7-28-93

069005

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW - II

ANTIMICROBIAL PROGRAM BRANCH

EPA Reg. No. or File Symbol 397-RG

Date Division Received 07-28-93

MRID No (s) 428412-01 to 428412-04

Product Manager PM 31 (Lee)

Product Name Steri-Fab2®

Company Name Noble Pine Products Company

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202.0 **Recommendations**

202.1 **Efficacy Supported by the Data:**

The submitted data are acceptable to support effectiveness of the product as a hospital and/or general disinfectant against Staphylococcus aureus ATCC 6538, Salmonella choleraesuis ATCC 10708, and Pseudomonas aeruginosa ATCC 15442 when used as an undiluted non-pressurized spray on hard, non-porous surfaces for a contact time of 10 minutes at 20°C.

The submitted data are also acceptable to support effectiveness of the product as a fungicide against Trichophyton mentagrophytes ATCC 9533 when used as an undiluted non-pressurized spray on hard, non-porous surfaces for a contact time of 10 minutes at 20°C.

The submitted data are also acceptable to support effectiveness of the product as a virucide against Herpes Simples Type 2 when used as an undiluted non-pressurized spray on hard, non-porous surfaces in the presence of 5% blood serum for a contact time of 10 minutes at 20°C.

The submitted data are also acceptable to support effectiveness of the product as a virucide against Vaccinia when used as an undiluted non-pressurized spray on hard, non-porous surfaces in the presence of 5% blood serum for a contact time of 10 minutes at 20°C.

202.2 **Data not Applicable:**

Also, the submitted data against Aspergillus niger to support efficacy as a fungistat is not considered to be directly related to human health. Therefore, under the efficacy data waiver, such data are not required to be submitted or reviewed.

203.0 **Labeling:**

Under the heading "Directions For Use" revise the statement "Allow treated items to dry before using" to read "Allow treated items to remain wet for at least 10 minutes and then dry before using."

Under the heading "Directions For Use" revise the statement "...until a dew like appearance is obtained" to read "...Until a dew like appearance is obtained and allow to remain wet for at least 10 minutes."

Under the heading "Directions For Use" revise the statement "TO KILL HERPES II...IS OBTAINED" to read "TO KILL HERPES SIMPLEX TYPE 2...IS OBTAINED AND ALLOW TO REMAIN WET FOR AT LEAST 10 MINUTES."

Under the heading "Directions For Use" revise the statement "TO KILL ATHLETE'S FOOT FUNGUS...UNTIL THOROUGHLY DAMPENED" to read "TO KILL ATHLETE'S FOOT FUNGUS...UNTIL THOROUGHLY DAMPENED AND ALLOW TO REMAIN WET FOR AT LEAST 10 MINUTES."

Under the heading "Directions For Use" revise the statement "SURFACES AND OBJECTS MUST BE CLEANED...UNTIL THOROUGHLY DAMPENED" to read "SURFACES AND OBJECTS MUST BE CLEANED...UNTIL THOROUGHLY DAMPENED AND ALLOW TO REMAIN WET FOR AT LEAST 10 MINUTES."

Under the heading "Directions For Use" revise the statement "AS A INSECTICIDE...UNTIL THOROUGHLY DAMPENED" to read "AS A INSECTICIDE...UNTIL THOROUGHLY DAMPENED AND ALLOW TO REMAIN WET FOR AT LEAST 10 MINUTES."

Under the heading "Directions For Use" revise the statement "TO DEODORIZE AND SANITIZE CARPETS...ODOR CAUSING BACTERIA AND FUNGUS" to read "TO DEODORIZE AND SANITIZE CARPETS...ODOR CAUSING BACTERIA AND FUNGUS AND ALLOW TO REMAIN WET FOR AT LEAST 10 MINUTES."

Under the heading "Directions For Use" revise the statement "TO SANITIZE AND DEODORIZE RESTROOMS...UNTIL A MOIST SURFACE IS OBTAINED" to read "TO SANITIZE AND DEODORIZE RESTROOMS...UNTIL A MOIST SURFACE IS OBTAINED AND ALLOW TO REMAIN WET FOR AT LEAST 10 MINUTES."

Under the heading "Directions For Use" revise the statement "TO SANITIZE ON PRE CLEANED NON POROUS SURFACES...MIST IS OBTAINED" to read "TO SANITIZE ON PRE CLEANED NON POROUS SURFACES...MIST IS OBTAINED AND ALLOW TO REMAIN WET FOR AT LEAST 10 MINUTES."

Note to P.M.:

the name Steri- (use of the term Steri-) in the name of the product is not permissible by published EPA regulations (40 CFR) because it implies sterilization. this is a claim that exceeds the activity of the product, which is disinfection. therefore it is false and misleading.

Z. Vaituzis
Head EETMS
9/21/93