

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

9480-6

9/26/2002

SEP 26 2002

1/13

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** ✓

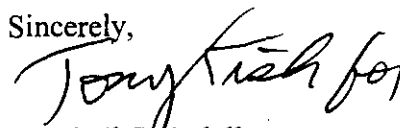
The three Notifications referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to add two round graphics to each product label showing that the product is not to be used as a baby wipe, or on the skin, are acceptable with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

231238

Application for Pesticide - Section I

1. Company/Product Number **9480-6**2. EPA Product Manager
Marshall Swindell

3. Proposed Classification

☐ None ☐ Restricted4. Company/Product (Name) **PDI, Healthcare Division of Nice-Pak Products, Inc./ Sani-Cloth Plus Germicidal Disposable Cloth**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 _____

otification - Explain below.

☐ Final printed labels in response to Agency letter dated _____☐ "Me Too" Application.☐ Other - 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 containerIf "Yes,"
Unit Package wgt. No. per container

2. 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)

February 7, 2001

MASTER LABEL COPY
FRONT COPY

SANI-CLOTH PLUS
GERMICIDAL DISPOSABLE CLOTH

For use in: CRITICAL CARE AREAS

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

Effective against *Staphylococcus aureus*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*

Exhibits effective virucidal activity on hard nonporous inanimate surfaces: kills Influenza A2/Hong Kong (representative of the common flu virus) and Herpes simplex Type II (causative agent of genital herpes) in 30 seconds

Kills dangerous viruses such as Influenza A2/Hong Kong and Herpes simplex Type II in 30 seconds.

An effective way to disinfect hard, nonporous environmental surfaces.

For use on external Ultrasound Transducers only

Aids in the reduction of cross contamination

Convenient Premeasured Premoistened

Kills *Mycobacterium bovis* BCG (Tuberculosis) in 5 minutes at 20°C.

*Kills HIV on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in 30 seconds at room temperature (20-25°C) in health care or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects 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).

*Kills HIV on pre-cleaned ultrasound probes previously soiled with blood/body fluids in 30 seconds at room temperature (20°C -25°C) in health care or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects 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).

Kills *Escherichia coli* (*E. coli*) 0157:H7 in 5 minutes

Bactericidal, Tuberculocidal, and Virucidal*

*Kills Canine Distemper and Pseudorabies Virus in 5 minutes

ACTIVE INGREDIENTS:

n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chlorides 0.125%

n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chlorides. .0.125%

Isopropyl Alcohol 14.85%

INERT INGREDIENTS 84.90%

TOTAL 100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION:

See back panel for additional precautionary statements

NET WT

NET CONTENTS . # OF CLOTHS SIZE

E. P. A. Reg. No. 9480-6

E. P.A. Est. No. 9480-NY-001

BACK PANEL

A dual chain Quaternary/Alcohol solution impregnated in a wiping cloth

For use on external Ultrasound Transducers only

To disinfect: Pre clean ultrasound gel from external transducer to be disinfected by using a clean wash cloth. Then thoroughly wet the probe with a towelette for 5 minutes.

Assures proper dilution strength and product effectiveness and standardized technique.

Greater quaternary dispersal with no hazard of cross contamination, quick drying

Non-woven disposable cloth

Effective in 5 minutes against *Staphylococcus aureus*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*

Kills *Mycobacterium bovis* BCG (Tuberculosis) in 5 minutes at 20°C.

*Kills Influenza A2/Hong Kong and Herpes simplex Type II in 30 seconds

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, ER, Orthopedics, New Born Nursery, Respiratory Therapy, Radiology, 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 originally 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."

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST
HIV-1 FOR SURFACES OR OBJECTS SOILED WITH BLOOD OR BODY FLUIDS**

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

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

CONTACT TIME: Use second germicidal cloth to thoroughly wet surface. Allow to remain wet 30 seconds, let air dry. Although efficacy at a 30 second contact time has been shown to be adequate against HIV-1 (AIDS VIRUS) this time would 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 disposal.

DIRECTIONS FOR USE:

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

TOWELETTE:

Use a wipe to remove gross filth. Open, unfold, second wipe to thoroughly wet surface. Allow to remain wet 5 minutes, let air dry.

TRAVEL PACK

Peel back label slowly. Pull out wipes as needed and reseal label. Use a wipe to remove gross filth. Open, unfold, second wipe to thoroughly wet surface. Allow to remain wet 5 minutes, let air dry.

DISPENSER:

To start feed: Remove large cover and discard seal from container. From center of towelette roll, pull up towelette corner, twist it into a point and thread it through the hole in the container cover. Pull through about one inch. Replace cover. Pull out first towelette and snap off at a 90° angle. Remaining towelettes feed automatically ready for next use. When through using, keep small center cap closed to prevent moisture loss.

Open, unfold, wipe to remove gross filth. Use second wipe to thoroughly wet surface. Allow to remain wet for 5 minutes, where required let air dry.

PRECAUTIONARY STATEMENTS: Hazards to humans and domestic animals.

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

STORAGE AND DISPOSAL: Towelette: 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.

BACK PANEL**DIRECTIONS FOR USE: TO DISINFECT FOOD CONTACT SURFACES**

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

TOWELETTE:

Use wipe to remove gross filth. Open, unfold, second wipe to thoroughly wet surface. Allow to remain wet 5 minutes, let air dry followed by a thorough potable water rinse.

TRAVEL PACK

Peel back label slowly. Pull out wipes as needed and reseal label. Use wipe to remove gross filth. Open, unfold, second wipe to thoroughly wet surface. Allow to remain wet 5 minutes, let air dry followed by a thorough potable water rinse.

DISPENSER:

To start feed: Remove large cover and discard seal from container. From center of towelette roll, pull up towelette corner, twist it into a point and thread it through the hole in the container cover. Pull through about one inch. Replace cover. Pull out first towelette and snap off at a 90° angle. Remaining towelettes feed automatically ready for next use. When through using, keep small center cap closed to prevent moisture loss.

Open, unfold, wipe to remove gross filth. Use second wipe to thoroughly wet surface. Allow to remain wet for 5 minutes where required, let air dry followed by a thorough potable water rinse.

DIRECTIONS FOR USE: TO DISINFECT NON - FOOD CONTACT SURFACES

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling

TOWELETTE:

Use a wipe to remove gross filth. Open, unfold, second wipe to thoroughly wet surface. Allow to remain wet 5 minutes, let air dry.

TRAVEL PACK

Peel back label slowly. Pull out wipes as needed and reseal label. Use wipe to remove gross filth. Open, unfold, second wipe to thoroughly wet surface. Allow to remain wet 5 minutes, let air dry

DISPENSER:

To start feed: Remove large cover and discard seal from container. From center of towelette roll, pull up towelette corner, twist it into a point and thread it through the hole in the container cover. Pull through about one inch. Replace cover. Pull out first towelette and snap off at a 90° angle. Remaining towelettes feed automatically ready for next use. When through using, keep small center cap closed to prevent moisture loss.

Open, unfold, wipe to remove gross filth. Use second wipe to thoroughly wet surface. Allow to remain wet for 5 minutes where required, let air dry.

CONSUMER LABEL

Antibacterial

Antimicrobial

Kills Many Germs

Bath and Kitchen wipes for hard, non-porous surfaces

Cleans and disinfects

Kills many bacteria and viruses

Cleans, deodorizes, and kills common household germs

No mixing

Multi purpose cleaner

Disinfects hard non-porous environmental surfaces

Kills common household germs such as *Staphylococcus aureus* (Staph) and *Salmonella choleraesuis*. Also effective against cold and flu viruses such as Influenza A2/HK (Hong Kong flu).

An effective way to clean, deodorize and sanitize against odor-causing organisms and disinfect hard, non-porous surfaces.

Aids in reducing cross-contamination.

A dual chain Quaternary/Alcohol solution impregnated in a wiping cloth

Assures proper dilution strength and product effectiveness and standardized technique. Greater quaternary dispersal with no hazard of cross contamination, quick drying.

Non-woven disposable cloth

Effective in 5 minutes against *Staphylococcus aureus*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*

Kills *Mycobacterium bovis* BCG (Tuberculosis) in 5 minutes at 20° C

Kills Influenza A2/Hong Kong and Herpes simplex Type II in 30 seconds

Kills *Escherichia coli* (*E. coli*) 0157:H7 in 5 minutes

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST
HIV-1 (AIDS VIRUS) FOR SURFACES OR OBJECTS SOILED WITH BLOOD OR
BODY FLUIDS**

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

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

CONTACT TIME: Use second germicidal cloth to thoroughly wet surface. Allow to remain wet 30 seconds, let air dry. Although efficacy at a 30 second contact time has been shown to be adequate against HIV-1 (AIDS VIRUS) this time would 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 disposal.

Use on hard non porous surfaces only. Test wipe on small inconspicuous area first

Some areas of use:

Kitchen**: Counter tops, appliances, sinks, faucets, cutting boards

Bathroom: Toilet seats, bathroom fixtures, vanity tops, shower stalls, bathtubs, tiles, sinks

General use: Doorknobs, telephones, laundry rooms, garbage cans, pet areas and more

**A potable water rinse is required for surfaces in direct contact with food.

Use wipes to kill Influenza A2/Hong Kong, Salmonella, Staphylococcus and other harmful germs on most bath and kitchen surfaces

Do not flush in toilet

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

To Clean, Sanitize and Deodorize hard nonporous nonfood contact surfaces.

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

TOWELETTE:

Open, unfold, towelette.

Use a towelette to clean heavily soiled surfaces. Use second towelette to disinfect surface. Thoroughly wet surface, allow to remain wet for 5 minutes, let air dry.

TRAVEL PACK

Peel back label slowly. Pull out wipes as needed and reseal label.

Use a wipe to clean heavily soiled surfaces. Use second towelette to disinfect surface. Thoroughly wet surface, allow to remain wet for 5 minutes let air dry.

DISPENSER:

To start feed: Remove large cover and discard seal from container. From center of wipe roll, pull up wipe corner, twist it into a point and thread it through the hole in the container cover. Pull through about one inch. Replace cover. Pull out first wipe and snap off at a 90° angle. Remaining wipes feed automatically ready for next use. When through using, keep small center cap closed to prevent moisture loss.

Open, unfold, wipe to remove gross filth. Use second wipe to thoroughly wet surface. Allow to remain wet for 5 minutes where required let air dry.

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



NOT A BABY WIPE

NOT FOR USE ON SKIN