

STUDY REPORT

STUDY TITLE

Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces

Virus: Porcine Epidemic Diarrhea Virus

PRODUCT IDENTITY

Gluquat 2
Lot #311011

AUTHOR

Shanen Conway, B.S.
Manager, Virology Laboratory Operations

STUDY COMPLETION DATE

June 6, 2014

PERFORMING LABORATORY

ATS Labs
1285 Corporate Center Drive, Suite 110
Eagan, MN 55121

SPONSOR

West Penetone, Inc.
10900 Secant
Anjou, QC H1J 1S5
Canada

PROJECT NUMBER

A16713

Page 1 of 6

STUDY REPORT

GENERAL STUDY INFORMATION

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

Project Number: A16713

Protocol Number: WPC02050714.PEDV

TEST SUBSTANCE IDENTITY

Test Substance Name: Gluquat 2

Lot: Lot #311011

STUDY DATES

Date Sample Received: January 27, 2014

Study Initiation Date: May 15, 2014

Experimental Start Date: May 27, 2014

Experimental End Date: June 3, 2014

Study Completion Date: June 4, 2014

TEST PARAMETERS

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

Virus: Porcine Epidemic Diarrhea Virus, Colorado 2013 Isolate

Exposure Time: 10 minutes

Exposure Temperature: Room temperature (20.0°C)

Organic Soil Load: 5% fetal bovine serum

Test Medium: Test medium used in this study was Minimum Essential Medium (MEM) supplemented with 10 µg/mL gentamicin, 100 units/mL penicillin, 2.5 µg/mL amphotericin B, 10% (v/v) tryptose phosphate broth and 5 µg/mL TPCK-trypsin.

Indicator Cell Cultures: Vero 76 cells

EXPERIMENTAL DESIGN

A film of virus, dried on a glass surface, was exposed to a 2.00 mL aliquot of the use dilution 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 Porcine Epidemic Diarrhea Virus following a 10 minute exposure time. Taking the cytotoxicity and neutralization control results into consideration, a $\geq 4.00 \log_{10}$ 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 Porcine Epidemic Diarrhea Virus Dried on an Inanimate Surface

Dilution	Input Virus Control	Dried Virus Control	Porcine Epidemic Diarrhea 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 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 ^{5.00}	10 ^{4.50}	≤10 ^{0.50}

(+) = Positive for the presence of test virus

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

TABLE 2: Cytotoxicity Control and Neutralization Control

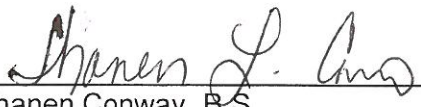
Dilution	Cytotoxicity Control Lot #311011	Neutralization Control Lot #311011
Cell Control	0 0 0 0	0 0 0 0
10 ⁻¹	0 0 0 0	+ + + +
10 ⁻²	0 0 0 0	+ + + +
10 ⁻³	0 0 0 0	+ + + +
10 ⁻⁴	0 0 0 0	+ + + +
10 ⁻⁵	0 0 0 0	+ + + +
10 ⁻⁶	0 0 0 0	+ + + +
TCD ₅₀ /100 µL	≤10 ^{0.50}	See below

(+) = 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.

PREPARED BY:


Shanen Conway, B.S.
Manager, Virology Laboratory Operations

6/6/14
Date

The use of the ATS Labs name, logo or any other representation of ATS Labs without the written approval of ATS Labs is prohibited. In addition, ATS Labs may not be referred to in any form of promotional materials, press releases, advertising or similar materials (whether by print, broadcast, communication or electronic means) without the expressed written permission of ATS Labs.