

4/9/90

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION
EFFICACY REVIEW - I

Antimicrobial Program Branch

IN 03-05-90 OUT 04-03-90

Reviewed By Emily H. Mitchell ^{WEC} _{4/9/90} Date 04-03-90

EPA Reg. No. or File Symbol 8714-8

EPA Petition or EUP No. None

Date Division Received 04-03-90

Type Product(s) Hospital Disinfectant/Sterilant

Data Accession No.(s) 414250-01-414250-02

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 additional data/
information.

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

Active Ingredient(s): 8

Sodium chlorite 0.85%

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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 03-15-90, is a resubmission with amendments to the label. Efficacy data and new labels provided.

201.0 Data Summary (MRID Nos. 414250-01-414250-02)

201.1 Brief Description of Tests:

- a. Reports of Bactericidal Tests by:
Kyle H. Sibinovic, Ph.D.
Shaldra Biotest, Inc.
W. Bethesda, Maryland 20817 (dated 07-23-89)

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	17060188	01-11-90	01-13-90
	17041089	01-11-90	01-13-90
	17012590	02-07-90	02-09-90
S. aureus	17060188	01-11-90	01-13-90
	17041089	01-11-90	01-13-90
	17012590	02-07-90	02-09-90
S. choleraesuis	17060188	01-11-90	01-13-90
	17041089	01-11-90	01-13-90
	17012590	02-07-90	02-07-90

4. Dilution: 1:18:1

5. Exposure: 5 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 ⁵ /ss
	1.5 x 10 ⁵ /ss
	1.5 x 10 ⁵ /ss
<u>S. aureus</u>	5.4 x 10 ⁵ /ss
	5.4 x 10 ⁵ /ss
	5.4 x 10 ⁵ /ss
<u>S. choleraesuis</u>	1.5 x 10 ⁵ /ss
	1.5 x 10 ⁵ /ss
	1.5 x 10 ⁵ /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>	17041089	60	0/60
	17060188	60	0/60
	17012590	60	0/60
<u>Staphylococcus aureus</u>	17041089	60	0/60
	17060188	60	0/60
	17012590	60	0/60
<u>Salmonella choleraesuis</u>	17041089	60	0/60
	17060188	60	0/60
	17012590	60	0/60

11. Conclusions: Results show satisfactory performance of the product against Pseudomonas aeruginosa, Staphylococcus aureus and Salmonella choleraesuis at a 1:18:1 dilution for 5 minutes at 20°C.