NON-GLP STUDY REPORT

STUDY TITLE
Pre-Saturated Towelettes for Hard Surface Sporicidal Activity

Test Organism:
*Clostridium difficile* - spore form (ATCC 43598)

PRODUCT IDENTITY
Clinell Sporicidal Lot 112G2 and Clorox Germicidal Wipes Lot Q62082 2041

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Research Scientist I

STUDY COMPLETION DATE
November 13, 2012

PERFORMING LABORATORY
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SPONSOR
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UK

PROJECT NUMBER
A13422

Page 1 of 7
STUDY REPORT

GENERAL STUDY INFORMATION

Study Title: Pre-Saturated Towelettes for Hard Surface Sporicidal Activity

Project Number: A13422

Protocol Number: GPC03041012.TOW

TEST SUBSTANCE IDENTITY

Test Substance Name: Clinell Sporicidal Lot 112G2 and Clorox Germicidal Wipes Lot Q62082 2041

STUDY DATES

Date Sample Received: May 16, 2012
Study Initiation Date: May 30, 2012
Experimental Start Date: June 13, 2012
Experimental End Date: July 6, 2012
Study Completion Date: November 13, 2012

<table>
<thead>
<tr>
<th>Test Organism</th>
<th>ATCC #</th>
<th>Growth Medium</th>
<th>Incubation Parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clostridium difficile - spore form</td>
<td>43598</td>
<td>CDC Anaerobic Blood Agar</td>
<td>35-37°C, anaerobic</td>
</tr>
</tbody>
</table>

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

Test Substance Dilution:
Clinell Sporicidal Wipes: Each wipe was prepared by unfolding wipe in a sterile pan and adding 70±5g of 400ppm hard water evenly across the surface of the wipe. After waiting 10 seconds, the wipe was folded in half five times and gently squeezed to remove the excess liquid. Each wipe was weighed and was between 30-35g. After preparation, each wipe was used within 5 minutes.

Clorox Germicidal Wipes: Ready to use (RTU)

Exposure Time:
Clinell Sporicidal: 1, 2, 3, 4 and 5 minutes
Clorox Germicidal Wipes: 5 minutes

Exposure Temperature: Ambient (21°C)

Number of Carriers Tested/Lot: 10 per exposure time

Soil Load Description: No organic soil load required

Wiping Instructions: Over and back, 2 times for a total of 4 passes

Agar Plate Medium: CCFA-HT Agar

Neutralizing Subculture Medium:
C diff Broth + 0.1% Sodium Thiosulfate (Primary)
Modified Fluid Thioglycollate Medium + 0.1% Cholic Acid (Secondary)
Modified Fluid Thioglycollate Medium (HCl Control)
EXPERIMENTAL DESIGN

A film of bacterial spores dried on an approximate 1" x 1" area of 1" x 3" glass carriers was wiped with the towelette. The area of the towelette was rotated between each carrier so as to expose a maximum amount of the towelette surface during the wiping procedure. Each carrier was wiped using a 2x2 motion which represents wiping the contaminated surface over and back twice for a total of 4 passes. The carriers were allowed expose for the exposure times. One towelette was used to wipe 10 carriers. After exposure, the carriers were transferred to vessels containing neutralizing subculture medium and were assayed for survivors. Following ≥30 minutes of neutralization, the carriers were transferred to secondary subcultures containing neutralizing subculture medium. Appropriate culture purity, viability, neutralizing subculture medium sterility, carrier sterility, carrier population, neutralization confirmation and HCl resistance controls were performed.

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.

TABLE 1: CONTROL RESULTS

The following results from controls confirmed study validity:

| Type of Control                             | Results | Results of Key Control
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Purity Control</td>
<td>Pure</td>
<td>Clostridium difficile - spore form (ATCC 43598)</td>
</tr>
<tr>
<td>Viability Control</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Modified Fluid Thioglycollate Medium</td>
<td>#1</td>
<td>Growth</td>
</tr>
<tr>
<td></td>
<td>#2</td>
<td>Growth</td>
</tr>
<tr>
<td>Modified Fluid Thioglycollate Medium + 0.1% Cholic Acid</td>
<td>#1</td>
<td>Growth</td>
</tr>
<tr>
<td></td>
<td>#2</td>
<td>Growth</td>
</tr>
<tr>
<td>Neutralizing Subculture Medium Sterility Control</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary Neutralizing Subculture Medium</td>
<td>No Growth</td>
<td></td>
</tr>
<tr>
<td>Secondary Neutralizing Subculture Medium</td>
<td>No Growth</td>
<td></td>
</tr>
<tr>
<td>Modified Fluid Thioglycollate Medium</td>
<td>No Growth</td>
<td></td>
</tr>
<tr>
<td>Carrier Sterility Control</td>
<td>No Growth</td>
<td></td>
</tr>
</tbody>
</table>
### TABLE 2: CARRIER POPULATION CONTROL RESULTS

<table>
<thead>
<tr>
<th>Test Organism</th>
<th>Carrier #</th>
<th>CFU/carryer</th>
<th>Log$_{10}$</th>
<th>Average Log$_{10}$</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Clostridium difficile</em> - spore form (ATCC 43598)</td>
<td>1</td>
<td>5.88 x 10$^5$</td>
<td>5.77</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>9.76 x 10$^5$</td>
<td>5.99</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>1.6 x 10$^6$</td>
<td>6.20</td>
<td>5.99</td>
</tr>
</tbody>
</table>

CFU = Colony Forming Unit

### TABLE 3: NEUTRALIZATION CONFIRMATION CONTROL RESULTS

<table>
<thead>
<tr>
<th>Test Organism</th>
<th>Test Substance</th>
<th>Average CFU Added</th>
<th>Number of Subcultures</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Clostridium difficile</em> - spore form (ATCC 43598)</td>
<td>Clinell Sporicidal Lot 112G2</td>
<td>56</td>
<td>$1^\circ=1$ $2^\circ=1$</td>
</tr>
<tr>
<td></td>
<td>Clorox Germicidal Wipes Lot Q62082 2041</td>
<td></td>
<td>$1^\circ=1$ $2^\circ=1$</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>$1^\circ=0$ $2^\circ=1$</td>
</tr>
</tbody>
</table>

CFU = Colony Forming Unit
$1^\circ$=Primary Subculture
$2^\circ$=Secondary Subculture

### TABLE 4: 2.5N HCl RESISTANCE CONTROL RESULTS

<table>
<thead>
<tr>
<th>Test Organism</th>
<th>2 Minutes</th>
<th>5 Minutes</th>
<th>10 Minutes</th>
<th>20 Minutes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1$^\circ$</td>
<td>2$^\circ$</td>
<td>1$^\circ$</td>
<td>2$^\circ$</td>
</tr>
<tr>
<td><em>Clostridium difficile</em> - spore form (ATCC 43598)</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>

+ = Growth of the test organism
$1^\circ$ = Primary Subculture
$2^\circ$ = Secondary Subculture
TABLE 5: TEST RESULTS

<table>
<thead>
<tr>
<th>Test Organism</th>
<th>Test Substance</th>
<th>Sample Dilution</th>
<th>Exposure Time</th>
<th>Number of Carriers</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Clinell Sporicidal Lot 112G2</td>
<td>70±5g of 400ppm hard water added to each wipe</td>
<td>1 minute</td>
<td>Exposed: 1°=10 2°=10  Showing Growth*: 1°=0 2°=4</td>
</tr>
<tr>
<td>Clostridium difficile - spore form (ATCC 43598)</td>
<td></td>
<td></td>
<td>2 minutes</td>
<td>Exposed: 1°=10 2°=10  Showing Growth*: 1°=0 2°=0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3 minutes</td>
<td>Exposed: 1°=10 2°=10  Showing Growth*: 1°=0 2°=0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>4 minutes</td>
<td>Exposed: 1°=10 2°=10  Showing Growth*: 1°=0 2°=0</td>
</tr>
<tr>
<td></td>
<td>Clorox Germicidal Wipes Lot Q62082 2041</td>
<td>Ready to use</td>
<td>5 minutes</td>
<td>Exposed: 1°=10 2°=10  Showing Growth*: 1°=0 2°=0</td>
</tr>
</tbody>
</table>

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

CONTROL RESULTS

The results of controls run for culture purity, viability, neutralizing subculture medium sterility, carrier sterility, carrier population, neutralization confirmation and HCl resistance controls were all acceptable.
ANALYSIS

Clinell Sporicidal Lot 112G2, saturated with 70±5g of 400ppm hard water, demonstrated growth of *Clostridium difficile* - spore form (ATCC 43598) in 0 of the 10 primary subcultures and growth in 4 of the 10 secondary subcultures following a 1 minute exposure time when tested at ambient temperature (21°C).

Clinell Sporicidal Lot 112G2, saturated with 70±5g of 400ppm hard water, demonstrated no growth of *Clostridium difficile* - spore form (ATCC 43598) in any of the 10 primary subcultures or 10 secondary subcultures following 2, 3, 4, and 5 minute exposure times when tested at ambient temperature (21°C).

The ready to use pre-saturated towelette, Clorox Germicidal Wipes Lot Q62082 2041, demonstrated no growth of *Clostridium difficile* - spore form (ATCC 43598) in any of the 10 primary subcultures or 10 secondary subcultures following a 5 minute exposure time when tested at ambient temperature (21°C).
PROFESSIONAL PERSONNEL INVOLVED:

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Adam W. Pitt, B.S. - Research Assistant II
Kathryn Thomas, B.S. - Research Assistant I
Philip Lange, B.S. - Research Assistant I
Lindsey Peach, B.A. - Research Assistant I
Kristen Niehaus, B.A. - Research Assistant I
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PREPARED BY:

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Date: 11-13-12

REVIEWS BY:

Quality Assurance Auditor

Date: 11-13-12

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