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US ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDES PROGRAMS
REGISTRATION DIVISION (TS-767)
WASHINGTON, DC 20460

EPA REGISTRATION NO.

DATE OF ISSUANCE
OCT 20 1995

9480-4

TERM OF ISSUANCE

NOTICE OF PESTICIDE:



(Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended)

NAME OF PESTICIDE PRODUCT

Sani-Cloth Germicidal Wipes

NAME AND ADDRESS OF REGISTRANT (Include ZIP code)

Nice-Pak Products, Inc.
Professional Disposables, Inc.
Two Nice-Pak Park
Orangeburg, NY 10962-1376

NOTE: Changes in labeling formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above U.S. EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby Registered/Reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act.

A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith.

Registration is in no way to be construed as an indorsement or approval of this product by this Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit/cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

2. Make the following changes listed below before you release the product for shipment.

- a. Add the phrase "EPA Registration No. 9480-4".
- b. Change "...Influenza A2HK..." to read "Influenza A2 Hong Kong..."
- c. Change the product name to read "Sani-Cloth Germicidal Wipes", and place the product name on the same panel as the ingredient section.



SIGNATURE OF APPROVING OFFICIAL



DATE

10/20/95

d. On the front panel, delete the claim "Kills Mycobacterium bovis BCG (Tuberculosis) in 1 minutes at 20°C". However, you may consider the statement "Sani-cloth is tuberculocidal against Mycobacterium bovis BCG by the Quantitative Tuberculocidal Test Method in 5 minute at 20°C".

NOTE: The EPA Product Performance Guidelines states that all products tested by the recommended methods must be tested at the exposure periods prescribed in those methods. However, in the Quantitative Tuberculocidal Activity Method, the time established for tuberculocidal efficacy claims must be in five minutes increments. For the protection of public health, the Agency does not accept contacts time shorter than five minutes for the Quantitative Tuberculocidal Activity Method. The contact time and temperature necessary to achieve effective use of the product as a tuberculocidal agent must be clearly reflected in the directions for use on the product label. The Agency has now determined that any attempt to do otherwise would be deemed misbranding, and would be inconsistent with the terms of this product's registration.

f. In the ingredient statement on the label, the terms "Active Ingredients" and "Inert Ingredients" must be given equal prominence and must be in the same type size.

g. The declared percentages in the ingredient statement should be declared to the same significant figure. It should be declared as:

0.25%
0.25%
55.00%
44.50%

4. On the Confidential Statement of Formula, check your calculations and note that the total weight is 7486 and not 7444.5.

5. Submit one (1) copy of the final printed label before you release the product for shipment. Refer to the A-79 enclosure for a further description of final printed labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the labeling is enclosed for your records.

If you have any questions concerning this letter, please contact Martha Terry at 703-305-6982.

Sincerely,



Marion J. Johnson, Jr.
Product Manager (31)
Antimicrobial Program Branch
Registration Division (7505C)

Enclosure

ACTIVE INGREDIENTS:

n-Alkyl (68% C12, 32% C14)
dimethyl ethylbenzyl ammonium chloride.....0.25%
n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18)
dimethyl benzyl ammonium chloride.....0.25%
- Isopropyl alcohol55%
INERT INGREDIENTS.....44.5%
TOTAL.....100.00%

Keep Out of Reach of Children

CAUTION

See back panel for additional precautionary statements

CONTENTS # OF CLOTHS SIZE

EPA Reg. No.

EPA Est. No. 9480-NY 1

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in EPA Letter Dated:
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SUPER SANI-CLOTH
MASTER LABEL COPY
Front Panel

GERMICIDAL CLOTH

For use in: CRITICAL CARE AREAS

Where control of the hazards of cross-contamination of prime importance.

Effective against a wide range of bacteria including *Staphylococcus aureus*, *Salmonella choleraesuis* and *Pseudomonas aeruginosa* in 5 minutes.

Kills *Mycobacterium bovis* BCG (Tuberculosis) in 1 minute at 20°C.

Kills Methicillin-resistant *Staphylococcus aureus* (MRSA) in 5 minutes.

Effective against *Klebsiella pneumoniae* in 4 minutes.

KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in 1 minute at room temperature (20-25°C) in healthcare settings or other settings in which there is an expected likelihood of soiling of inanimate environmental surfaces with blood or body fluids, and in which the environmental surface likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency Virus Type I (HIV-I).

Kills dangerous viruses such as Influenza A2/HK and Herpes Simplex Type II in 1 minute.

Kills Vaccinia virus and Adeno virus Type 5 in 1 minute.

Kills Rhinovirus in 1 minute.

Kills *Candida albicans* in 4 minutes at 20°C.

Kills Pseudorabies in 1 minute.

A novel way to effectively disinfect environmental surfaces.

Convenient - premeasured - premoistened

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BACK PANEL

A Dual Chain Quaternary/Alcohol Solution Impregnated in a Wiping Cloth

A non-woven disposable cloth for use in hospitals and other critical care areas where control of the hazards of cross-contamination is required. Use on surfaces and equipment such as stainless steel, Formica, glass tables, carts, baskets, counters, cabinets, telephones and other hard non-porous surfaces.

Some Areas of Use: Hard surfaces in surgery, recovery, anesthesia, x-ray CAT lab, emergency room, new-born nursery, respiratory therapy radiology and central supply.

"This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection".

Special Instructions for Cleaning and Decortamination against HIV-1 for Surfaces or objects soiled with blood or body fluids:

PERSONAL PROTECTION-When using the disinfectant cloth wear disposable latex gloves, protective gowns, face masks, or eye coverings as appropriate when handling HIV-1 infected blood or body fluids.

CLEANING PROCEDURES-All blood and other body fluids must be thoroughly cleaned from surface and objects before a disinfection by the cloth. Open, unfold first disinfectant cloth to remove gross filth.

CONTACT TIME-Use second disinfectant cloth to thoroughly wet surface. Allow to remain wet for 30 seconds. Let air dry. Although efficacy at a 1 minute contact time has been shown to be adequate against HIV-1. This time should not be sufficient for other organisms. Use listed disinfection times against all of the organisms claimed.

Disposal of Infectious Materials: Dispose of used towelette in accordance with local regulations for infectious waste disposable.

Direction for Use: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Dispenser Directions: To start feed, remove large cover and discard seal from container. From center of towelette roll, pull up a towelette corner, twist it into a point and thread it through the hold in the container cover. Pull through about one inch. Replace cover. Pull out first towelette and snap off at a 90° angle. Remaining towelettes pop-up automatically ready for next use. When not in use, keep small center cap closed to prevent moisture loss. Open, unfold, wipe to remove gross filth. Use second towel to thoroughly wet surface. Allow to remain wet 5 minutes, where required. Let air dry.

Precautionary Statements: Hazards to humans and domestic animals

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BACK PANEL (CONTINUED)

Caution: Avoid contact with eyes. In case of eye contact, flush with plenty of water for a least 15 minutes. If irritation persists, call a physician.

Storage and Disposal: Do not reuse empty container. Wrap container and put in trash collection. Do not reuse towel. Dispose of used towel in trash.

DO NOT STORE NEAR HEAT OR OPEN FLAME. FLAMMABLE.

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