

NON-GLP STUDY REPORT

STUDY TITLE

Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces

Virus: Feline Calicivirus

PRODUCT IDENTITY

CLEANKILL DIFFICIL-S
BATCH NO. 110707

TRF NUMBER

CMX01072607.FCAL

AUTHOR

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STUDY COMPLETION DATE

September 24, 2007

PERFORMING LABORATORY

ATS Labs
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SPONSOR

Clinimax Ltd.
Shepherds Grove Industrial Estate West Stanton
Bury St. Edmunds
Suffolk IP31 2AR
England

PROJECT NUMBER

A05307

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

Page 1 of 5

STUDY REPORT

GENERAL STUDY INFORMATION

Study Title: Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces
Project Number: A05307
TRF Number: CMX01072607.FCAL

TEST SUBSTANCE IDENTITY

Test Substance Name: CLEANKILL DIFFICIL-S, Part A and Part B
Lot/Batch(s): BATCH NO. 110707

STUDY DATES

Date Sample Received: August 6, 2007
Study Initiation Date: August 20, 2007
Experimental Start Date: September 10, 2007
Experimental End Date: September 17, 2007
Study Completion Date: September 24, 2007

TESTING PARAMETERS

Dilution: 1:400 in filter sterilized tap water (1 packet Part A + 1 packet Part B in 10L sterile tap water)
Virus: Feline Calicivirus, ATCC VR-782, Strain F-9
Exposure Time: Five minutes
Exposure Temperature: Room temperature (19.9°C)
Organic Soil Load: 5% fetal bovine serum
Test Medium: Minimum Essential Medium (MEM) supplemented with 5% heat-inactivated fetal bovine serum, 100 units/mL penicillin, 10 µg/mL gentamicin, and 2.5 µg/mL amphotericin B.
Indicator Cell Cultures: CRFK cells

EXPERIMENTAL DESIGN

A film of virus, dried on a glass surface, was exposed to the test substance for the five minute Sponsor specified contact time. Following the exposure time, the virucidal and cytotoxic activities were removed from the virus-test substance mixtures utilizing a Sephadex gel column, and the mixtures were assayed for viral infectivity by an accepted assay method. Appropriate virus, test substance cytotoxicity, and neutralization controls were run concurrently.

CONCLUSION

Under these test conditions, CLEANKILL DIFFICIL-S (Batch No. 110707) **demonstrated complete inactivation** of Feline Calicivirus. Taking the cytotoxicity and neutralization control results into consideration, a $>6.0 \log_{10}$ reduction in viral titer was demonstrated for CLEANKILL DIFFICIL-S.

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 CLEANKILL DIFFICIL-S (Batch No. 110707) Following a Five Minute Exposure to Feline Calicivirus Dried on an Inanimate Surface

Dilution	Dried Virus Control	Feline Calicivirus + CLEANKILL DIFFICIL-S
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
10 ⁻⁷	0 0 0 0	0 0 0 0
10 ⁻⁸	0 0 0 0	0 0 0 0
TCID ₅₀ /0.1 mL	10 ^{6.5}	≤10 ^{0.5}

TABLE 2: Cytotoxicity Control and Neutralization Control

Dilution	Cytotoxicity Control CLEANKILL DIFFICIL-S	Neutralization Control CLEANKILL DIFFICIL-S
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	++++
10 ⁻⁷	0 0 0 0	++++
10 ⁻⁸	0 0 0 0	++++
TCD ₅₀ /0.1 mL	≤10 ^{0.5}	See below

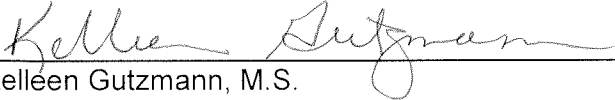
(+) = Positive for the presence of test virus
 (0) = No test virus recovered and/or no cytotoxicity present

Results of the non-virucidal level control indicate that the test substance was neutralized at a TCID₅₀ of ≤0.5 log₁₀.

PROFESSIONAL PERSONNEL INVOLVED:

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Kelleen Gutzmann, M.S.	- Research Scientist II
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9-24-07
Date

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Quality Assurance Auditor

9-24-07
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