

9480-4

9-26-2002

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SEP 26 2002

Christina Griffin,
Agent for PDI, Healthcare Division of Nice-Pak Products, Inc.
c/o Delta Analytical Corp.
7910 Woodmont Avenue, Suite 1000
Bethesda, MD 20814

Subject:**Sani-Cloth Germicidal Wipes; EPA Reg. No. 9480-4; Your Notification Dated 9/5/02** ✓**Sani-Cloth Germicidal Disposable Wipes; EPA Reg. No. 9480-5; Your Notification Dated 9/5/02****Sani-Cloth Plus Germicidal Disposable Cloth; EPA Reg. No. 9480-6; Your Notification Dated 9/5/02**

The three Notifications referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to add two round graphics to each product label showing that the product is not to be used as a baby wipe, or on the skin, are acceptable with the following comment.

We note that the label for EPA Reg. No. 9480-5 declares the official product name as, "Sani-Cloth Germicidal Disposable Cloth", whereas your notification and cover letter declare it as "Sani-Cloth Germicidal Disposable Wipes". Please address this discrepancy with your next notification or amendment for this product so that the Agency has the correct product name on file.

Your notification has been made a part of the permanent records for this file.

If you have any questions about the comments in this letter, please feel free to contact Tony Kish at 703-308-9443, or myself at 703-308-6341.

Sincerely,



Marshall Swindell,
Product Manager Team 33,
Regulatory Management Branch I
Antimicrobials Division (7510C)

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

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United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

231231

Application for Pesticide - Section I

1. Company/Product Number **9480-4**2. EPA Product Manager
Marshall Swindell

3. Proposed Classification

☐ None ☐ Restricted4. Company/Product (Name) **PDI, Healthcare Division of Nice-Pak Products, Inc./ Sani-Cloth Germicidal Wipes**PM# **33**

5. Name and Address of Applicant (Include ZIP Code)

PDI, Health Care Div. of Nice-Pak
c/o Delta Analytical Corp.
7910 Woodmont Ave. Suite 1000
Bethesda MD 20814

☐ Check if this is a new address6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☐ Amendment - Explain below☐ Resubmission in response to Agency letter dated _____☐ Final printed labels in response to Agency letter dated _____☐ "Me Too" Application.☐ Other - explain below.☐ Notification - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.) **Notification to add graphics and "Not a Baby Wipe" statement to labeling. Additions are shown on last page of labeling.**

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material this Product will be Packaged in:

Child-Resistant Packaging

☐ Yes*
☐ No

Unit Packaging

☐ Yes
☐ No

Water Soluble Packaging

☐ Yes
☐ No

2. Type of Container

☐ Metal
☐ Plastic
☐ Glass
☐ Paper
☐ Other (Specify) _____

* **Certification must be submitted.**

If "Yes,"
Unit Package wgt. No. per container

If "Yes,"
Unit Package wgt. No. per container

3. Location of Net Contents Information

☐ Label ☐ Container

4. Size(s) of Retail Container

5. Location of Label Direction

☐ On Label
☐ On Labeling accompanying product

6. Manner In Which Label Is Affixed to Product

☐ Lithograph
☐ Paper glued
☐ Stenciled

☐ Other _____

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name
Cristina GriffinTitle
Agent for PDITelephone No. (Include Area Code)
301-652-5495

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any kind of knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature

3. Title
Agent for PDI4. Typed Name
Cristina Griffin5. Date
September 5, 2002

6. Date Application Received

(Stamped)

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SANI-CLOTH GERMICIDAL WIPES

GERMICIDAL DISPOSABLE CLOTH

Disinfects Hard Non Porous Environmental Surfaces

ACTIVE INGREDIENTS:

n-Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl ethylbenzyl ammonium chlorides.....	0.25%
n-Alkyl (60% C ₁₄ , 30% C ₁₆ , 5%C ₁₂ , 5%C ₁₈) dimethyl benzyl ammonium chloride. . .	0.25%
Isopropyl Alcohol.....	55.00%
<u>OTHER INGREDIENTS</u>	44.50%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See back panel for additional precautionary statements

NET WT

NET CONTENTS # OF CLOTHS SIZE

EPA Reg. No.: 9480-4

EPA Est. No.: 9480-NY-001

Manufactured by:

PDI Healthcare Division of Nice Pak Inc.

Two Nice Pak Park

Orangeburg NY 10962-1376

PRECAUTIONARY STATEMENTS:

Hazards to humans and domestic animals.

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

FIRST AID

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

STORAGE AND DISPOSAL: Towel: Do not reuse towel. Dispose of used towel in trash. Dispenser: Do not reuse empty container. Wrap container and put in trash collection.

DO NOT USE OR STORE NEAR HEAT OR OPEN FLAME.

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For use in: CRITICAL CARE AREAS

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

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

Effective against *Mycobacterium bovis* BCG (Tuberculosis).

Kills Methicillin-resistant *Staphylococcus aureus* (MRSA).

Kills Vancomycin resistant *Enterococcus* (VRE).

Effective against *Klebsiella pneumoniae*.

Kills *Escherichia coli* (E. Coli).

*Kills dangerous viruses such as Influenza A2/Hong Kong and Herpes Simplex II.

*Kills Rhino virus.

*Kills Vaccinia virus and Adeno virus Type 5.

*Kills Pseudorabies virus.

Kills *Candida albicans*.

Effective in five (5) minutes against: *Staphylococcus aureus*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Klebsiella pneumoniae*, *Mycobacterium bovis* BCG (Tuberculosis), Methicillin-resistant *Staphylococcus aureus* (MRSA), Vancomycin resistant *Enterococcus* (VRE), *Escherichia coli* (E. Coli), *Candida albicans*.

*Kills viruses in five minutes: Influenza A2/Hong Kong, Herpes Simplex II, Rhino virus, Vaccinia virus, Adeno virus Type 5, Pseudorabies virus.

***KILLS HIV-1 ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS**

PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS 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 surfaces likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type I (HIV-1).

Convenient - Premeasured - Premoistened

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. Organisms are removed from the surface by thoroughly wiping the surface with the towel. Remaining organisms are killed within five minutes by exposure to the liquid in the towel.

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 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 pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection."

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DIRECTIONS 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 towel roll, pull up towel corner, twist it into a point and thread it through the hole in the container cover. Pull through about one (1) inch. Replace cover. Pull out first towel and snap off at a 90° angle. Remaining towels feed (pop-up) automatically ready for next use. When not in use, (When through using) keep small center cap closed to prevent moisture loss.

TOWEL

TO DISINFECT:

NON FOOD CONTACT SURFACES

Open, unfold, wipe to remove gross filth. Use a second towel to wet surface thoroughly. Treated surface must remain visibly wet for a full five (5) minutes. Let air dry.

FOOD CONTACT SURFACES

Use only for the following food contact applications listed on this label; tables, baskets, and counters. Open, unfold, wipe to remove gross filth. Use a second towel to wet surface thoroughly. Treated surface must remain visibly wet for a full five (5) minutes. Let air dry, followed by a potable water rinse.

***Special Instructions for Cleaning and Decontamination Against HIV-1 for Surfaces or Objects Soiled with Blood or Body Fluids:**

PERSONAL PROTECTION: When using the disinfectant cloth, wear disposable protective 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 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 1 minute. Let air dry. Although efficacy at a 1 minute contact time has been shown to be adequate against *HIV-1 (AIDS VIRUS), this time would not be sufficient for other organisms.

DISPOSAL OF INFECTIOUS MATERIALS: Dispose of used towel in accordance with local regulations for infectious waste disposal.

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[The following graphics and statements are optional.
They may be placed anywhere on label/container.]



NOT A BABY WIPE

NOT FOR USE ON SKIN