

10/20/89

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION  
EFFICACY REVIEW - I

Antimicrobial Program Branch

IN 08-16-89

OUT 10-10-89

Reviewed By Emily H. Mitchell <sup>WEC</sup> <sub>10/24/89</sub> Date 10-10-89

PA Reg. No. or File Symbol 8714-8

EPA Petition or EUP No. None

Date Division Received 09-26-89

Type Product(s) Hospital Disinfectant/Sterilant

Data Accession No.(s) 412045-01-412045-02

Product Mgr. No. PM 32 (Kempter)

Product Name(s) Clidox™-S Base & Clidox™-S Activator

Company Name(s) Pharmacal Research Laboratories, Inc.

Submission Purpose Resubmission to provided data for additional label claims.

Chemical & Formulation Liquid concentrate to be diluted with water before acidifying with activator

Active Ingredient(s): 8

Sodium chlorite . . . . . 0.85%

SODIUM CHLORITE

1

200.0 Introduction

200.1 Uses:

A sterilant and a disinfectant for use in laboratory animal breeding and research animal quarters on instruments and surfaces such as aluminum, plastics, stainless steel instruments, glass, and tile. Label bears claims as sporicidal, virucidal, bactericidal, fungicidal and tuberculocidal.

200.2 Background Information:

The submission received 08-16-89, is a resubmission with amendments to the label. Efficacy data and new labels provided.

201.0 Data Summary (MRID Nos. 412045-01-412045-02)

201.1 Brief Description of Tests:

- a. Reports of Bactericidal, Fungicidal and Tuberculo-cidal Tests by Kyle H. Sabinovic, Ph.D.  
Shaldra Biotest, Inc.  
W. Bethesda, Maryland 20817 (dated 07-23-89)
- b. Reports of Virucidal Tests by Philip R. Roane, Ph.D.  
Integrity Bioservices Inc.  
12280 Wilkins Avenue  
Rockville, Maryland 20852 (dated 09-12-88)

201.2 Test Summaries:

a. Bactericidal Tests

1. Method: A.O.A.C. Use Dilution Test, 14th Edition, 1984.
2. Modifications: None
3. Samples:

<u>Test Bacteria</u>	<u>Lot No.</u>	<u>Date Started</u>	<u>Date Completed</u>
P. aeruginosa	17072088	08-11-88	08-13-88
	17041089	04-26-89	04-28-89
S. aureus	17072088	08-11-88	08-13-88
	17041089	04-26-89	04-28-89
S. choleraesuis	17072088	08-11-88	08-13-88
	17041089	04-26-89	04-28-89

2

4. Dilution: 1:18:1
5. Exposure: 3 minutes at 20°C
6. Subculture Medium/Neutralizer: .1 N Na Thio-sulfite
7. Incubation of Subcultures: 48 hours at 37°C
8. Test Bacteria:

<u>Test Bacteria</u>	<u>ATTC No.</u>	<u>Phenol Res.</u>
<u>Pseudomonas aeruginosa</u>	15442	1:90
<u>Staphylococcus aureus</u>	6538	1:60
<u>Salmonella choleraesuis</u>	10708	1:90

9. Survival of Inoculum on Control Carriers:

<u>Test Bacteria</u>	<u>Organism/Carrier</u>
<u>P. aeruginosa</u>	1.5 x 10 <sup>5</sup> /ss
	1.5 x 10 <sup>5</sup> /ss
<u>S. aureus</u>	5.4 x 10 <sup>5</sup> /ss
	5.4 x 10 <sup>5</sup> /ss
<u>S. choleraesuis</u>	1.5 x 10 <sup>5</sup> /ss
	1.5 x 10 <sup>5</sup> /ss

10. Test Results:

<u>Test Bacteria</u>	<u>Lot No.</u>	<u>No. Carriers Tested</u>	<u>No. of Carriers Demonstrating Growth</u>
<u>Pseudomonas aeruginosa</u>	17072088	90	0/90
	17041089	90	0/90
<u>Staphylococcus aureus</u>	17072088	90	0/90
	17041089	90	0/90
<u>Salmonella choleraesuis</u>	17072088	90	0/90
	17041089	90	0/90

11. Conclusions: Results show satisfactory performance of the product against Pseudomonas aeruginosa, Staphylococcus aureus and Salmonella choleraesuis at a 1:18:1 dilution for 3 minutes at 20°C. However, one additional sample is required for each test organism.

b. Fungicidal Tests

1. Method: Official Methods of Analysis of the A.O.A.C., 14th Edition, 1984.
2. Modifications: None
3. Samples:

<u>Test Organism</u>	<u>Sample Number</u>	<u>Started Date</u>	<u>Completed Date</u>
T. <u>mentagrophytes</u>	Clidox 3 17072088	08-11-88	08-21-88
	Clidox 2 17041089	04-24-89	05-04-89

4. Dilution: 1:18:1
5. Exposure: 3 minutes at 20°C
6. Subculture Medium/Neutralizer: .1 N Na Thiosulfite
7. Incubation of Subcultures: 10 days at 25°C to 30°C
8. Test Organism:

<u>Test Organism</u>	<u>ATCC No.</u>	<u>Phenol Res.</u>
<u>Trichophyton mentagrophytes</u>	9533	1:70

9. Test Results:

<u>Test Organism</u>	<u>Sample No.</u>	<u>No. Carriers Tested</u>		<u>No. Pos./ Total Carriers</u>
<u>Trichophyton mentagrophytes</u>	17072088	Subculture 1	10	0/10
	Clidox 3	Subculture 2	10	0/10
	17041089	Subculture 1	10	0/10
	Clidox 2	Subculture 2	10	0/10

Cell Count  $6.0 \times 10^6$ /ml

10. Conclusions: Results show satisfactory performance of the product against Trichophyton mentagrophytes when used at a 1:18:1 dilution for a contact time of 3 minutes at 20°C.

4

c. Tuberculocidal Tests

1. Method: A.O.A.C. Tuberculocidal Test
2. Modifications: None
3. Samples:

<u>Sample No.</u>	<u>Started Date</u>	<u>Completed Date</u>
Clidox 1 (17060188)	04-24-89	07-23-89
Clidox 2 (17041089)	04-24-89	07-23-89

4. Dilution: 1:18:1
5. Exposure Time: 5 minutes at 20°C.
6. Subculture Medium/Neutralizer:  
Modified Proskauer-Beck  
Middlebrook 7H9 broth  
Kirchner's Medium
7. Incubation of Subcultures: 60 days at 37°C  
Re-incubate negative or very faint growth for  
an additional 30 days.
8. Test Organism:

<u>Test Organism</u>	<u>ATCC No.</u>	<u>Phenol Res.</u>
<u>Mycobacterium bovis</u>	35743	1:50 (no growth) 1:70 (growth)

9. Test Results:

Number of Positive Carriers

<u>Sample No.</u>	<u>Proskauer Beck Modified</u>	<u>Middlebrook 7H9</u>	<u>Kirchner</u>	<u>No. of Pos. Carriers</u>
Clidox 1 (17060188)	0	0	0	0/10
Clidox 2 (17041089)	0	0	0	0/10

10. Conclusions: Results show satisfactory performance of product against Mycobacterium bovis (BCG) at a 1:18:1 dilution for 5 minutes at 20°C.

d. Virucidal Tests

1. Method: EPA Test Method (DIS/TSS-7)
2. Modifications: None
3. Samples:
 

<u>Sample Number</u>	<u>Started Date</u>
17111787	05-09-88
17031088	05-09-88
10707288	08-12-88
17081888	08-30-88
4. Dilution: 1:18:1
5. Exposure: 3 minutes at 20°C
6. Recovery Medium/Neutralizer/Diluent: Lethen Broth
7. Incubation: 37°C up to 7 days
8. Test Virus Host System:  
Herpes Simplex, Type 2-Vero Cells  
Poliovirus 1-BGM
9. Drying Time and Temperature: 2 hrs. at 20°C
10. Assay System for Virus Recovery:  
Herpes Simplex, Type 2-HEP II  
Poliovirus 1-BGM
11. Method For Estimating 50 per cent end point:  
Reed Muench Method
12. Test Virus:  
Herpes Simplex, Type 2 (G Strain)  
Poliovirus 1 (Brunhilde-VR-ATCC-58)
13. Test Results:

ID-50 (-log 10)

<u>Test Virus</u>	<u>Sample No.</u>	<u>Virus Control</u>	<u>Virus Disin.</u>	<u>Toxicity Control</u>	<u>Virus Inactivation</u>
Herpes Simplex	17111787	7.5	1.5	1.5	6.0
	17031088	7.5	1.5	1.5	6.0
Poliovirus 1	10707288	7.5	1.5	1.5	6.0
	17081888	7.5	1.5	1.5	6.0

14. Conclusions: This product showed satisfactory performance against the test viruses when used at a 1:18:1 dilution for 3 minutes at 20°C.