exposure Time	Carrier #	Number of Survivors (Neutralized Solution)			
			Dilution	CFU/plate	CFU/Carrier	Log_{10}
Staphylococcus aureus (ATCC 6538)	24 hours	1	10^0	0,0	$<5 \times 10^1$	<1.7
			10^{-1}	0,0		
			10^{-2}	0, 0		
			10^{-3}	0, 0		
			10^{-4}	0, 0		
		2	10^0	0,0	$<5 \times 10^1$	<1.7
			10^{-1}	0,0		
			10^{-2}	0,0		
			10^{-3}	0,0		
			10^{-4}	0,0		

Test Substance: Richlite/AFM/M-1x2

Test Organism	Exposure Time	Carrier #	Number of Survivors (Neutralized Solution)			
			Dilution	CFU/plate	CFU/Carrier	Log_{10}
Staphylococcus aureus (ATCC 6538)	24 hours	1	10^0	0,0	$<5 \times 10^1$	<1.7
			10^{-1}	0,0		
			10^{-2}	0, 0		
			10^{-3}	0, 0		
			10^{-4}	0, 0		
		2	10^0	0,0	$<5 \times 10^1$	<1.7
			10^{-1}	0,0		
			10^{-2}	0,0		
			10^{-3}	0,0		
			10^{-4}	0,0		

A value of <1 was used in place of zero for calculation purposes.
CFU = colony forming unit

TABLE 5: CALCULATED VALUES

Test Substance: Richlite

Exposure Time: 24 hours

Test Organism	Carrier #	Number of Survivors/ Carrier	Log_{10}	Average Log_{10}	Geometric Mean	Percent Reduction
Staphylococcus aureus (ATCC 6538)	1 2	2×10^2 5×10^1	2.3 1.7	2.0	1.0×10^2	99.9%

Test Substance: Richlite/AFM

Exposure Time: 24 hours

Test Organism	Carrier #	Number of Survivors/ Carrier	Log_{10}	Average Log_{10}	Geometric Mean	Percent Reduction
Staphylococcus aureus (ATCC 6538)	1 2	$<5 \times 10^1$ $<5 \times 10^1$	<1.7 <1.7	<1.7	$<5.0 \times 10^1$	>99.9%

Test Substance: Richlite/AFM/M-1

Exposure Time: 24 hours

Test Organism	Carrier #	Number of Survivors/ Carrier	Log_{10}	Average Log_{10}	Geometric Mean	Percent Reduction
Staphylococcus aureus (ATCC 6538)	1 2	$<5 \times 10^1$ $<5 \times 10^1$	<1.7 <1.7	<1.7	$<5.0 \times 10^1$	>99.9%

Test Substance: Richlite/AFM/M-1x2

Exposure Time: 24 hours

Test Organism	Carrier #	Number of Survivors/ Carrier	Log_{10}	Average Log_{10}	Geometric Mean	Percent Reduction
Staphylococcus aureus (ATCC 6538)	1 2	$<5 \times 10^1$ $<5 \times 10^1$	<1.7 <1.7	<1.7	$<5.0 \times 10^1$	>99.9%

ANALYSIS

Richlite, ready to use, demonstrated a 99.9% of *Staphylococcus aureus* (ATCC 6538) following a 24 hour exposure period when tested at 35-37°C and ≥ 90% relative humidity.

Richlite/AFM, ready to use, demonstrated greater than a 99.9% of *Staphylococcus aureus* (ATCC 6538) following a 24 hour exposure period when tested at 35-37°C and ≥ 90% relative humidity.

Richlite/AFM/M-1, ready to use, demonstrated greater than a 99.9% of *Staphylococcus aureus* (ATCC 6538) following a 24 hour exposure period when tested at 35-37°C and ≥ 90% relative humidity.

Richlite/AFM/M-1x2, ready to use, demonstrated greater than a 99.9% of *Staphylococcus aureus* (ATCC 6538) following a 24 hour exposure period when tested at 35-37°C and ≥ 90% relative humidity.

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