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1. EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW - I

ANTIMICROBIAL DIVISION

IN 05-11-97 OUT 06-03-97  
 Reviewed by Bruce H. Mann Date 06-03-97  
 LAN Code 70369-R-697  
 EPA Reg. No. or File Symbol 70369-R  
 EPA Petition or EUP No. None  
 Date Division Received 10-22-96  
 Type Product Hospital and General Disinfectant  
 MRID No (s) MRID's 442698-01  
 Product Manager PM-32 (Brennis)  
 Product Name Microstat 2 (TM)  
 Company Name Southland LTD.,

Submission Purpose A new application with basic clarification and informational data in support of the subject product Hospital & General Disinfectant Claims, Virucidal Claims, Fungicidal Claim, Tuberculocidal Claim and in support of the previous deficiencies cited in Efficacy Review Pt II dated 03-31-97.

Type Formulation Pelleted/Tablets (A and B) in foil packets which are added separately to water to prepare the end-use solution.

	<u>%</u>
<u>Active Ingredient (s):</u>	
013907 Sodium Bromide*	9.70
081407 Sodium Dichloroisocyanurate Dihydrate **	24.75

Tablet A\* contains 19.40 sodium bromide as the sole active ingredient.  
 Tablet B\*\* contains 49.50 sodium dichloroisocyanurate dihydrate as the sole active ingredient.

200.0 Introduction:

200.1 Use (s):

See the attached proposed label, and dated 04-29-97. The current submission received 04-29-97, is a new application which include basic, additional, tuberculocidal, fungicidal and virucidal efficacy data in support of the proposed label claims indicated on the subject product proposed label claims. For proposed label claims, see the proposed label dated 04-29-97.

201.0 Data Summary:

201.1 Brief Description of Tests:

For each lot, tablet A was dropped into a dark colored bottle which contain 1 quart of room temperature water (22 C). Once effervesence had started, tablet B was added to the solution. After effervescence was complete and the tablets completely dissolved, the screw cap was tightened. The solution was mixed by swirling the bottle gently, and stored at room temperature away from direct lighting. The samples were tested after 7 days of storage.

Product Identity:

Test samples #1 (lots 37-198-1 and 37-197-1) (mfg 5/10-10/96),

Test samples #2 (lots 37-199-1 and 37-196-1) (mfg 6/26-96 & 6/25/96)

Test samples #3, (lots 37-200-1-1 and 37-195-1) (mfg 6/26/96 & 6/25/96 .

- A. AOAC Use Dilution Test Methods, Official Methods of. Analysis of the AOAC, Chapter 6-Disinfectants, 15th ed., 1990. Data were generated against S. choleraesuis, S. aureus, and Ps. aeruginosa in hard water and in organic soil on the test samples after 7 days at room temperature. Tests were performed by MicroChem Laboratories, 7423 Airport Freeway, Fort Worth, Texas 76118. Authored by Cheri D. Carr. Statement of Good Laboratoy signed by Norman Miner, 05-05-97. Quality Assurance Statement signed by Norman Miner, Study Director, dated 05-05-97. Laboratory project ID numbers 9700423-1, 970430-1, and 970501-1.
- B. For "Materials", "Methods", "Test Orgainsms", "Activation of Test Samples and Test Procedures", "Description of Data Reports", and "Results", refer to Attachment #1. Refer to attachment #2 for a summary of total halogen concentration on a zero day stock activated solution and for a 7 day shelf-life activated solution stock.
- C. Data Summaries and Conclusions:  
The submitted data developed by the AOAC Use Dilution

minutes at 20°C from a stock solution which has a shelf life of 7 days (sample for all three test samples) when tested in the presence of 5% organic soil and 400 ppm of hard water.

- 202.0 Recommendations
- 202.0 Claims Related to Human Health
- 202.1 Efficacy Supported by the Data

- A. The submitted microbiological data developed by the AOAC Use Dilution Method are supportive of the product effectiveness as a general/hospital disinfectant vs. S. aureus, S. choleraesuis, and Ps. aeruginosa in the presence of 5% organic soil load (animal serum) and hard water (400 ppm as CaCO<sub>3</sub>) with an activated use solution (Tablets A and B/per quart of hard water) allowed to age for 7 days at room temperature in a dark amber bottle or dark cabinet) when used on hard, nonporous, inanimate surfaces and when thoroughly wetted and allowed to remain wet for a contact time of 10 minutes with a single application.
- B. The submitted data also are supportive of the product as a disinfectant with a use solution as prepared above in A, under the above conditions against the additional test microorganism Escherichia coli.
- C. The data also supportive of the product effectiveness as a fungicide (pathogenic fungi) vs. Trichophyton mentagrophytes at a use solution as prepared above in A, for appropriate use areas under the conditions indicated above for A.
- D. The submitted data are also supportive of the product effectiveness as a virucide vs. Herpes simplex Type 1, Herpes simplex Type 2, Poliovirus Types 1 and 2, Influenza A<sub>2</sub>(hong kong), Coxsackievirus, and HIV-1 (AIDS virus) with a use solution as specified above in A and under the test conditions indicated above for A.
- E. The submitted data also are supportive of the product effectiveness as a tuberculocide vs. Mycobacterium bovis (BCG) at 20°C by the TB Quantitative Log. Reduction Test Method with a use solution as prepared above in A when used on hard nonporous surface which are thoroughly wetted and allowed to remain wet for a contact time of 10 minutes at a temperature of 20°C.

- F. The submitted data indicated above in A, B, C, D, and E appears to be satisfactory and are supportive of the product effective shelf-life only for one week (7 days).

203.0 Label comments:

The following comments are applicable for the subject product "MicroStat 2" dated 04-29-97.

- A. Under directions to prepare solution for use on the left panel, the use directions should be expanded to specify that the 7 day stock solution should be mixed in a dark bottle and stored in a dark cabinet away from direct lighting between uses.
- B. On the left panel, revise Influenza Viruses Types 1 and 2 to read "Influenza A2(hong kong)". The accepted virucidal data supports only the strain "influenza A2(hong kong)".  
To show consistency for all of the proposed virucidal claims, the label directions should be expanded to include and add an asterick by each specific virus claim on the label.
- C. On the left panel, revise "Trichophytin" to read "Trichophyton". After mentagrophytes, add "(pathogenic fungi)".
- D. On the center panel, revise "on inanimate surfaces" to read "on hard, nonporous, inanimate surfaces".
- E. Under the direction for disinfection, the types of surfaces intended for treatment should be expanded to include hard surfaces found in bathrooms, shower areas, dressing rooms and locker rooms. These surfaces are areas where Trichophyton mentagrophytes are normally found.