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NON-GLP STUDY REPORT

STUDY TITLE

Efficacy of a Disinfectant Applied to a Room Via a Fogger or Misting Device

Test Organism(s):

Trichophyton interdigitale (ATCC 9533)

PRODUCT IDENTITY

VigorOx Liquid Sanitizer and Disinfectant
Lot 17622C1420

DEVICE IDENTITY

V2 Fog Tank, Serial Number 2219

AUTHOR

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STUDY COMPLETION DATE

September 25, 2023

PERFORMING LABORATORY

Element Materials Technology Eagan
1285 Corporate Center Drive, Suite 110
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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

A38430

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

STUDY REPORT

GENERAL STUDY INFORMATION

Study Title: Efficacy of a Disinfectant Applied to a Room Via a Fogger or Misting Device

Project Number: A38430

TRF Number: PUR006071423.FRDT.1

TEST SUBSTANCE IDENTITY

Device Name: V2 Fog Tank, Serial Number 2219

Test Substance Name: VigorOx Liquid Sanitizer and Disinfectant

Batch/Lot(s): Lot 17622C1420

STUDY DATES

Date Sample Received: May 12, 2023 (Test Substance)
May 11, 2023 (Test Device)
Study Initiation Date: September 1, 2023
Experimental Start Date: September 7, 2023
Experimental End Date: September 21, 2023
Study Completion Date: September 25, 2023

Test Organism	ATCC #	Growth Medium	Incubation Parameters
Trichophyton interdigitale	9533	Sabouraud Dextrose Agar	25-30°C, aerobic

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

Test Substance Dilution: 19.2 oz/gal (defined as 19.2 ounces test substance + 108.8 ounces sterile deionized water)
Total Exposure (Cycle) Time: 8 minute 50 second run time, 45 minute dwell time
Exposure Temperature: Room temperature (21.0-21.6°C)
Exposure Humidity: Ambient Conditions (53.7-57.3% RH)
Number of Carriers Tested/Lot: 22 carriers per test organism
Soil Load Description: 5% Fetal Bovine Serum
Neutralizing Subculture Medium: Sabouraud Dextrose Broth + 0.07% Lecithin +0.5% Tween 80 + 0.01% Catalase (Primary) and Sabouraud Dextrose Broth + 0.07% Lecithin +0.5% Tween 80 (Secondary)
Agar Plate Medium: Glucose Agar

EXPERIMENTAL DESIGN

Inoculated 100% cotton fabric carriers (wrapped around 3" x 1" glass slides) were placed at diverse locations at horizontal and near vertical positions within a sealed testing room. The inoculated carriers were exposed to the test substance for a specified exposure time. Following exposure, the carriers were transferred to vessels containing neutralizing subculture medium. The subcultures were incubated and assayed for survivors. Appropriate culture purity, viability, organic soil load sterility, neutralizing subculture medium sterility, carrier sterility, carrier population, non-active treatment and neutralization confirmation 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: CONTROL RESULTS

The following results from controls confirmed study validity:

Type of Control	Results
	***Trichophyton interdigitale* (ATCC 9533)**
Purity Control	Pure
Viability Control	Growth
Organic Soil Load Sterility Control	No Growth
Primary Neutralizing Subculture Medium Sterility Control	No Growth
Secondary Neutralizing Subculture Medium Sterility Control	No Growth
Carrier Sterility	No Growth

TABLE 2: NON-ACTIVE TREATMENT CONTROL RESULTS

Test Organism	CFU/carrier	Log_{10}
Trichophyton interdigitale (ATCC 9533)	2.27×10^5	5.36

CFU = Colony Forming Unit

TABLE 3: CARRIER POPULATION CONTROL RESULTS

Test Organism	Carrier Set	CFU/carrier	Log_{10}
Trichophyton interdigitale (ATCC 9533)	Initial Population	2.2×10^5	5.34
	Post-testing	1.9×10^5	5.28

CFU = Colony Forming Unit

TABLE 4: NEUTRALIZATION CONFIRMATION CONTROL RESULTS

Test Substance	Test Organism	Average CFU Added	Number of Subcultures	
			Tested	Positive
VigorOx Liquid Sanitizer and Disinfectant Lot 17622C1420	*Trichophyton interdigitale* (ATCC 9533)	52	1°= 1 2°= 1	1°= 1 2°= 1

CFU = Colony Forming Unit
1°= Primary Neutralizer, 2°= Secondary Neutralizer

TABLE 5: TEST RESULTS

Test Substance	Test Organism	Sample Dilution	Number of Carriers	
			Exposed	Showing Growth*
VigorOx Liquid Sanitizer and Disinfectant Lot 17622C1420	*Trichophyton interdigitale* (ATCC 9533)	19.2 oz/gallon, defined as 19.2 ounces test substance + 108.8 ounces diluent	22	1°= 0 2°= 0

* Number of carriers showing growth of the test organism.
1°= Primary Neutralizer, 2°= Secondary Neutralizer

CONTROL RESULTS

The results of controls run for culture purity, viability, organic soil load sterility, neutralizing subculture medium sterility, carrier sterility, carrier population, non-active treatment and neutralization confirmation controls were all acceptable.

ANALYSIS

VigorOx Liquid Sanitizer and Disinfectant (Lot 17622C1420) diluted to 19.2 oz/gallon (defined as 19.2 ounces test substance + 108.8 ounces sterile deionized water) and applied by the V2 Fog Tank, demonstrated no growth of *Trichophyton interdigitale* (ATCC 9533) in any of the 22 subcultures following an 8 minute 50 second exposure (cycle) time and 45 minute dwell time when tested at room temperature (21.0-21.6°C) and 53.7-57.3% RH.

PREPARED BY:

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9/25/23
Date