

9480-4

03/15/2006

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

1/11

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

MAR 15 2006

Attention: Cristina Griffin

Subject: **Sani-Cloth Germicidal Wipes**
EPA Registration No. 9480-4
Amendment Application Date: March 3, 2006
EPA Received Date: March 3, 2006

This will acknowledge receipt of your notification, submitted under the provisions of FIFRA section 3 (c) 9. Based on a review of the material, the following comment apply.

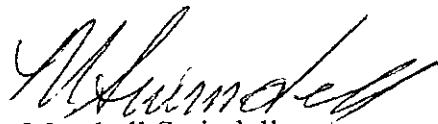
- Adding the following sentence to comply with the Agency's TB guidance.

"These directions also apply to Mycobacterium bovis BCG (Tuberculosis) at 68°F (20°C)."

This application is acceptable and has been made a part of the records for this file.

If you have any comments or questions concerning this letter, please contact me at (703) 308-6341 or Portia Jenkins at (703) 308-6230.

Sincerely,



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

CONCURRENCES

SYMBOL							
SURNAME							
DATE							



2/11

March 3, 2006

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Ave. NW
Washington DC 20460

Attn: Marshall Swindell, PM 33

RE: Notification per PR Notice 98-10 to add minor clarification to directions
Product: Sani-Cloth Germicidal Wipes, EPA Reg. No. 9480-4
Company: PDI, The Healthcare Division of Nice-Pak Products, Inc.

Dear Marshall:


On behalf of PDI, The Healthcare Division of Nice-Pak Products, Inc., I am submitting a notification per PR Notice 98-10 for the product Sani-Cloth Germicidal Wipes, EPA Reg. No. 9480-4. The purpose is to add the following sentence to the Directions for Use: "These directions also apply to Mycobacterium bovis BCG (Tuberculosis) at 68°F (20°C)." The purpose of this sentence is to comply with EPA's TB guidance issued in 1986, that requires "The contact/exposure time and temperature necessary to achieve effective use of the product must be reflected in the directions for use on the product label." California DPR raised this issue and we have discussed the content of this notification with EPA's Nancy Whyte.

Enclosures

- EPA form 8570-1
- 1 copy of the revised label (addition is highlighted)

If you have any questions regarding this submission, please contact me at 301-652-5495 or cgriffin@delta-ac.com.

Sincerely,


Cristina Griffin
Agent for PDI

Enclosures

cc: David Jones, PDI

3/11

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
307008

Application for Pesticide - Section I

1. Company/Product Number 9480-4	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. 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 <input type="checkbox"/> Check if this is a new address	6. 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 _____
 Notification - 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 per PR Notice 98-10 to add minor clarification to directions.

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 <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> 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 Griffin	Title Agent for PDI	Telephone 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

6. Date Application Received

(Stamped)

2. Signature 	3. Title Agent for PDI	6. Date Application Received (Stamped)
4. Typed Name Cristina Griffin	5. Date March 3, 2006	

4/11

SANI-CLOTH® GERMICIDAL WIPES GERMICIDAL DISPOSABLE CLOTH

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 chlorides.....	0.25%
Isopropyl Alcohol.....	55.00%
<u>OTHER INGREDIENTS</u>	<u>44.50%</u>
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See back [side] panel for additional precautionary statements

Net weight

Net contents # of cloths and size

EPA Reg. No.: 9480-4

EPA Est. No. : 9480-NY-1

or

EPA Est. No. A=9480-NY-1, B=9480-IN-1

Alpha character will precede batch code on product

Manufactured by:

PDI, The Healthcare Division of Nice-Pak Products, 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.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

Physical or chemical hazard

Combustible. Do not use or store near heat or open flame. Do not use on natural marble, windows, unpainted wood, brass, clear plastic or colored grout.

Storage and disposal

For canisters:

Storage: Do not store near heat or open flame. When not in use keep center cap of lid closed to prevent moisture loss.

Towelette Disposal: Do not reuse towelette. Dispose of used towelette in trash. Do not flush in toilet.

Dispenser Disposal: Do not reuse empty container. Wrap container and put in trash collection.

For packets and travel packs:

Storage: Do not store near heat or open flame.

Towelette Disposal: Do not reuse towelette. Dispose of used towelette in trash. Do not flush in toilet.

Travel Pack [or Packet] Disposal: Put empty travel pack [or packet] in trash collection.

The terms "wipe(s)", "towel(s)", "towelette(s)", and "cloth(s)" and the product name may be used interchangeably except for within the product primary brand name.

Bactericidal

Virucidal*

*Adenovirus Type 5, Herpes Simplex Type 2, Influenza A2/Hong Kong, Respiratory Syncytial Virus (RSV), Rhinovirus, Vaccinia virus, HIV-1[†], Hepatitis B Virus[†], Hepatitis C Virus[†]

Virucidal against Adenovirus Type 5, Herpes Simplex Type 2, Influenza A2/Hong Kong, Respiratory Syncytial Virus (RSV), Rhinovirus, Vaccinia virus, HIV-1[†], Hepatitis B Virus[†], Hepatitis C Virus[†]

Tuberculocidal

[Product name] kills bacteria listed on this label

Candida albicans

Escherichia coli (E. coli)

Klebsiella pneumoniae

Methicillin Resistant Staphylococcus aureus (MRSA)

Mycobacterium bovis BCG (Tuberculosis)

Pseudomonas aeruginosa

Salmonella choleraesuis

Staphylococcus aureus

Vancomycin Resistant Enterococcus faecalis (VRE)

in the presence of organic soil (5% blood serum)

[Product name] is virucidal against Adenovirus Type 5, Herpes Simplex Type 2 (causative agent of genital herpes), Influenza A2/Hong Kong (representative of the common flu virus), Respiratory Syncytial Virus (RSV), Rhinovirus and Vaccinia virus in the presence of organic soil (5% blood serum)

[†]KILLS HIV-1 (AIDS VIRUS), HEPATITIS B VIRUS (HBV) AND HEPATITIS C VIRUS (HCV) ON THE PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS AND PRE-CLEANED EXTERNAL SURFACES OF ULTRASOUND TRANSDUCERS AND PROBES PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in two (2) minutes at room temperature (68°- 77°F) or (20°- 25°C) in healthcare 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 1 (HIV-1) (associated with AIDS), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV).

A quaternary/alcohol solution impregnated in a wiping cloth. A non-woven disposable cloth for use in hospitals and other critical care areas where the control of the hazards of cross-contamination between treated surfaces is required. Use on hard non-porous surfaces and equipment listed on this label made of stainless steel, plastic, Formica® and glass. Some organisms are removed from the surface by thoroughly wiping the surface with the wipe. Most remaining organisms are killed within five (5) minutes by exposure to the liquid in the wipe.

Areas of Use:

Hospital and Healthcare Settings: Ambulances, Anesthesia, CAT Labs, CCU, Central Supply, Clinics, Dental Offices, Dialysis Clinics, Doctors Offices, Emergency Rooms, E.R., Emergency Vehicles, Healthcare settings, Health Care Facilities, Home Health Care, Hospices, Hospitals, ICU, Laboratory, Laundry rooms, Neonatal Intensive Care Units (NICU), Newborn nursery, Nursing homes, Operating Rooms, Pediatrics, Pediatric Intensive Care Units (PICU), Physical therapy, Physician's offices, Radiology, Recovery Rooms, Rehabilitation, Respiratory therapy, Surgery, Transport vehicles and X-Ray.

and/or

Critical Care Areas: CCU, Emergency Rooms, E.R., ICU, Neonatal Intensive Care Units (NICU), Operating Rooms, Pediatric Intensive Care Units (PICU) and Surgery.

and

Hospital, Healthcare, and Critical Care Use Sites: May be used on hard non-porous surfaces of: bed railings; cabinets, carts, chairs; counters, exam tables; gurneys; isolettes, IV poles; stethoscopes; stretchers; tables; telephones; toilet seats; and hard non-porous outside surfaces of: apheresis machines, diagnostic equipment, dialysis machines; patient monitoring equipment, patient support and delivery equipment, toilets; and ultrasound transducers and probes.

The terms "wipe(s)", "towel(s)", "towelette(s)", and "cloth(s)" and the product name may be used interchangeably except for within the product primary brand name.

6/11

[Areas of Use continued]

Grocery Stores or Shopping Centers or Supermarkets or Delicatessens: Disinfects grocery cart handles and grocery cart child seats. Disinfects shopping cart handles and child seats. Cleans grocery carts or shopping carts.

Nursery or Daycare Centers: Changing tables, cribs, diaper pails, trash cans, toys and other hard, non-porous surfaces listed on this label.

Bathroom: Bathtubs, bathroom fixtures, shower stalls, sinks, tiles, toilet seats and vanity tops, and other hard non-porous surfaces listed on this label.

Health club facilities: Gym equipment and other hard non-porous surfaces listed on this label.

Schools or Classrooms or Office Buildings or Public Facilities or Manufacturing Facilities: Cabinets, chairs, computers, counters, countertops, desks, desktops, doorknobs, fax machines, garbage cans, headsets, keyboards, railings, seats, sinks, tables, tabletops, telephones, trashcans, and other hard non-porous surfaces listed on this label.

Transport vehicles, school busses, public busses, fire trucks, police cars: Hard non porous surfaces of vehicles including steering wheel, hard plastic or metal flooring, seats, and walls.

Restaurants: Hard non porous, non food contact surfaces only including chairs, display cabinets, garbage cans, booster seats, floor, sinks, bathroom surfaces, tiled walls, telephones, cash registers, and doorknobs.

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.

Directions for use

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

Dispenser directions:

Canister directions:

To start feed: Remove lid and discard inner seal from canister. Find center of wipe roll, remove first wipe for use, twist corner of next wipe into a point and thread through the hole in the canister lid. Pull through about one inch. Replace lid. Dispense remaining wipes as necessary by pulling out at an angle. When not in use keep center cap of lid closed to prevent moisture loss.

Travel pack directions:

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

Box directions:

Open along perforations as indicated. Remove packets as needed.

Packet:

Tear open packet. Unfold and use as directed. Discard after single use.

To disinfect nonfood contact surfaces only:

Use a wipe to remove heavy soil. Unfold a clean wipe and thoroughly wet surface. Treated surface must remain visibly wet for a full five (5) minutes. Use additional wipe(s) if needed to assure continuous five (5) minute wet contact time. Let air dry. [When TB is included on the label, add the following:] These directions also apply to Mycobacterium bovis BCG (Tuberculosis) at 68°F (20°C).

The terms "wipe(s)", "towel(s)", "towelette(s)", and "cloth(s)" and the product name may be used interchangeably except for within the product primary brand name.

[optional directions] Ultrasound transducers and probes:

For use on external surfaces of ultrasound transducers and probes only.

To disinfect: Pre-clean gel from external surface of ultrasound transducer or probe to be disinfected by using a clean washcloth. Then thoroughly wet the probe with a towelette. Treated surface must remain visibly wet for a full five (5) minutes. Use additional wipe(s) if needed to assure continuous five (5) minute wet contact time. Let air dry.

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1, HEPATITIS B VIRUS AND HEPATITIS C VIRUS OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS

Personal protection: When using this product, wear disposable protective gloves, protective gowns, face masks, or eye coverings as appropriate when handling HIV-1 (AIDS Virus), HBV or HCV infected blood or body fluids.

Cleaning procedure: All blood and other body fluids must be thoroughly cleaned from surfaces and objects before disinfection by the germicidal wipe. Open, unfold first germicidal cloth to remove heavy soil.

Disposal of infectious materials: Dispose of used towelette in accordance with local regulations for infectious waste disposal.

Contact time: Use second germicidal cloth to thoroughly wet surface. Allow to remain wet two (2) minutes, let air dry. Although efficacy at a two (2) minute contact time has been shown to be adequate against HIV-1, HBV and HCV this time is not sufficient for the other organisms listed on this label. Therefore a five (5) minute wet contact time must be used for other listed organisms.

To clean: Wipe surfaces and let air dry.

The terms "wipe(s)", "towel(s)", "towelette(s)", and "cloth(s)" and the product name may be used interchangeably except for within the product primary brand name.

8/11

Optional Claims

An effective method to clean, deodorize and disinfect against odor-causing organisms on hard non-porous surfaces listed on this label.

An effective way to disinfect hard, non-porous environmental surfaces listed on this label.

A non-woven disposable cloth for use in hospitals and other critical care areas where control of the hazards of cross contamination between treated surfaces is required.

Antibacterial

Antimicrobial

A One Step[†] Cleaner/Disinfectant (except precleaning is required for blood and body fluids)

Are pre-measured to have the recommended amount of germicidal solution, wipe after wipe.

Assures proper dilution strength, product effectiveness and standardized technique.

Cellulosic non-woven disposable cloth

Cleans and disinfects

Cleans, deodorizes, and kills common household germs

Cleans, disinfects and deodorizes

Cleans grocery carts and shopping carts

Convenient

Disinfects grocery cart handles or shopping cart handles or grocery cart child seats or shopping cart child seats

Disinfects hard non-porous environmental surfaces listed on this label

Does not produce mist or overspray

Easy One Step[†] Cleaning and Disinfecting (except precleaning is required for blood and body fluids)

No measuring

No mixing

Non-woven disposable cloth

Premeasured

Premoistened

Ready to Use

Require no mixing or measuring and are ready-to-use

Tear at perforation

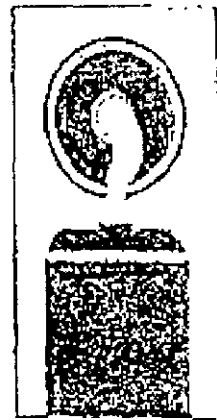
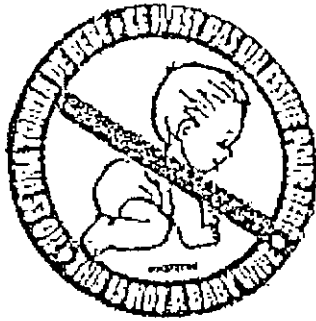
Time to reorder

Where control of the hazards of cross contamination between treated surfaces is of prime importance

The terms "wipe(s)", "towel(s)", "towelette(s)", and "cloth(s)" and the product name may be used interchangeably except for within the product primary brand name.

9/11

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

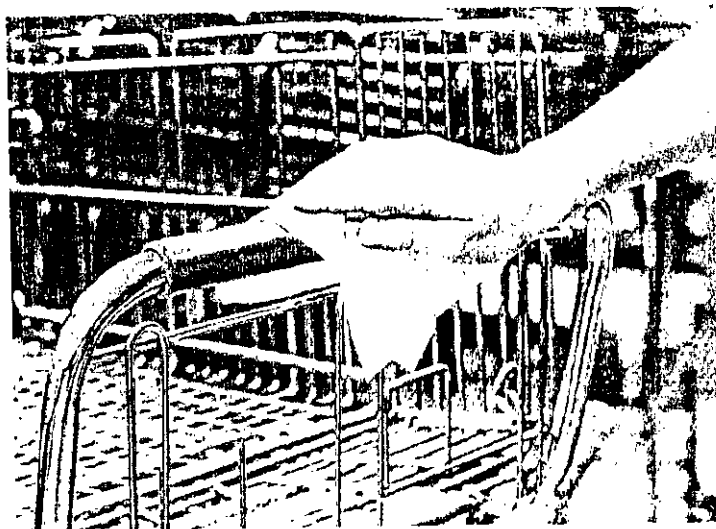
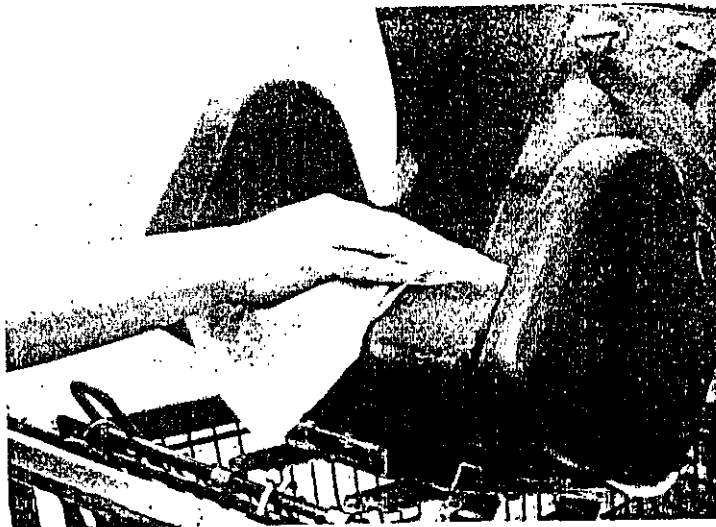


This graphic shows use of the wipe dispenser.

NOT A BABY WIPE

NOT FOR USE ON SKIN

The terms "wipe(s)", "towel(s)", "towelette(s)", and "cloth(s)" and the product name may be used interchangeably except for within the product primary brand name.



The terms "wipe(s)", "towel(s)", "towelette(s)", and "cloth(s)" and the product name may be used interchangeably except for within the product primary brand name.

11/11



Not a Skin Wipe.
For Use on Hard Surfaces Only.



Not a Skin Wipe.
For Use on Hard Surfaces Only.