

NON-GLP STUDY REPORT

STUDY TITLE

Quantitative Evaluation of Air Treatment Efficacy Against Airborne Fungi in a Large Indoor Space

Test Organism(s):

Cladosporium cladosporioides (ATCC 16022)

PRODUCT IDENTITY

VigorOx Liquid Sanitizer and Disinfectant Lot 17622C1420

TEST DEVICE IDENTITY

V2 Fog Tank, Serial Number 2219

AUTHOR

Thomas Breyen Senior Virologist

STUDY COMPLETION DATE

August 31, 2023

PERFORMING LABORATORY

Element Materials Technology Eagan 1285 Corporate Center Drive, Suite 110 Eagan, MN 55121

SPONSOR

Pure Maintenance LLC 334 Marshall Way, Suite D Layton, UT 84041

SPONSOR REPRESENTATIVE

Keller and Heckman LLP 1001 G Street NW, Suite 500 West Washington, DC 20001

PROJECT NUMBER

A37949

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:

Quantitative Evaluation of Air Treatment Efficacy Against Airborne

Fungi in a Large Indoor Space

Project Number:

A37949

TRF Number:

PUR006013023.AIRB.2

TEST SUBSTANCE IDENTITY

Test Substance	VigorOx Liquid Sanitizer and Disinfectant, Lot 17622C1420	
Test Substance Dilution	19.2 oz/108.8 oz defined as 19.2 oz of test substance + 108.8 oz Deionized Water	

TEST PARAMETERS

Delivery Mechanism	V2 Fog Tank			
Spray Conditions	Device prepared and operated by the Sponsor. Spray duration was 8 minutes 50 seconds.			
Sample Timepoints	Time zero, 10 minutes, 30 minutes, 45 minutes			
Exposure Conditions (Target)	18-25°C at 40-60% RH			

STUDY DATES

Date Sample Received	May 11, 2023 (Test Device) May 12, 2023 (Test Substance)
Study Initiation Date	May 17, 2023
Experimental Start Date	August 15, 2023
Experimental End Date	August 22, 2023
Study Completion Date	August 31, 2023



TEST ORGANISM

Test Organism	ATCC#	Growth Medium	Incubation Parameters	
Cladosporium cladosporioides	16022	Sabouraud Dextrose Broth	25-37°C aerobic	

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

INOCULUM PREPARATION

Organism	Cladosporium cladosporioides ATCC# 16022		
Target Time Zero Concentration	10 ⁶ CFU/m ³		
Diluent	0.85% saline		
Organic Soil Load	Tri-Part Soil		
Agar Plate Medium	Sabouraud Dextrose Agar		

ENVIRONMENTAL CONDITIONS

Pre-Nebulization Temperature	21.1°C (Baseline)
Pre-Nebulization reinperature	21.2°C (Test)
Pre-Nebulization Humidity	52.4% (Baseline)
1 re-Nebalization Hamilarty	55.1% (Test)
Post-Sampling Temperature	20.6°C (Baseline)
Tost-Sampling Temperature	20.3°C (Test)
Post-Sampling Humidity	59.4% (Baseline)
Post-Sampling Humarity	83.0% (Test)
HVAC Status During Nebulization	OFF
HVAC Status During Treatment	OFF
Ceiling Fan Setting During Nebulization	ON
Ceiling Fan Setting During Treatment	ON

AIR SAMPLING - BioSpot VIVAS 310™

Collection Fluid/Neutralizer	PBS
Sample Location	6' at interior wall
Replicates	1 per time point



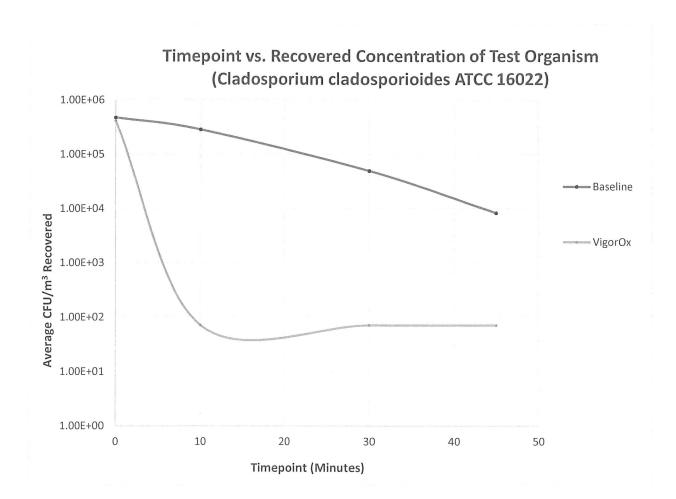
EXPERIMENTAL DESIGN

Airborne organism was generated from a liquid inoculum using a Collison nebulizer and introduced into the containment lab at a target concentration of 10⁶ CFU/m³. The organism was exposed to the test substance using the Sponsor supplied device V2 Fog Tank for the specified exposure time of 8 minutes 50 seconds. Following exposure, air samples were collected in neutralization fluid and analyzed for survivors. Log reductions are based on time zero value and normalized to account for natural decay of the organism in air. Appropriate neutralization confirmation, background contamination, organism purity, inoculum count, organic soil sterility and neutralization subculture medium sterility controls were performed.

Per Sponsor's direction, the study was not required to be conducted under U.S. EPA 40 CFR Part 160 or U.S. FDA 21 CFR Part 58.

STUDY RESULTS

TABLE 1: RESULTS SUMMARY



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TABLE 2: CONTROL RESULTS

The following results from controls confirmed study validity:

	Results		
Type of Control	Cladosporium cladosporioides (ATCC 16022)		
Purity Control	Pure		
Inoculum Count	1.68 x 10 ⁷ CFU/mL		
Neutralizing Subculture Medium Sterility Control	No Growth		
Background Contamination Control	No Growth		
Organism Preparation Diluent Sterility Control	No Growth		

TABLE 3: NEUTRALIZATION CONFIRMATION CONTROL RESULTS

Test Substance	Test Organism		lization tion (CFU)	Percent	Pass/Fail ≥50%)
Test Substance	Test Organism	Numbers Control	Results	Recovery	
VigorOx Liquid Sanitizer and Disinfectant, applied using the V2 Fog Tank	Cladosporium cladosporioides (ATCC 16022)	133	147	111%	Pass

CFU = Colony Forming Unit

TABLE 4: BASELINE RESULTS

Organism	Timepoint	CFU/m ³	Log/m³	Log ₁₀ Decay vs. Time Zero
Cladosporium cladosporioides (ATCC 16022)	Time Zero	4.75E+05	5.68	NA
	10 minutes	2.85E+05	5.45	0.22
	30 minutes	4.95E+04	4.69	0.98
	45 minutes	8.29E+03	3.92	1.76

CFU = Colony Forming Unit

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TABLE 5: TEST RESULTS

Organism	Timepoint	Average CFU/m³	Average Log/m³	Log ₁₀ Reduction vs. Time Zero	Normalized Log ₁₀ Reduction
Cladosporium cladosporioides (ATCC 16022)	Time Zero	4.15E+05	5.62	N/A	
	10 minutes	* 7.14E+01	1.85	3.76	3.54
	30 minutes	* 7.14E+01	1.85	3.76	2.78
	45 minutes	* 7.14E+01	1.85	3.76	2.01

^{*}No organism recovered. Represents test Limit of Detection.

CONTROL RESULTS

The results of controls performed for neutralization confirmation, background contamination, organism purity, inoculum count, organism preparation diluent sterility, and neutralization subculture medium sterility were all acceptable.

CONCLUSION

VigorOx Liquid Sanitizer and Disinfectant (17622C1420) diluted 19.2 oz/108.8 oz defined as 19.2 oz of test substance + 108.8 oz sterile deionized water, applied using the V2 Fog Tank demonstrated a 3.54 log₁₀ reduction of *Cladosporium cladosporioides* (ATCC 16022) following a 10 minute exposure time when compared to the corresponding baseline result in the presence of a Tri-Part soil organic soil load.

PREPARED BY:

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8/3//23 Date

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