

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION  
EFFICACY REVIEW - II

Antimicrobial Program Branch

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Product Manager No. PM 32 (Kempter)

Product Name Clidox<sup>™</sup>-S Base & Clidox<sup>™</sup>-S Activator

Company Name Pharmacal Research Laboratories, Inc.

SODIUM CHLORITE

020502

202.0 Recommendations

202.1 Efficacy Supported by the Data:

- a. The submitted efficacy data appear adequate to support effectiveness of the product as a disinfectant against Staphylococcus aureus, Salmonella choleraesuis, and Pseudomonas aeruginosa when used at a 1:18:1 dilution ( 1 part activator:18 parts water:1 part base) for a contact time of 5 minutes at 20°C on hard non-porous surfaces.

203.0 Labeling (Clidox-S Activator & Clidox-S Base)

- a. In lieu of data, under Disinfecting Level change "CLIDOX-S diluted 1:18:1 kills vegetative bacteria including Pseudomonas aeruginosa, Staphylococcus aureus and Salmonella choleraesuis, pathogenic fungi and viruses\* in 3 minutes at 20°C, and M. bovis in 5 minutes at 20°C when used on pre-cleaned surfaces" to read "CLIDOX-S diluted 1:18:1 kills vegetative bacteria including Pseudomonas aeruginosa, Staphylococcus aureus and Salmonella choleraesuis, pathogenic fungi and viruses\* in 5 minutes at 20°C, and M. bovis in 5 minutes at 20°C when uses on pre-cleaned surfaces."
- b. Under Disinfecting Level change "Herpes Simplex II and Polio virus I" to read "Herpes Simplex, Type 2 and Poliovirus, Type 1".
- c. The unqualified recommendation for the use of an antimicrobial agent on plastics will no longer be accepted. Since there are several types of plastics used by the healthcare industry, the product label should indicate generically plastics compatibility.