

NON-GLP STUDY REPORT

STUDY TITLE

Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces

Virus: Swine Influenza A (H1N1) virus

PRODUCT IDENTITY

SANITIZER CONCENTRATED

Lot: 9BR035DESC

TRF NUMBER

AUK01062909.SFLU

AUTHOR

Mary J. Miller, M.T.
Research Scientist II

STUDY COMPLETION DATE

September 10, 2009

PERFORMING LABORATORY

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

SPONSOR

Arch UK Biocides
P.O. Box 42, Blackley
Old Market Street
Manchester, UK M9 8ZS
UNITED KINGDOM

PROJECT NUMBER

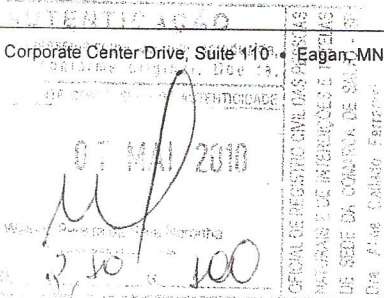
A08073

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

Page 1 of 6



1285 Corporate Center Drive, Suite 110 • Eagan, MN 55121 • 877.287.8378 • 651.379.5510 • Fax: 651.379.5549



STUDY REPORT

GENERAL STUDY INFORMATION

Study Title: Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces
Project Number: A08073
TRF Number: AUK01062909.SFLU

TEST SUBSTANCE IDENTITY

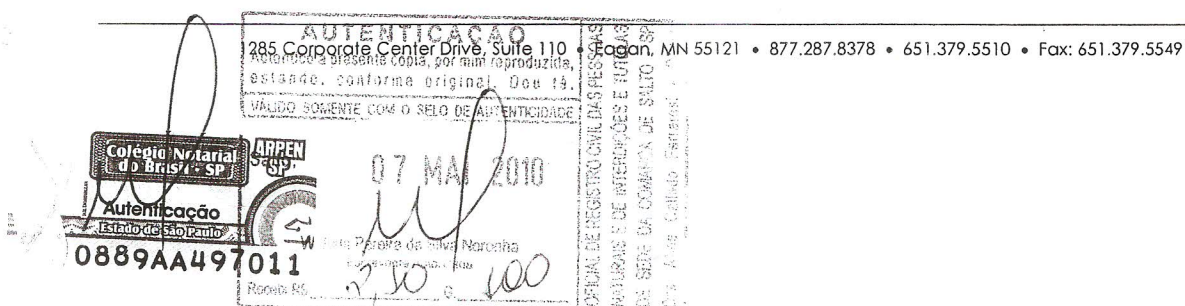
Test Substance Name: SANITIZER CONCENTRATED
Lot/Batch(s): Lot: 9BR035DESC
Manufacture Date: February 4, 2009
Expiration Date: February 4, 2010
Test Substance Active Concentration: 8.6% of cationic active ingredient based on Quats and PHMB

STUDY DATES

Date Sample Received: July 24, 2009
Study Initiation Date: August 5, 2009
Experimental Start Date: August 18, 2009
Experimental End Date: August 25, 2009
Study Completion Date: September 10, 2009

TEST PARAMETERS

Dilution: 0.5% product in filter sterilized deionized water
1% product in filter sterilized deionized water
2% product in filter sterilized deionized water
Virus: Swine Influenza A (H1N1) virus, ATCC VR-333
Strain A/Swine/Iowa/15/30
Exposure Time: Ten minutes
Exposure Temperature: Room temperature (20.0°C)
Organic Soil Load: 1% fetal bovine serum
Test Medium: Minimum Essential Medium (MEM) supplemented with 1% heat-inactivated fetal bovine serum, 100 units/mL penicillin, 10 µg/mL gentamicin, and 2.5 µg/mL amphotericin B.
Indicator Cell Cultures: Rhesus monkey kidney (RMK) cells



EXPERIMENTAL DESIGN

For each concentration of the test substance, a film of virus, dried on a glass surface, was exposed to a 2.00 mL aliquot of the test substance for the ten 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 mixtures utilizing individual Sephadex gel columns, and the mixtures were assayed for viral infectivity by an accepted assay method. Appropriate virus, test substance cytotoxicity, and neutralization controls were run concurrently.

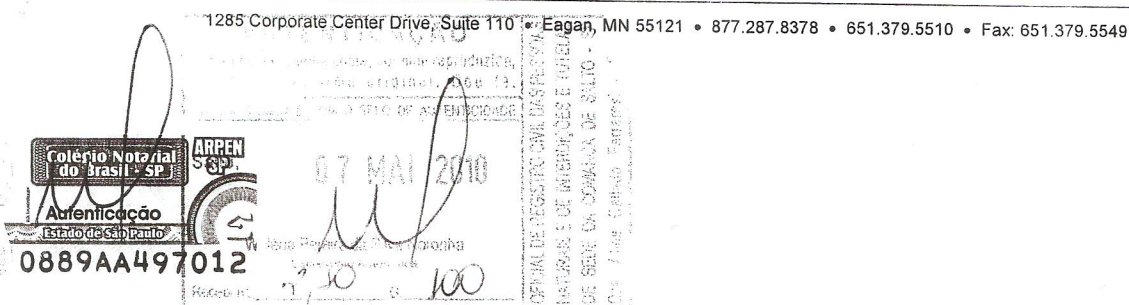
REFERENCES

1. Annual Book of ASTM Standards, Section 11 Water and Environmental Technology Volume 11.05 Pesticides; Environmental Assessment; Hazardous Substances and Oil Spill Response, E 1053-97 (Reapproved 2002).
2. Annual Book of ASTM Standards, Section 11 Water and Environmental Technology Volume 11.05 Pesticides; Environmental Assessment; Hazardous Substances and Oil Spill Response, E 1482-04.
3. U.S. Environmental Protection Agency Pesticide Assessment Guidelines, Subdivision G: Product Performance, 91-2(f), November 1982.
4. U.S. Environmental Protection Agency, Registration Division, Office of Pesticide Programs, DIS/TSS-7, November 12, 1981.
5. Diagnostic Procedures for Viral, Rickettsial, and Chlamydial Infections. Lennette, E.H., Lennette, D.A. and Lennette, E.T. editors. Seventh edition, 1995.
6. Blackwell, J.H., and J.H.S. Chen. 1970. Effects of various germicidal chemicals on HEP-2 cell culture and Herpes simplex virus: J. AOAC 53:1229-1236.

CONCLUSION

Under the conditions of this investigation and in the presence of a 1% fetal bovine serum organic soil load, three concentrations of SANITIZER CONCENTRATED (0.5%, 1%, and 2%) **demonstrated complete inactivation** of Swine Influenza A (H1N1) virus following a ten minute exposure time at room temperature (20.0°C). Taking the cytotoxicity and neutralization control results into consideration, a $\geq 5.0 \log_{10}$ reduction in viral titer was demonstrated for all three concentrations of SANITIZER CONCENTRATED 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 SANITIZER CONCENTRATED (Lot: 9BR035DESC) Following a Ten Minute Exposure to Swine Influenza A (H1N1) Virus Dried on an Inanimate Surface

Dilution	Dried Virus Control	Swine Influenza A (H1N1) virus + SANITIZER CONCENTRATED Lot: 9BR035DESC		
		0.5% Concentration	1% Concentration	2% Concentration
Cell Control	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0
10 ⁻¹	+	0 0 0 0	0 0 0 0	0 0 0 0
10 ⁻²	+	0 0 0 0	0 0 0 0	0 0 0 0
10 ⁻³	+	0 0 0 0	0 0 0 0	0 0 0 0
10 ⁻⁴	+	0 0 0 0	0 0 0 0	0 0 0 0
10 ⁻⁵	+	0 0 0 0	0 0 0 0	0 0 0 0
10 ⁻⁶	+	0 0 0 0	0 0 0 0	0 0 0 0
TCID ₅₀ /0.1 mL	10 ^{5.5}	≤10 ^{0.5}	≤10 ^{0.5}	≤10 ^{0.5}

TABLE 2: Cytotoxicity of SANITIZER CONCENTRATED on RMK Cell Cultures

Dilution	Cytotoxicity Controls SANITIZER CONCENTRATED Lot: 9BR035DESC		
	0.5% Concentration	1% Concentration	2% Concentration
Cell Control	0 0 0 0	0 0 0 0	0 0 0 0
10 ⁻¹	0 0 0 0	0 0 0 0	0 0 0 0
10 ⁻²	0 0 0 0	0 0 0 0	0 0 0 0
10 ⁻³	0 0 0 0	0 0 0 0	0 0 0 0
10 ⁻⁴	0 0 0 0	0 0 0 0	0 0 0 0
10 ⁻⁵	0 0 0 0	0 0 0 0	0 0 0 0
10 ⁻⁶	0 0 0 0	0 0 0 0	0 0 0 0
TCD ₅₀ /0.1 mL	≤10 ^{0.5}	≤10 ^{0.5}	≤10 ^{0.5}

(+) = Positive for the presence of test virus

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

Autenticação 1285 Corporate Center Drive, Suite 110 • Eagan, MN 55121 • 877.287.8378 • 651.379.5510 • Fax: 651.379.5549
estando, conforme original. Doc 13.
VÁLIDO SOMENTE COM O SELLO DE AUTENTICACAO



Autenticação
0889AA497013

07 MAI 2010

Waldia Pereira da Silva Moronça
Secretaria Autenticadora

CRUAL DE REGISTRO CIVIL DAS FILIAS
MUNICÍPIO DE HENRIQUES E FILHO
RUA SENA DA COSTA DE SAULO
100 - Vila Colado Fátima -

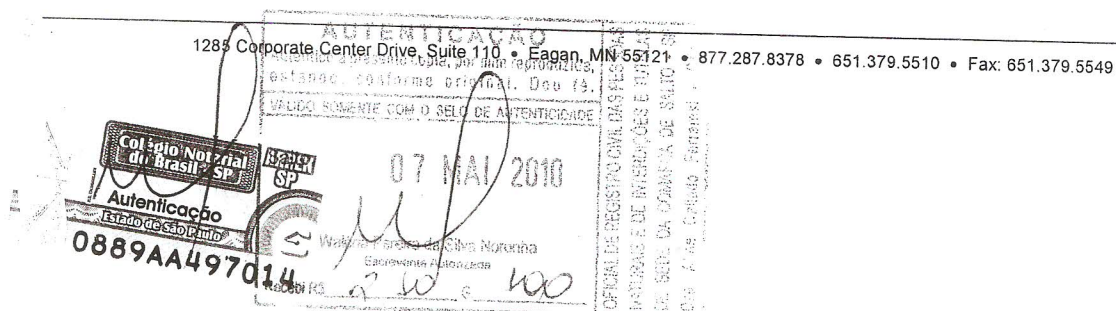
TABLE 3: Non-Virucidal Level of Test Substance (Neutralization Control)

Dilution	Neutralization Controls SANITIZER CONCENTRATED Lot: 9BR035DESC		
	0.5% Concentration	1% Concentration	2% Concentration
Cell Control	0 0 0 0	0 0 0 0	0 0 0 0
10 ⁻¹	+	+	+
10 ⁻²	+	+	+
10 ⁻³	+	+	+
10 ⁻⁴	+	+	+
10 ⁻⁵	+	+	+
10 ⁻⁶	+	+	+
TCID ₅₀ /0.1 mL	≤10 ^{0.5}	≤10 ^{0.5}	≤10 ^{0.5}

(+) = Positive for the presence of test virus

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

Results of the non-virucidal level control (neutralization control) indicate that all three concentrations of the test substance were neutralized at a TCID₅₀/0.1 mL of ≤0.5 log₁₀.



PROFESSIONAL PERSONNEL INVOLVED:

Karen M. Ramm, B.A.	- Technical Director
Mary J. Miller, M.T.	- Research Scientist II
Katherine A. Paulson, M.L.T.	- Research Assistant II
Shanen Conway, B.S.	- Research Assistant II

PREPARED BY:

Mary J. Miller
Mary J. Miller, M.T.
Research Scientist II

9-10-09
Date

REVIEWED BY:

Wayne Almeida
Quality Assurance Auditor

9/10/09
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 express written permission of ATS Labs.

1285 Corporate Center Drive, Suite 110 • Eagan, MN 55121 • 877.287.8378 • 651.379.5510 • Fax: 651.379.5549



07 MAI 2010

100

March 12, 2010

Arch Quimica Brasil Ltda
Av. Brasília, 1.500 - Bairro Buru
13327-901 - Salto - SP - CEP 13320-970

Arch Quimica Brasil Ltda.,

ATS Labs is an efficacy testing laboratory; we do not offer active level testing, this would be performed by an analytical laboratory.

Please feel free to contact me with any additional questions or concerns you may have.

Sincerely,

Karen M. Ramm

Karen M. Ramm, B.A.
Director, New Business Development

