MICROCHEM LABORATORY

STUDY REPORT

Study Title

Antibacterial Activity and Aerosol Efficacy of Scientific Air Management's Device

Test Method

Custom Aerosol Study

Study Identification Number

NG6997

Study Sponsor

Dr. Gary Russotti
Scientific Air Management LLC
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Test Facility

MicrochemLaboratory
1304 W.Industrial Blvd
Round Rock, TX 78681
(512) 310-8378

Test Device Information

The test device was received on 10 MAR 2016 .

(note: photos depict the test device analyzed in this study)
Test device received: Scientific Air Management SAM 400

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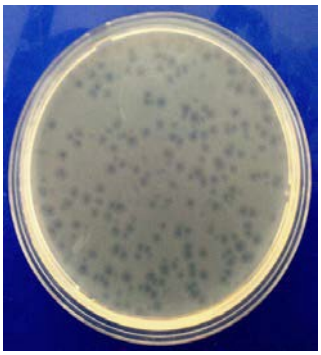
Test MicroorganismInformation

The following test microorganisms were selected for this test:



MS2 Bacteriophage (MS2), 15597-B1

This virus is a non-enveloped positive-stranded RNA virus of the bacteriophage family Leviviridae. Bacterial cells are the hosts for bacteriophages, and *E. coli* 15597 serves this purpose for MS2 bacteriophage. Its small size, icosohedral structure, and environmental resistance has made MS2 ideal for use as a surrogate virus (particularly in place of picornaviruses such as poliovirus and human norovirus) in water quality and disinfectant studies.

Permissive Host Cell System for MS2: *Escherichia coli*, 15597

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Summary of the Procedure

- Bacterial cultures, fungal culture, and a virus stock are pooled to target concentrations as appropriate.
- The test inoculum is split into two equal parts and added to two nebulizers. Liquid culture should not exceed 18ml per nebulizer.
- The chamber is setup and the safety checklist is completed prior to test initiation.
- The nebulizers are activated for 60 minutes to ensure target microbial concentrations are achieved prior to activation of the device.
- An SKC bio-sampler is used to take a time zero sample to determine starting chamber concentration for baseline comparison.
- Device is activated for the study sponsor determined contact time. After each contact time, the SKC bio-samplers are activated for 10 minutes to determine microbial concentrations.
- Samples are enumerated using standard dilution and plating techniques.
- Microbial concentrations are determined after 24-48 hours of incubation for bacteria and viruses. Fungal plates are incubated at room temperature for 5-7 days.
- Reductions of microorganisms are calculated relative to concentration at Time Zero.

Study Timeline

MS2 15597-B2

05 APR 2016	07 APR 2016	07 APR 2016	07 APR 2016	08 APR 2016	14 APR 206

Amended report delivered 31 AUG 2016

PROCEDURE

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Criteria for Scientific Defensibility of a Custom Device Study

For Microchem Laboratory to consider a Device Study to be scientifically defensible, the following criteria must be met:

1. The average number of viable bacteria recovered from the time zero samples must be approximately 1×10^5 cells/m^3 or greater.
2. Positive/Growth controls must demonstrate growth of the appropriate test microorganism.
3. Negative/Purity controls must demonstrate no growth of test microorganism.

Passing Criteria

Because of the nature of the study, passing criteria may be determined by the Study Sponsor.

Testing Parameters used in this Study

Volume of Inoculum added to Nebulizer	15 ml per nebulizer (30 ml total)
SKC Biosampler Media (Vol.)	Phosphate Buffered Saline (20 ml)
Nebulization Time	60 minutes
SKC Biosampler Time	10 minutes
Sampling Time Points	Time zero, 5 minutes 15 minutes, 30 minutes
SKC Biosampler Sampling Rate	12.5 L/minute
SKC Biosampler Liters Sampled	125 L sampled per sampling time point

Test Microorganism	MS2 Bacteriophage
Culture Growth Media	N/A Stock Solution
Culture Growth Time	N/A Stock Solution
Culture Dilution Media	Phosphate buffered saline
Target Concentration	≥1.0 x 10^6 CFU/m^3
Enumeration Media	50% Tryptic Soy Agar
Enumeration Type	Poured with *E. coli* 15597
Enumeration Incubation Time	18-24 hours

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Study Notes

No additional observations or notations were made for this study.

Study Photographs

Photographs are the device received by the laboratory on 10 MAR 2016. The device is photographed operating within the chamber and the SKC bio-sampler in the foreground.

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Control Results

Neutralization Method: Not applicable
Growth Confirmation: Confirmed

Media Sterility: Sterile

Calculations

$$\text{Percent Reduction} = \left(\frac{B-A}{B}\right) \times 100$$

Where:
B = Number of viable test microorganisms on the control carriers immediately after inoculation
A = Number of viable test microorganisms on the test carriers after the contact time

$$\text{Log}_{10}\text{Reduction} = \text{Log}\left(\frac{B}{A}\right)$$

Where:
B = Number of viable test microorganisms on the control carriers immediately after inoculation
A = Number of viable test microorganisms on the test carriers after the contact time

$$\text{CFU/m}^3 = 1000 \times \left(\frac{\frac{\text{CFU}}{\text{ml}} \times (V_s)}{T_s(12.5)}\right)$$

Where:
V_S = Bio-sampler volume (ml)
T_S = Time sampled (min)

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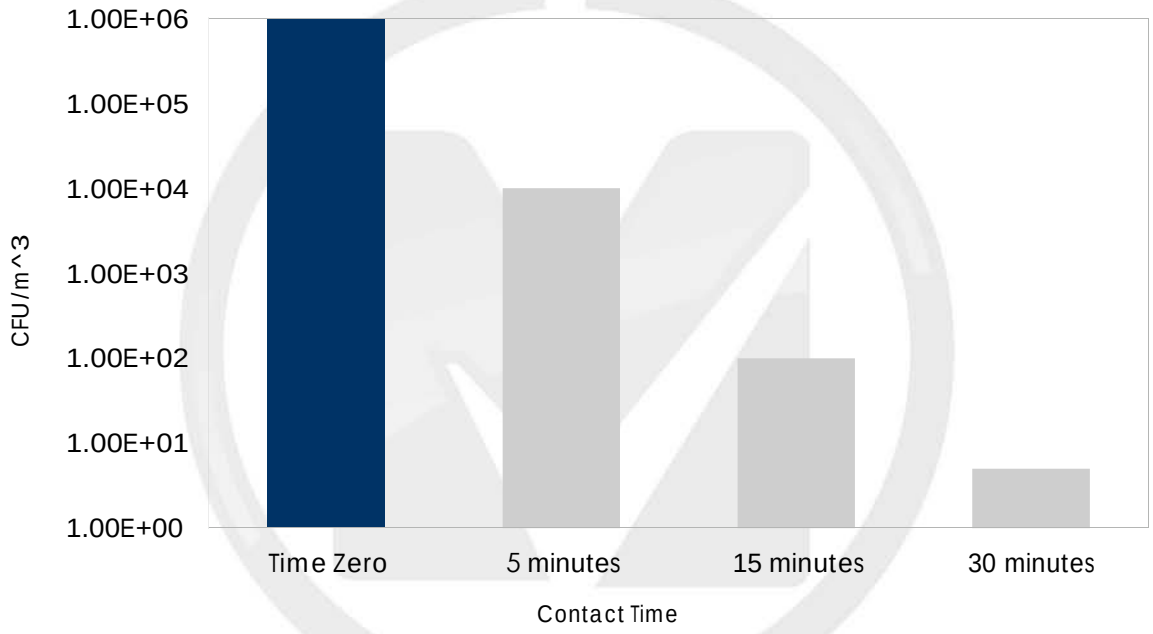
Results of the Study

Test Device	Microorganism	Inoculum Concentration (CFU/ml)	Treatment Time Point	Recovery (CFU/m³)	Percent Reduction vs. Time Zero	Log_{10} Reduction vs. Time Zero
Scientific Air Manage-ment S400	MS2 Bacteriophage ATCC 15597-B1	1.00E+07	Time Zero	1.00E+06	N/A	
			5 minutes	1.00E+04	99.0%	2.00
			15 minutes	1.00E+02	99.990%	4.00
			30 minutes	5.00E+00	99.9995%	5.30



The results of this study apply to the tested substances(s) only. Extrapolation of findings to related materials is the responsibility of the Sponsor.