EFFICACY EVALUATION - TEAM 2

RISK ASSESSMENT & SCIENCE SUPPORT BRANCH
ANTIMICROBIALS DIVISION

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Reviewed By: David Bays, Microbiologist

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EPA Reg. No. or File Symbol: D239500 777-83

Product Name: Lysol Brand Disinfectant Bleach Plus

Product Type: Disinfectant

Company Name: Household Products Division, Reckitt & Colman, Inc

MRID No(s): 443793-01

Product Manager/Reviewer & Team No.: Marianne Clark/Robert Brennis #32

Submission Purpose: Review submitted data for efficacy amendment changes

Product Formulation:

200.0 **INTRODUCTION**

The registrant, Reckitt & Colman, Inc., has submitted an efficacy study, AOAC Use Dilution Test, to support an alternate formulation amendment for Lysol Brand Disinfectant Bleach Plus. Since the formulation was changed, the new formulation needed to be tested to support a claim for killing *Salmonella choleraesuis*, *Staphylococcus aureus* and *Pseudomonas aeruginosa*. The alternate formulation involves a change in inert ingredients only.

200.1 **USE(S):**

Uses not specified.

200.2 **BACKGROUND INFORMATION**

The active ingredient of Lysol Brand Disinfectant Bleach Plus is Sodium Hypochlorite.

201.0 **DATA SUMMARY**

Two lots of the disinfectant were tested in the study. None of the carriers tested demonstrated any growth of *Salmonella choleraesuis* (ATCC# 10708), *Staphylococcus aureus* (ATCC# 6538)or *Pseudomonas aeruginosa* (ATCC# 15442). The viability (positive) controls demonstrated growth of the test organisms. Two of the test organisms did not deviate from expected phenol resistance patterns. However, *Staphlyococcus aureus* did exhibit a phenol resistance outside the expected range for this organism, but the results were not considered significant because variation in phenol resistance is common for this organism.

The test disinfectant was effectively neutralized by AOAC Letheen Broth. Neutralization was demonstrated by the occurrence of growth in both the primary and secondary subculture tubes. No significant difference in the numbers of bacteria recovered from the neutralizer versus the phosphate buffer dilution water showed that the neutralizer was not toxic to the test

bacteria.

201.1 **BRIEF DESCRIPTION OF TESTS**

The study was conducted according to the Use-Dilution Method as described in Chapter 6, Disinfectants, Official Methods of Analysis of the AOAC, 15th Edition, 1990 Sections 955.14, 955.15, 964.02 (Appendix I). Test substance was prepared a use dilution of 8.5:500 and 9.0:500 (v/v) in sterile, distilled water. Test organisms were incubated in growth media over two nights and then supplemented with organic soil. The Sterile stainless steel carriers were soaked in this organic soil culture for 16 minutes and then dried for 40 minutes at 33.8-36.3C. Stainless steel carriers, which approximates the surface to be disinfected, were contaminated with the test organisms.

Ten carriers/sample lot were then exposed to dilutions of the test disinfectant. After a 5 minute exposure at 20.2-20.8C, the test samples were placed in tubes containing the neutralizer, Letheen Broth, and incubated for 48 hours at 32.8-36.0C. The tubes were then observed for bacterial growth.

The effectiveness and toxicity of the neutralizer was determined by exposing two stainless steel carriers per batch of test substance, which were previously inoculated with the test organism, to the neutralizer for 5 minutes. The carriers were then subcultured into another 10 ml of sterile distilled water for 10 minutes at 20±1 C. A second set of carriers was exposed to the test disinfectant for 10 minutes at 20±1 C. After 10 minutes, the test carriers were transferred to a tube containing 10 ml of the neutralizer (primary subculture). After 30 minutes, the carriers were resubcultured into another tube of neutralizer (secondary subculture). All tubes were incubated at 20.6-20.8C for 5 minutes and then observed for growth.

RECOMMENDATIONS

The results of the test demonstrate that the alternate formulation of Lysol Brand Disinfectant Beach Plus completely killed *Salmonella choleraesuis*, *Staphylococcus aureus* and *Pseudomonas aeruginosa*. Therefore, the registrant will be able to state that the alternate formulation of Lysol Brand Disinfectant Beach Plus passes the AOAC use-dilution test against *Salmonella choleraesuis*, *Staphylococcus aureus* and *Pseudomonas aeruginosa*.

202.1 **EFFICACY SUPPORTED BY THE DATA**

The efficacy of the alternative formulation of Lysol Brand Disinfectant Bleach Plus against *Salmonella chloreraesuis*, *Staphylococcus aureus* and *Pseudomonas aeruginosa* was supported by the data.

202.2 **EFFICACY NOT SUPPORTED BY THE DATA**

Not Applicable

203.0 **LABELING**

No change in label language was proposed by the registrant.