

STUDY REPORT

STUDY TITLE

Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces

Virus: Infectious Laryngotracheitis virus

PRODUCT IDENTITY

Gluquat 2
Lot# 311011

TRF NUMBER

WPC02011714.ILGT

AUTHOR

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STUDY COMPLETION DATE

February 26, 2014

PERFORMING LABORATORY

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SPONSOR

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PROJECT NUMBER

A16214

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STUDY REPORT

GENERAL STUDY INFORMATION

Study Title: Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces

Project Number: A16214

TRF Number: WPC02011714.ILGT

TEST SUBSTANCE IDENTITY

Test Substance Name: Gluquat 2

Lot: Lot# 311011

STUDY DATES

Date Sample Received: January 27, 2014

Study Initiation Date: February 7, 2014

Experimental Start Date: February 14, 2014

Experimental End Date: February 21, 2014

Study Completion Date: February 26, 2014

TEST PARAMETERS

Dilution: 0.4% defined as 4 mL test substance + 1 liter 300 ppm AOAC Synthetic Hard Water

Virus: Infectious Laryngotracheitis virus, strain LT-IVAX modified live vaccine, obtained from Poultry Health and Specilities, Inc. St. Cloud, MN.

Exposure Time: 10 minutes

Exposure Temperature: Room temperature (20.0°C)

Organic Soil Load: 5% lamb serum

Test Medium: Minimum Essential Medium (MEM) supplemented with 5% lamb serum, 5% tryptose phosphate broth, L-glutamine, and antibiotics.

Indicator Cell Cultures: Chicken embryo kidney (CEK) cells

EXPERIMENTAL DESIGN

A film of virus, dried on a glass surface, was exposed to a 2.00 mL aliquot of the test substance for the 10 minute Sponsor specified exposure time at room temperature (20.0°C). Following the exposure time, the virucidal and cytotoxic activities were removed from the virus-test substance mixture utilizing a Sephadex gel column, and the mixture was assayed for viral infectivity by an accepted assay method. Appropriate virus, test substance cytotoxicity, and neutralization controls were run concurrently. Per Sponsor's direction, the study was not required to be conducted under US EPA 40 CFR Part 160 or US FDA 21 CFR Part 58.

CONCLUSION

Under these test conditions, Gluquat 2 **demonstrated complete inactivation** of Infectious Laryngotracheitis virus following a 10 minute exposure time. Taking the cytotoxicity and neutralization control results into consideration, a $\geq 4.25 \log_{10}$ reduction in viral titer was demonstrated for Gluquat 2 as compared to the titer of the virus control.

In the opinion of the Author, there were no circumstances that may have affected the quality or integrity of the data.

STUDY RESULTS

TABLE 1: Effects of Gluquat 2 (Lot# 311011) Following a 10 Minute Exposure to Infectious Laryngotracheitis Virus Dried on an Inanimate Surface

Dilution	Input Virus Control	Dried Virus Control	Infectious Laryngotracheitis virus + Lot# 311011
Cell Control	0 0	0 0 0 0	0 0 0 0
10 ⁻¹	++	++++	0 0 0 0
10 ⁻²	++	++++	0 0 0 0
10 ⁻³	++	++++	0 0 0 0
10 ⁻⁴	++	++++	0 0 0 0
10 ⁻⁵	++	+ 0 0 0	0 0 0 0
10 ⁻⁶	0 0	0 0 0 0	0 0 0 0
10 ⁻⁷	0 0	NT	NT
TCID ₅₀ /100 µL	10 ^{5.50}	10 ^{4.75}	≤10 ^{0.50}

(+) = Positive for the presence of test virus
 (0) = No test virus recovered and/or no cytotoxicity present
 (NT) = Not tested

TABLE 2: Cytotoxicity Control and Neutralization Control

Dilution	Cytotoxicity Control Lot# 311011	Neutralization Control Lot# 311011
Cell Control	0 0 0 0	0 0 0 0
10 ⁻¹	0 0 0 0	+ + + +
10 ⁻²	0 0 0 0	+ + + +
10 ⁻³	0 0 0 0	+ + + +
10 ⁻⁴	0 0 0 0	+ + + +
10 ⁻⁵	0 0 0 0	+ + + +
10 ⁻⁶	0 0 0 0	+ + + +
TCD ₅₀ /100 µL	≤10 ^{0.50}	See below

(+) = Positive for the presence of test virus

(0) = No test virus recovered and/or no cytotoxicity present

Results of the non-virucidal level control indicate that the test substance was neutralized at a TCID₅₀/100 µL of ≤0.50 log₁₀.

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2/26/14
Date

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