

US EPA ARCHIVE DOCUMENT

9/26/88

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW-I

Antimicrobial Program Branch

IN 07/27/88 OUT 09/26/88

Reviewed By Srinivas Gowda ^{Srinivas Gowda WEC} _{9/26/88} Date 09/26/88

EPA Reg. No. or File Symbol 8714-I

EPA Petition or EUP NO. NONE

Date Division Received 07/27/88

Type Product Hospital Sterilant/Disinfectant

MRID No.(s). None

Product Manager PM 32 (Kempter)

Product Name Clidox™- S Base & Clidox™-S Activator

Company Name Pharmacal Research Laboratories, Inc.

Submission Purpose Resubmission to provide requested data*
and revised proposed labeling

Type Formulation Liquid concentrate to be diluted with
water before acidifying with activator

Active Ingredient(s): / 8

Sodium Chlorite.....0.85

*Requested data are summarized in the attached table.

The submitted data/information completes and clarifies the data report.

SODIUM CHLORITE

QUANTITATION OF ORGANISM / CARRIER BY PLATE COUNT METHOD

3 CARRIERS, CONTAMINATED WITH THE APPROPRIATE TEST ORGANISM, DRIED PER AOAC, 14TH EDITION METHODOLOGY, WERE SEPARATELY PLACED INTO 100 ML STERILE SALINE AND SHAKEN VIGOROUSLY FOR 2 MINUTES. SERIAL 10-FOLD DILUTIONS WERE PREPARED AND ONE ML SAMPLES WERE PLATED IN DUPLICATE FROM EACH DILUTION.

INCUBATION TEMPERATURE / TIME: 48 HOURS AT 35'C
SUBCULTURE MEDIUM: LETHEN AGAR

RESULTS: (AVERAGE OF DUPLICATE COUNTS / CARRIER)

| | ORGANISM / CARRIER |
|---|--|
| STAPHYLOCOCCUS AUREUS - ATCC 6538 | 1.3 X 10E6 7.5 X 10E5 9.6 X 10E5 |
| SALMONELLA CHOLERAESUIS - ATCC 10708 | 1.2 X 10E6 1.7 X 10E6 1.0 X 10E6 |
| PSEUDOMONAS AERUGINOSA - ATCC 15442 | 1.5 X 10E6 1.1 X 10E6 1.6 X 10E6 |
| TRICHOPHYTON MENTAGROPHYTES - ATCC 9533 | 1.0 X 10E5 4.8 X 10E4 9.2 X 10E4 |