

9480-5

1/7/2003

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JAN -7 2003

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

Subject: Sani-Cloth Germicidal Disposable Cloth
EPA File Symbol 9480-5
Your Notification Dated 12/9/02

The Notification referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to add pictures and graphics depicting bathroom sinks, a "Go USA" statement, and graphics of the cloth being used, is acceptable with the following condition.

These added graphics and pictures were only part of the submitted "Consumer" label, and not on the submitted Master Label which is the only label ever stamped, and on which they should have been added. Therefore, you must eventually add them to the actual "Master Label" for this product in order for the Master Label to be stamped when submitted with a subsequent amendment.

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							

2. 8. 16

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060.



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

231253

Application for Pesticide - Section I

1. Company/Product Number **9480-5**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 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 _____

Justification - 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. 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

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
December 9, 2002

6. Date Application Received

(Stamped)

3 7 16

MASTER LABEL COPY

SANI-CLOTH

GERMICIDAL DISPOSABLE CLOTH

ACTIVE INGREDIENTS:

n-Alkyl (68% C₁₂, 32% C₁₄) dimethyl ethylbenzyl ammonium chlorides 0.14%
n-Alkyl (60% C₁₄, 30% C₁₆, 5% C₁₂, 5% C₁₈) dimethyl benzyl ammonium chlorides. 0.14%
Isopropyl Alcohol 8.00%

OTHER INGREDIENTS 91.72%

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.: 9480-5

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: Avoid contact with eyes.

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: 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.

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*, *Klebsiella pneumoniae* in 5 minutes.

*Exhibits effective virucidal activity; 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 surfaces of Ultrasound Transducers only

Aids in the reduction of cross contamination

Convenient Premeasured Premoistened

Kills *Mycobacterium bovis* BCG (Tuberculosis) in 10 minutes at 20°C.

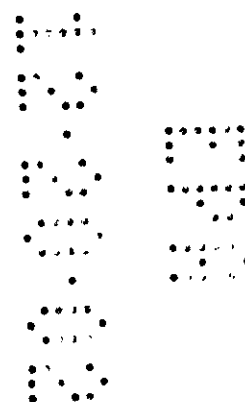
*Kills HIV-1 on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in 30 seconds at room temperature (20-25°C) in health care or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the 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-1 on pre-cleaned ultrasound probes 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).

Bactericidal, Tuberculocidal, and Virucidal*

*Kills Canine Distemper, Pseudorabies Virus, Vaccinia Virus and Adenovirus Type 5 in 5 minutes.

Kills *Candida albicans* in 5 minutes at 20°C.



BACK PANEL

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

For use on external surfaces of 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 and Klebsiella pneumoniae.

Kills Mycobacterium bovis BCG (Tuberculosis) in 10 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.

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. To disinfect, unfold a clean wipe and thoroughly wet surface. Allow to remain wet 5 minutes (10 minutes for Mycobacterium bovis BCG-tuberculosis), let air dry.

TRAVEL PACK:

Peel back label slowly. Pull out wipes as needed and reseal label. Use a wipe to remove gross filth. To disinfect, unfold a clean wipe and thoroughly wet surface. Allow to remain wet 5 minutes (10 minutes for Mycobacterium bovis BCG-tuberculosis), 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.

Use a wipe to remove gross filth. To disinfect, unfold a clean wipe and thoroughly wet surface. Allow to remain wet for 5 minutes (10 minutes for Mycobacterium bovis BCG-tuberculosis), let air dry.

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 a wipe to remove gross filth. To disinfect, unfold a clean wipe and thoroughly wet surface. Allow to remain wet 5 minutes (10 minutes for Mycobacterium bovis BCG-tuberculosis), 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 a wipe to remove gross filth. To disinfect, unfold a clean wipe to thoroughly wet surface. Allow to remain wet 5 minutes (10 minutes for Mycobacterium bovis BCG-tuberculosis), let air dry followed by a 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.

Use a wipe to remove gross filth. To disinfect, unfold a clean wipe and thoroughly wet surface. Allow to remain wet for 5 minutes (10 minutes for Mycobacterium bovis BCG-tuberculosis), 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. To disinfect, unfold a clean wipe and thoroughly wet surface. Allow to remain wet 5 minutes (10 minutes for Mycobacterium bovis BCG-tuberculosis), let air dry.

TRAVEL PACK:

Peel back label slowly. Pull out wipes as needed and reseal label. Use a wipe to remove gross filth. To disinfect, unfold a clean wipe and thoroughly wet surface. Allow to remain wet 5 minutes (10 minutes for Mycobacterium bovis BCG-tuberculosis), 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.

Use a wipe to remove gross filth. To disinfect, unfold a clean wipe and thoroughly wet surface. Allow to remain wet for 5 minutes (10 minutes for Mycobacterium bovis BCG-tuberculosis), let air dry.

CONSUMER LABEL COPY
FRONT PANEL

9 8 16

SANI-CLOTH
GERMICIDAL DISPOSABLE CLOTH

ACTIVE INGREDIENTS:

n-Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl ethylbenzyl ammonium chlorides	0.14%
n-Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈) dimethyl benzyl ammonium chlorides. .	0.14%
Isopropyl Alcohol	8.00%
<u>OTHER INGREDIENTS</u>	<u>91.72%</u>
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.: 9480-5		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: Avoid contact with eyes.

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: 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.

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

Effective against Staphylococcus aureus, Salmonella choleraesuis, Pseudomonas aeruginosa, Klebsiella pneumoniae in 5 minutes.

*Exhibits effective virucidal activity; 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 viruses such as Influenza A2/Hong Kong and Herpes Simplex Type II in 30 seconds.

Cleans and disinfects common hard non-porous surfaces

Effectively disinfects common household surfaces

An effective way to disinfect hard non-porous environmental surfaces.

Use to clean, deodorize, sanitize and disinfect hard, non-porous surfaces in the nursery.

Aids in the reduction of cross contamination

Convenient -Premeasured -Premoistened- Disposable

Bactericidal and Virucidal*

Kills many common household germs

*Kills Canine Distemper, Pseudorabies Virus, Vaccinia Virus and Adenovirus Type 5 in 5 minutes .

Kills Candida albicans in 5 minutes at 20°C.

Antibacterial
 Cleans, deodorizes, and kills common household germs
 Antimicrobial
 Kills Many Common Household Germs
 Bath and Kitchen wipes for hard non-porous surfaces
 Cleans and disinfects
 Kills many common household bacteria, and viruses*
 No mixing
 Multi purpose cleaner
 Disinfects hard non-porous environmental surfaces
 Bath and Kitchen wipes
 Bath and Kitchen disinfectant wipes
 Bath and Kitchen sanitizing wipes
 Moist Wipes
 Bath and Kitchen wipes for sanitizing hard non-porous surfaces
 Household surface wipes for sanitizing hard non-porous surfaces
 Nursery wipes
 Household surface wipes
 Telephone disinfectant wipes

Areas of use:

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

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

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

Nursery: Changing tables, cribs, diaper pail, trash cans, toys and other hard, non-porous surfaces

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

To Clean, Sanitize and Deodorize.

Cleans and disinfects telephone surfaces and telephone equipment surfaces

A hospital disinfectant cloth for use on telephone surfaces and other telecommunications equipment surfaces

Cleans and disinfects telephone surfaces, dictating equipment surfaces, and other telecommunications equipment surfaces

CONSUMER LABEL

Back label copy

Antibacterial

Antimicrobial

Kills Many Common Household Germs

Bath and Kitchen wipes for hard non-porous surfaces

Cleans and disinfects

Kills many common household bacteria, and viruses*

Cleans, deodorizes, and kills common household germs

No mixing

Multi purpose cleaner

Disinfects environmental surfaces

Bath and Kitchen wipes

Bath and Kitchen disinfectant wipes

Bath and Kitchen sanitizing wipes

Moist Wipes

Bath and Kitchen wipes for sanitizing hard non-porous surfaces

Household sanitizing wipes for hard non-porous surfaces

Nursery wipes

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

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

Cleans and disinfects common hard non-porous surfaces

Effectively disinfects common hard non-porous household surfaces

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

Areas of use:

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

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

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

Nursery: Changing tables, cribs, diaper pail, trash cans, toys and other hard non porous surfaces

****A thorough rinse with potable water 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 hard, non-porous 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.

TOWELETTE:

Use a wipe to remove heavy soil. To disinfect, unfold a clean wipe and thoroughly wet surface. Allow to remain wet for 5 minutes, let air dry. A thorough rinse with potable water is required for surfaces in direct contact with food.

TRAVEL PACK:

Peel back label slowly. Pull out wipes as needed and reseal label. Use a wipe to remove heavy soil. To disinfect, unfold a clean wipe and thoroughly wet surface. Allow to remain wet for 5 minutes, let air dry. A thorough rinse with potable water is required for surfaces in direct contact with food.

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.

Use a wipe to remove heavy soil. To disinfect, unfold a clean wipe and thoroughly wet surface. Allow to remain wet for 5 minutes, let air dry. A thorough rinse with potable water is required for surfaces in direct contact with food.

Lemon Scent
Citrus Scent
Floral Scent
Fresh Air Scent
Mint Scent

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



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

