



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

June 28, 2001

MEMORANDUM:

Subject: Product Efficacy Review for EPA Reg. No.: 9480-4/ Super Sani-Cloth
Germicidal Wipes

DP Barcode: D273385
Case No: 014278

To: Marshall Swindell, PM 33 / *Tony Kish*
Regulatory Management Branch
Antimicrobials Division (7510C)

From: Ian Blackwell, Biologist *Ian Blackwell*
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

Through: Emily Mitchell, Team Leader *Emily Mitchell 7/13/01*
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

Applicant: PDI, the Health Care Division of Nice-Pak Products

FORMULATION FROM LABEL:

<i>069154</i>	<u>Active Ingredient(s):</u>	<u>% by wt.</u>
	N-Alkyl dimethyl ethylbenzyl ammonium chloride	0.25
	N-Alkyl dimethyl benzyl ammonium chloride	0.25
	Isopropyl alcohol	55.00
	<u>Other Ingredient(s):</u>	<u>44.50</u>
	Total:	100.00%

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BACKGROUND: PDI has submitted two tuberculocidal assays that were conducted using PDI/Nice-Pak's Super Sani-Cloths. One study (MRID Number 453328-01) was conducted by ViroMed Biosafety Laboratories, Inc. The other study (MRID Number 453328-02) was conducted by Mycoscience, Inc.

These studies were conducted to determine the tuberculocidal efficacy of PDI/Nice-Pak's Super Sani-Cloths. This product is sold as a towelette premoistened with a germicidal liquid. Both studies were conducted using a variation of the AOAC Tuberculocidal Activity of Disinfectants Test (965.12).

RECOMMENDATIONS: PSB findings are:

1. MRID Number 453328-01: "Screening of Pre-Saturated Towelettes for Hard Surface Disinfection – Single Use" by Brad K. Onstad. ViroMed Biosafety Laboratories. Project Number 6930.1 Study Completion Date 7/2/99.

Glass slides measuring 25 mm x 25 mm x 1 mm were contaminated with *Mycobacterium bovis* - BCG (the standard organism for this assay) with enough Fetal Bovine Serum to yield a 5% organic soil load. The contaminated carriers were tested by wiping the surface of the glass slides continuously for 30 seconds with the saturated towelette, using a different section of the towelette for each carrier. The liquid test substance from the towelette remained on the carrier for a one minute exposure at 21°C. Aliquots of 0.1 mL and 1.0 mL of the microbes from the slide/disinfectant/neutralizer were transferred to tubes of 20 mL Middlebrook 7H9 broth and tubes of Kirchner's broth. The tubes were incubated at 35-37°C for 60 days and observed for growth. No growth was demonstrated in any of the 10 primary or 10 secondary subcultures or in any of the expressed liquid from the towelettes when tested against *Mycobacterium bovis* – BCG. Under the conditions of this study, Super Sani-Cloth Towelettes were demonstrated to be tuberculocidal.

2. MRID Number 453328-02: "Nice-Pak Products, Inc. Efficacy Study of Single Use Impregnated Towelettes for Hard Surface Disinfection (Tuberculocidal Modification) **Bacterium: *Mycobacterium bovis* BCG, ATCC #35743**" by Richard E. Arsenault. Mycoscience, Inc. Project Number 99-010NP. Study Completion Date 7/14/99.

Glass slides were inoculated with 0.01 mL of prepared culture suspension. Enough Fetal Bovine Serum was added to equal a 5% soil load. One towelette, or wipe, was used to wipe ten slides. Liquid was expressed from each used wipe into AOAC Neutralizing Broth. Aliquots of 2 mL were subcultured into 20 mL tubes of Modified Proskauer-Beck Medium, Middlebrook 7H9 Borth and Kirchners Medium. After wiping, each slide was allowed to set for **one minute** at ambient room temperature and was then transferred to 10 mL of AOAC Neutralizing broth and was vortexed thoroughly. The slide was then aseptically removed and transferred to 20 mL of Modified Proskauer Medium containing 0.05% asolectin. Two mL of the AOAC

Netutralizing Broth were also transferred to 20 mL of Middlebrook 7H9 Broth and two mL of Kirchners Medium w/ADC enrichment. The tubes were incubated at 37°C for 60 days. No growth was observed in the sample tubes after 60 days; the incubation was continued for an additional 30 days at 37°C. A dry carrier count was conducted on the test slides to determine the numbers of bacteria present on the carriers. Under the conditions of this study, Sani-Cloth Towelettes were demonstrated to be an effective hard surface tuberculocidal disinfectant against ten carriers inoculated with *Mycobacterium bovis* BCG in the presence of a 5% serum organic soil load.

LABELING:

No current label was submitted with this submission. However, the submitted data do imply that this product is an effective tuberculocidal disinfectant.