

9480-5

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

JUL 27 2001

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

PDI Healthcare Division of Nice pak Products
Two Nice-pak Park
Orangeburg, NY 10962-1376

Attention: Cristina Griffin, Agent

Subject: Sani-Cloth Germicidal Disposable Wipes
EPA Registration Number 9480-5
Your Submission Dated July 2nd, 2001
EPA Received Date July 9th, 2001

The submission referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided that you make the following labeling revisions:

- 1) Under item #2, you must include the asterisk (*) with every statement listing specific viruses on the master label. The use of the asterisk (*) is suppose to lead the user to statements which lists the specific viruses.
- 2) Under item #5, the "Consumer" label must contain all the elements of the master label to be considered pesticide labeling. Place the first page of the master label at the beginning of the "consumer" label.
- 3) On page 7 of 11 change "Disposaable" to "Disposable."
- 4) On page 3 of 11 change "For use on external of Ultrasound Transducers only" to read "For use on external surfaces of Ultrasound Transducers only."
- 5) As per PR Notice 20001-1, revise the "If in eyes" statement to read as follows:

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.

The Confidential Statements of Formula for nine alternate formulations dated January 25, 2001, are approved.

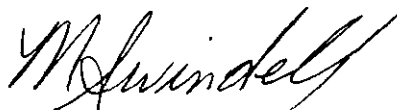
The new certified limits of isopropyl alcohol also is approved.

A stamped copy of the labeling is enclosed for your records.

Submit five (5) copies of final printed labeling to the Agency for our review.

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely,

A handwritten signature in black ink, appearing to read "M. Swindell", with a stylized flourish at the end.

Marshall Swindell
Product manager 33
Regulatory Management Branch I
Antimicrobial Division(7510C)

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MASTER LABEL COPY

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>	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

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PRECAUTIONARY STATEMENTS:

Hazards to humans and domestic animals.

CAUTION: Avoid contact with eyes.

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
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FIRST AID

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.

[Information on this page to be on all labels for this product]

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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 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.

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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 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."

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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.

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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.

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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.

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CONSUMER LABEL COPY
FRONT PANEL
SANI-CLOTH
GERMICIDAL DISPOSABLE CLOTH

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.

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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

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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

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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

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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

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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.

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Lemon Scent
Citrus Scent
Floral Scent
Fresh Air Scent
Mint Scent

[These graphics will be on the label to show examples of places the product can be used.]



[This graphic shows use of the wipe dispenser.]



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