



Ensuring Medical Device Safety and Compliance™

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M_S

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Lab No. 04G_36016_01
P.O. No. Pre-Paid - Check #1017
Test Facility: NAMSA
3400 Cobb International
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Kennesaw, GA 30152

MICROBIOLOGICAL ANALYSIS

Test Article: Sand
ID No. Not Supplied

The test article was received on May 18, 2004.

Test Organism: *Aspergillus niger* ATCC 16404
Sample Size: Adequate amount to absorb 0.1 mL of inoculum
Neutralizer: Letheen Broth
Inoculum Concentration: 1.1×10^3 CFU/0.1 mL

Procedure: The test sample was inoculated with 0.1 mL of a $(1-2) \times 10^4$ CFU/mL population of *A. niger*.
The test sample was incubated for 24 hours at 20-25°C and serial dilutions performed.

Sample ID	Results (CFU/ml)	
	Zero Contact Time	24 Hour Contact Time
Sand	1.3×10^3	7.5×10^2

Results and conclusions apply only to the test article tested. No further evaluation of these results is made by NAMSA. Any extrapolation of these data to other samples is the responsibility of the sponsor. All procedures were conducted in conformance with good laboratory practice and ISO 17025.

Record Storage: All raw data pertaining to this study and a copy of the final report are to be retained in designated NAMSA archive files for a period of 5 years.

jsm Date Completed 5.26.04 Approved By Fabian R. Mejias
Fabian R. Mejias, B.S., M.B.A.
Supervisor

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 Kennesaw, GA 30152

MICROBIOLOGICAL ANALYSIS

Test Article: Crum rubber
 ID No. Not Supplied

The test article was received on May 18, 2004.

Test Organism: *Aspergillus niger* ATCC 16404
 Sample Size: Adequate amount to absorb 0.1 mL of inoculum
 Neutralizer: Lethen Broth
 Inoculum Concentration: 1.1×10^3 CFU/0.1 mL

Procedure: The test sample was inoculated with 0.1 mL of a $(1-2) \times 10^4$ CFU/mL population of *A. niger*.
 The test sample was incubated for 24 hours at 20-25°C and serial dilutions performed.

Sample ID	Results (CFU/ml)	
	Zero Contact Time	24 Hour Contact Time
Crum Rubber	1.3×10^3	9.0×10^2

Results and conclusions apply only to the test article tested. No further evaluation of these results is made by NAMSA. Any extrapolation of these data to other samples is the responsibility of the sponsor. All procedures were conducted in conformance with good laboratory practice and ISO 17025.

Record Storage: All raw data pertaining to this study and a copy of the final report are to be retained in designated NAMSA archive files for a period of 5 years.

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jsm Date Completed 5-27-04 Approved By Fabian R. Mejias
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MICROBIOLOGICAL ANALYSIS

Test Article: Special Turf Filler
ID No. Not Supplied

The test article was received on June 22, 2004.

Test Organism: *Aspergillus niger* ATCC 16404
Sample Size: Adequate amount to absorb 0.1 mL of inoculum
Neutralizer: Letheen Broth
Inoculum Concentration: 1.5×10^3 CFU/0.1 mL

Procedure: The test sample was inoculated with 0.1 mL of a $(1-2) \times 10^4$ CFU/mL population of *A. niger*.
The test sample was incubated for 24 hours at 20-25°C and serial dilutions performed.

Sample ID	Results (CFU/ml)	
	Zero Contact Time	24 Hour Contact Time
Special Turf Filler	1.7×10^3	< 10

Results and conclusions apply only to the test article tested. No further evaluation of these results is made by NAMSA. Any extrapolation of these data to other samples is the responsibility of the sponsor. All procedures were conducted in conformance with good laboratory practice and ISO 17025.

Record Storage: All raw data pertaining to this study and a copy of the final report are to be retained in designated NAMSA archive files for a period of 5 years.

jsm Date Completed 7-2-04 Approved By Fabian R. Mejias
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