

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

NOV 6 2003

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

**Subject: Sani-Cloth Germicidal Wipes**  
**EPA Reg. No. 9480-4**  
**Submission Dated 8/26/03 (Revised label)**

These submission referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to provide a revised label which responds to the label changes required in the EPA letter dated 6/24/03, is acceptable providing a final printed "Master Label" is submitted within 90 days of the date of this letter which makes the following label clarifications and changes.

**Global Change**

1. Claims that the product is a "one-step" cleaner and disinfectant do not apply to "HIV" and to "Ultrasound transducers [probes]", where a pre-cleaning step is required as stated on the label. Therefore, all "one-step" or similar type claims must be clearly qualified as not applicable to HIV and ultrasound transducers [probes]. This is considered a required qualification that must not have the optional brackets "[ ]".

2. As a clarification, all virucidal type claims and uses which currently have the required (not optional) asterisk (\*) must always refer to a required (not optional) comprehensive list of viruses which also has the same asterisk.

**Page 3/9**

Delete "most" from "...the spread of germs on most hard, non-porous surfaces".

**Page 5/9**

1. Delete the unspecified "equipment surfaces" use site or qualify it (eg., "telephone equipment surfaces", etc.).

2. Add the missing use site "Ultrasound transducers [probes]" to the "section B2".

**CONCURRENCES**

SYMBOL							
SURNAME							
DATE							

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Page 6/9

Change the subheading "Non Food Contact Surfaces" to "Non Food Contact Surfaces Only".

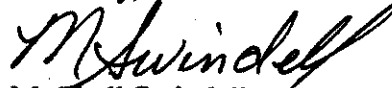
Page 7/9

Add the use sites at the top of the page for "[Hospices]", and "[Healthcare Settings]" to Paragraph B2 on page 5/9.

A copy of the label stamped "Accepted with comments" is enclosed. Please include a copy of this letter with your response.

If you have any questions concerning this letter, please contact myself at 703-308-6341, or Tony Kish at (703) 308-9443.

Sincerely,



Marshall Swindell

Product Manager 33

Regulatory Management Branch 1

Antimicrobial Division (7510C)

Enclosure

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

**SANI-CLOTH® GERMICIDAL WIPES**

[GERMICIDAL DISPOSABLE CLOTH]  
 [Disinfects Hard Non-Porous Environmental Surfaces]  
 [Germicidal Wipe]

**ACTIVE INGREDIENTS:**

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

KEEP OUT OF REACH OF CHILDREN

**CAUTION**

See back [side] panel for additional precautionary statements

NET WT  
 NET CONTENTS # OF CLOTHS SIZE

[The following registration and establishment number information and registrant address information is mandatory, but may appear in any appropriate place on the label:]

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

[For information: [phone number to be inserted]] [website address]

[e-mail address]

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Under the Federal Insecticide,  
 Fungicide, and Rodenticide Act as  
 amended, for the pesticide,  
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9480-4

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**PRECAUTIONARY STATEMENTS:**

Hazard 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:**

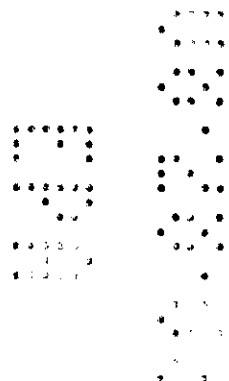
Combustible. Do not use or store near heat or open flame.

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[All statements below within the brackets (all of pages 3 and 4) are optional; choose from the following as appropriate; location is optional:]

[For use in: CRITICAL CARE AREAS]

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

[Effective against a wide range of bacteria including Staphylococcus aureus, Salmonella choleraesuis, Pseudomonas aeruginosa] [in the presence of organic soil (5% blood serum)]

[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 viruses including Influenza A2/Hong Kong and Herpes Simplex Type 2]

[\*Kills Influenza A2/Hong Kong (Hong Kong flu) and Herpes Simplex Type 2]

[\*Kills Rhinovirus]

[\*Kills Vaccinia Virus and Adenovirus Type 5]

[Kills Candida albicans]

[Kills Staphylococcus aureus and Salmonella choleraesuis]

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

[A One Step Cleaner/Disinfectant]

[\*Exhibits effective virucidal activity; kills Influenza A2/Hong Kong (representative of the common flu virus) and Herpes Simplex Type 2 (causative agent of genital herpes) [in the presence of organic soil (5% blood serum)]]

[\*Also effective against flu viruses Influenza A2/Hong Kong (Hong Kong flu)]

[Kills Mycobacterium bovis BCG (Tuberculosis)] [in the presence of organic soil (5% blood serum)]

[Effective against: [Staphylococcus aureus] [Salmonella choleraesuis] [Pseudomonas aeruginosa] [Klebsiella pneumoniae] [Methicillin Resistant Staphylococcus aureus (MRSA)] [Vancomycin Resistant Enterococcus (VRE)] [Escherichia coli (E. Coli)] [Candida albicans] [in the presence of organic soil (5% blood serum)]]

[\*Kills viruses including Influenza A2/Hong Kong, Herpes Simplex Type 2, Vaccinia Virus, Adenovirus Type 5, [in the presence of organic soil (5% blood serum)]]

[Effective against Staphylococcus aureus, Salmonella choleraesuis, Pseudomonas aeruginosa, and Klebsiella pneumoniae] [in the presence of organic soil (5% blood serum)]

[Sani-Cloth Germicidal Disposable Wipes [or this product] control[s] the spread of germs on most hard, non-porous surfaces.]

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

[Antibacterial]

[Aids in reducing [in the reduction of] cross contamination between treated surfaces]

[Bactericidal]

[Tuberculocidal]

[\*Virucidal]

[An effective method to disinfect hard, non-porous environmental surfaces]

[Effectively disinfects common hard, non-porous household surfaces]

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

[Cleans and disinfects]

[Cleans, deodorizes and disinfects]

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[Cleans and disinfects common hard, non-porous surfaces]  
[Use to clean, deodorize, and disinfect hard, non-porous surfaces in the nursery]  
[Kills many common household bacteria and \*viruses]  
[Disinfects hard, non-porous environmental surfaces]  
[Disinfects environmental surfaces]  
[Bathroom wipes]  
[Bathroom wipes for hard, non-porous surfaces]  
[Bathroom disinfectant wipes]  
[\*Use wipes to kill Influenza A2/Hong Kong, Salmonella and [Staphylococcus] [Staph] on bathroom  
hard, non-porous surfaces]  
[Nursery wipes]  
[Household surface wipes]  
[Telephone] [cell phone] [cellular phone] [wireless phone] [mobile phone] [digital phone] [disinfectant  
wipes]  
[A disinfectant cloth for use on [telephone] [cell phone] [cellular phone] [wireless phone] [mobile  
phone] [digital phone] surfaces [and other telecommunications equipment surfaces]]  
[Cleans and disinfects [telephone] [cell phone] [cellular phone] [wireless phone] [mobile phone] [digital  
phone] surfaces, [telephone] [cell phone] [cellular phone] [wireless phone] [mobile phone]  
[digital phone] [equipment surfaces] [dictating equipment surfaces, and other  
telecommunications equipment] [surfaces] [devices]]  
[Disinfects headsets, telephones, [cell phones] [cellular phones] [wireless phones] [mobile phones]  
[digital phones]]  
[Quick drying]  
[Ready to use]  
[Assures proper dilution strength, product effectiveness and standardizes technique]  
[Greater quaternary dispersal with no hazard of cross contamination between treated surfaces]  
[Non-woven disposable cloth]  
[A dual chain Quaternary/Alcohol solution impregnated in a wiping cloth]  
[A dual chain Quaternary/Alcohol solution that contains 5,000 parts per million (ppm) of active...  
ingredient/dual chain quaternary ammonium chlorides and 55% isopropyl alcohol] \*.....  
[Convenient] .....  
[Premeasured] .....  
[Premoistened] .....  
[Disposable] .....  
[No mixing] .....  
[No measuring] .....  
[Moist Wipes] .....  
[Strong, Real Cloth Wipes] .....  
[Pre-Moistened Towelettes] .....  
[To Clean and Deodorize] .....  
[Use on hard, non-porous surfaces only. Test wipe on small inconspicuous area first.] .....  
[To Clean: Wipe surfaces and let air dry. Safe for most non-porous surfaces.] .....  
[Not recommended for natural marble, windows, unpainted wood, brass, clear plastic, or colored  
grout.] .....  
[Easy, One Step Cleaning and Disinfecting]  
[Suitable for hospital use]  
[Are pre-measured to have the recommended amount of germicidal solution, wipe after wipe]

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[choose from the following areas of use as appropriate; they may be listed in any order; at least one use site (including corresponding list of surfaces) must be used on the label:]

## AREAS OF USE

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[Bathroom: [Toilet seats,] [bathroom fixtures,] [vanity tops,] [shower stalls,] [bathtubs,]  
[tiles,] [sinks]]  
[General use: [Doorknobs,] [telephones,] [laundry rooms,] [garbage cans,] [pet areas] [and  
other] [hard, non-porous surfaces]] [headsets] [cell phone] [cellular phone]  
[wireless phone] [mobile phone] [digital phone] surfaces, [equipment  
surfaces] [dictating equipment surfaces] [and other telecommunications  
equipment] [surfaces] [devices]] [computers [and keyboards]  
[Nursery: [Changing tables,] [cribs,] [diaper pails,] [trash cans,] [toys] [and other] [hard,  
non-porous surfaces]]

[Optional: None, one, or both of the following paragraphs may be used as appropriate; paragraph #“B” may be used before “A” on the label if both are used]

[A]

### [Hospital and Health Care Settings]

[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. Use on hard, non-porous surfaces and equipment including stainless steel, Formica, glass, tables, carts, counters, cabinets, telephones and other hard, non-porous surfaces. Some organisms are removed from the surface by thoroughly wiping the surface with the towel. Most remaining organisms are killed within five (5) minutes by exposure to the liquid in the towel.]

[B]

[B 1] [Areas of Use: Hard, non-porous surfaces in: [Surgery,] [Hospitals,] [Emergency Room,] [E.R.,] [Recovery Room,] [ICU,] [CCU,] [Anesthesia,] [Laboratory,] [Physical therapy,] [Respiratory therapy,] [Radiology,] [X-Ray,] [CAT Lab,] [Newborn nursery,] [Pediatrics,] [Central Supply,] [Operating Room,] [Nursing homes,] [Home Health Care,] [Physician's offices,] [Dental offices,] [Ambulances,] [Clinics] [Transport vehicles,] [Health Club facilities,] [Veterinary facilities,] [Dialysis Clinics]

[Section B 1 must be used if section B2 (below) is on the label]

[B2] [May be used on: Hard, non-porous surfaces of: [Exam tables,] [Gurneys,] [IV poles,] [Bed railings,] [Outside surfaces of equipment,] [Toilet seats [and] [outside surfaces of toilets,] [Tables,] [Chairs,] [Stretchers,] [and other hard, non-porous surfaces.]]

[If paragraph A and/or paragraph B are used, then all of the following paragraph must be used on label.]

[“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 pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.”]

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## DIRECTIONS FOR USE

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

[Use one of the following as applicable to type of container:]

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
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### [TOWELETTE] [WIPE] [TOWEL]

#### [DISPENSER 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.]

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#### [TRAVEL PACK:

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

[Use one or more of the following as appropriate; at least one set of directions must be used; they may be used in any order as long as the entire paragraph is used:]

### TO DISINFECT:

#### NON FOOD CONTACT SURFACES

Use a wipe to remove gross filth [or 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 5 minute wet contact time. Let air dry.

#### ULTRASOUND TRANSDUCERS

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. Treated surface must remain visibly wet for a full five (5) minutes. Use additional wipe(s) if needed to assure continuous 5 minute wet contact time. Let air dry.

[At least one of the disinfection directions above must be used on the label in addition to the directions below.] [The following directions are for hospital/medical facility use labels only:]

[\*VIRUS AND [OR] TUBERCULOSIS (TB) OUTBREAKS \*Influenza A2/Hong Kong, \*Vaccinia Virus, \*Adenovirus Type 5, \*Herpes Simplex Type 2, \*Rhinovirus, Mycobacterium bovis BCG (Tuberculosis) (TB)]

[When viruses listed above or TB are the sole concern,] or [For specific outbreaks of viruses listed above or TB the following directions may be used: Use a wipe to remove gross filth [or heavy soil]. Unfold a clean wipe and thoroughly wet surface. Treated surface must remain visibly wet for one (1) full minute. Let air dry. Although efficacy at a one (1) minute contact time has been shown to be adequate against the specific organisms listed above, this time is not sufficient for other organisms listed on the label. Therefore a 5 minute wet contact time must be used for all listed non-viral/non-TB organisms.

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[The following headings are optional; choose as appropriate:]

[Hospital Use] [Nursing Homes] [Doctor's Offices] [Hospices] [Healthcare Settings]

[If directions for HIV are to be used, then use the following heading:]

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

[Use A, B, or C]

[A]

**\*KILLS HIV-1 (AIDS VIRUS) ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in one (1) minute 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).

[B]

**\*KILLS HIV-1 ON THE PRE-CLEANED EXTERNAL SURFACES OF ULTRASOUND [TRANSDUCERS] [PROBES] PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in one (1) minute 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).

[C]

**\*KILLS HIV-1 ON THE PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS AND PRE-CLEANED EXTERNAL SURFACES OF ULTRASOUND [TRANSDUCERS] [PROBES] PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in one (1) minute 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).

[If paragraph A, B, and/or C are used, then all of the language below must be used on label.]

**PERSONAL PROTECTION:** When using this product, 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 [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 one (1) minute, let air dry. Although efficacy at a one (1) minute contact time has been shown to be adequate against \*HIV-1 (AIDS VIRUS) this time is not sufficient for the other non-HIV organisms listed on this label. Therefore a 5 minute wet contact time must be used for all listed non-HIV organisms.

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[Use storage/disposal statement A if towelette dispenser directions used. Use storage/disposal statement B if travel pack or packet directions used.]

[A]

#### STORAGE AND DISPOSAL

Towelette: Do not reuse towelette. Dispose of used towelette in trash. Do not flush in toilet.  
Dispenser: Do not reuse empty container. Wrap container and put in trash collection.

[B]

#### STORAGE AND DISPOSAL

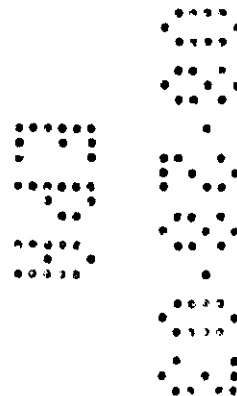
Towelette: Do not reuse towelette. Dispose of used towelette in trash. Do not flush in toilet.  
Travel Pack [or Packet]: Put empty travel pack [or packet] in trash collection.

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



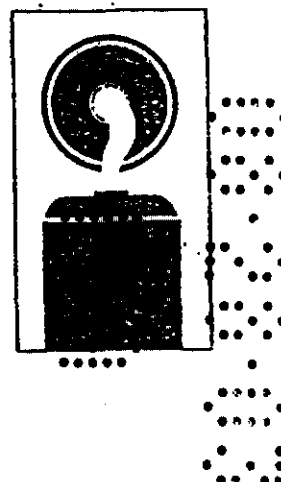
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[This graphic shows use of the wipe dispenser.]



NOT A BABY WIPE

NOT FOR USE ON SKIN

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