

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 Plus Germicidal Disposable Cloth
EPA Reg. No. 9480-6
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 7/25/03, 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

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 2/8

1. Change the current "Precautionary Statement" which states "Avoid contact with eyes" to the following, "Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling". This is in harmony with the other PDI towelette products.

2. In the second claim, delete the brackets before and after "[between treated surfaces]".

Page 3/8

1. Delete "most" from "For most non-porous surfaces".

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

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

2 8 10

Page 4/8

1. In the use sites for kitchens, change "[appliances surfaces]" to "outside of appliance surfaces" and also list the intended appliances. The Agency does not allow towelette disinfectant use for the insides of residential appliances such as blenders, microwaves, refrigerators, stoves, etc. which are considered food contact sites. The Agency has issue with residential consumers complying with the potable water rinse requirement.
2. In the "General use" section, delete the unspecified "[and other hard non-porous surfaces]", and "[equipment surfaces]".
3. Note that the potable water rinse statement is required (not optional) if any food contact use sites are listed.
4. Add the missing use site "Ultrasound transducers [probes]" to the "section B2".

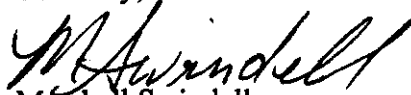
Page 6/8

Add the use sites at the top of the page for "[Hospices]", and "[Healthcare Settings]" to Paragraph B2 on page 4/8.

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							

3810

SANI-CLOTH® PLUS

GERMICIDAL DISPOSABLE CLOTH

ACTIVE INGREDIENTS:

n-Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl ethylbenzyl ammonium chlorides.....	0.125%
n-Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈) dimethyl benzyl ammonium chlorides.....	0.125%
Isopropyl Alcohol.....	14.850%
OTHER INGREDIENTS	84.900%
TOTAL	100.000%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See back [side] panel for additional precautionary statements

NET WT
[NET CONTENTS # OF CLOTHS SIZE]

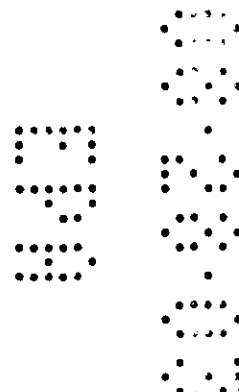
[The following registration and establishment number information and registrant address information is mandatory, but may appear in any appropriate place on the label:]

EPA Reg. No.: 9480-6

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]

ACCEPTED
with COMMENTS
in EPA Letter Dated:

NOV 06 2003

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.

9480-6

THE INFORMATION IN THIS BOX IS NOT PART OF THE LABELING

Statements in brackets [] are optional or instructional. Italicized words in brackets are not included. Sequence of phrases is optional unless specified in 40 CFR 156.10. Capitalization, plurals or singular, bold and italics are all variable unless specified in 40 CFR. The terms "wipe(s)", "towel(s)", "towelette(s)", and "cloth(s)" may be used interchangeably throughout except for the product primary brand name which can be only changed by notification or amendment. Lists of uses and use sites can be used partially or in their entirety. Any individual statement, claim, restriction or other wording must be used in its entirety, and can not be expanded or shortened by combination, partial deletion, merging, or similar.

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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.

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.

[All statements below within the brackets (from here through all of page 3) are optional; choose from the following claims 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 Staphylococcus aureus, Salmonella choleraesuis, and Pseudomonas aeruginosa in (5) minutes.] [Effective in five (5) minutes against Staphylococcus aureus, Salmonella choleraesuis, and Pseudomonas aeruginosa.]

[*Exhibits effective virucidal activity on hard non-porous inanimate surfaces][:] [Kills Influenza A2/Hong Kong (representative of the common flu virus) and Herpes Simplex Type 2 (causative agent of genital herpes)]

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

[Kills common household germs: Staphylococcus aureus (Staph) and Salmonella choleraesuis.]

[*Also effective against cold and flu viruses Influenza A2/HK (Hong Kong flu).]

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

[For use on external surfaces of Ultrasound Transducers only.]

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

[Convenient] [Premeasured] [Premoistened]

[Kills Mycobacterium bovis BCG (Tuberculosis)][in five (5) minutes at 20°C.]

[Kills Escherichia coli (E. Coli) 0157:H7][in five (5) minutes.]

[Bactericidal]

[Tuberculocidal] [and] [Virucidal*]

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

[Assures proper dilution strength, product effectiveness and standardized technique.]

[Greater quaternary dispersal with no hazard of cross contamination between treated surfaces]

[Quick drying.]

[A dual chain Quaternary/Alcohol solution that contains 2,500 parts per million (ppm) of active ingredient/dual chain quaternary ammonium chlorides and 14.85% alcohol.]

[Non-woven disposable cloth]

[Antibacterial] [Antimicrobial]

[Kills household germs]

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

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

[Bath and Kitchen wipes for hard, non-porous surfaces]

[Cleans and disinfects] [Cleans, disinfects and deodorizes]

[Kills bacteria and viruses*]

[Cleans, deodorizes, and kills common household germs]

[No mixing]

[No measuring]

[Disinfects hard non-porous environmental surfaces]

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

[To clean: wipe surfaces and let air dry.] [For most non-porous surfaces.]

[Ready to Use]

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

[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]]

[Cleans [grocery carts] [shopping carts]]

[Disinfects [grocery cart handles] [shopping cart handles] [grocery cart child seats] [shopping cart child seats]]

ACCEPTED
with COMMENTS
in EPA Letter Dated:

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Under the Federal Insecticide,
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9480-6

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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; "Kitchen" areas of use must be included if "food contact surfaces" directions (see next page) are used.]

AREAS OF USE

[Kitchen:** [Counter tops,] [appliance surfaces,] [sinks,] [faucets,] [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
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]
[Changing tables,] [cribs,] [diaper pails,] [trash cans,] [toys] [and other] [hard,
non-porous surfaces]
[Grocery Stores], and/or [Shopping Centers], and/or [Delicatessens]: Disinfects [grocery cart
handles,] [shopping cart handles,] [grocery cart child seats,] [shopping cart child
seats] [and other hard non-porous surfaces] [Cleans [grocery carts] [shopping
carts]

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

[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. 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: [Hospitals,] [Surgery,] [Recovery,] [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,]

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

[B 2] 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,] [Portable medical equipment,] [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

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.

9480-6

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

[[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.]

[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; they may be used in any order as long as the entire paragraph is used; food contact directions must be used if "kitchen" is one of the areas of use or listed in the claims section:]

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.

[Kitchen Areas of Use section (shown on page 4) must be included on label if food contact directions below are used.]

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 followed by a thorough potable water rinse.

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 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* OUTBREAKS Influenza A2/Hong Kong,* Herpes Simplex Type 2*

[When either of the viruses listed above is the sole concern,] or [For specific outbreaks of either of the viruses listed above,] 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) minute. Let air dry. For food contact surfaces, follow one (1) minute contact time with a thorough potable water rinse. Although efficacy at a one (1) minute contact time has been shown to be adequate against the specific viruses listed above, this time is not sufficient for the non-viral organisms listed on the label. Therefore a 5 minute wet contact time must be used for all listed non-viral organisms.

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

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

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

*SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 OF
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, or C are used, then all of the language below must be used on labels]

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 surfaces and
objects before disinfection by the germicidal cloth. Open, unfold first germicidal cloth to remove gross filth
or [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.

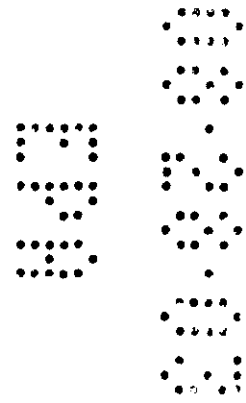
Travel Pack [or Packet]: Put empty travel pack [or packet] in trash collection.

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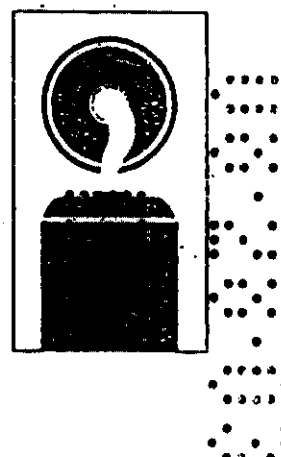
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[The following graphics and statements are optional.
They may be placed anywhere on label/container.]



[This graphic shows use of the wipe dispenser.]



NOT A BABY WIPE

NOT FOR USE ON SKIN

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in EPA Letter Dated:

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