

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

9480-5

4-5-1999

APR 05 1999

1/14

PDI, The Health Care Division of Nice Pak
Two Nice-Pak Park
Orangeburg, NY 10962

Mailed To: Sally Hayes, Agent for PDI
SRC Scientific and Regulatory Consultants, Inc.
P. O. Box 1014
Columbia City, IN 46725

RE: Sani-Cloth Germicidal Disposable Cloth
EPA Reg. No. 9480-5
Your Re-submission Dated 1/11/99

The re-submission referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to correct the label changes required in the EPA letter dated 9/24/98, is acceptable subject to the following conditions.

LABEL CORRECTIONS

You must submit 5 copies of final printed labels which address each of the following items. One of the final printed copies should be highlighted in yellow to show each of the required changes.

1. You must change the phrase "HIV" to read "**HIV-1**" everywhere it appears on the label.
2. The use of an asterisk (*) after the generic word "virucidal" which appears on page 1 and on page 8 of the label, is supposed to lead the user to statements which list the specific viruses. However, not all statements which include specific viruses have the asterisk. For example, on page 1, the two phrases, "Exhibits effective virucidal activity; kills Influenza A2/Hong Kong...", and the statement, "Kills dangerous viruses such as Influenza A2/Hong Kong...", must have the asterisk. Therefore, you must include the asterisk (*) with every statement listing specific viruses on this master label.
3. For food contact uses, a potable water rinse statement was integrated into the "Towelette", "Travel Pack", and "Dispenser" use directions in the "Critical Care Areas" label. Therefore, on page 12 of the "Consumer Label", you must also add a similar statement at the end of each of the use directions for "Towelette", "Travel Pack", and "Dispenser". You can use the sentence "**A thorough rinse with potable water is required for surfaces in direct contact with food**", or

similar language.

CONCURRENCES

SYMBOL	SURNAME	DATE						

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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The following identical stand alone statement on page 9 of the label should be kept, but it is not considered to offer adequate food contact protection for the user, "***A thorough rinse with potable water is required for surfaces in direct contact with food".

4. All registered pesticides must have a subsection titled "Statement of Practical Treatment". On page 5, you must add the subtitle, "Statement of Practical Treatment" in front of the statement, "Caution; Avoid contact with eyes. In case of...".

5. Even though your Master Label is separated into "Critical Care" and "Consumer" portions, by definition, it contains only one Ingredients Statement, one "Signal Word", one "Precautionary Statements" section (which includes one Statement of Practical Treatment sub-section), one "Physical or Chemical Hazards" sub-section (if applicable), and one Storage and Disposal section. The "Consumer" label is lacking these required sections. Therefore, when marketing just the "Consumer" label, you must integrate all the missing required sections which are only listed in the "Critical care" label portion.

A label stamped "Acceptable With Comments" is attached for your records.

If you have any questions about the comments in this letter, please feel free to contact Tony Kish at 703-308-9443.

Sincerely,

Marshall Swindell

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

CONCURRENCES

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SURNAME								
DATE								

Monday, January 11, 1999a

3/14

MASTER LABEL COPY
FRONT COPY

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Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
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9480-5

SANI-CLOTH

GERMICIDAL DISPOSABLE CLOTH

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 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 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).

*Kills Rhinovirus 13 in 3 minutes

Bactericidal, Tuberculocidal, and Virucidal*

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

Kills *Trichophyton mentagrophytes*, *Aspergillus niger* and *Candida albicans* in 5 minutes at 20°C.

Kills pathogenic fungi in 5 minutes.

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%

INERT 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

E. P. A. Reg. No.: 9480-5

E. P. A. Est. No. : 9480-NY-001

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9480-5

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

*Kills Rhinovirus 13 in 3 minutes

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.

SOME 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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9480-35

***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

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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.

PRECAUTIONARY STATEMENTS: Hazards to humans and domestic animals.

CAUTION: Avoid contact with eyes. In case of eye contact, flush with plenty of water for at least 15 minutes. If irritation persists, call a physician.

STORAGE AND DISPOSAL: Toweleette: 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.

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Under the Federal Insecticide,
Fungicide, and Rodenticide Act, as
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9486-5

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BACK PANEL**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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10/14

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- Disposaaable

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

*Kills HIV 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).

Inhibits mold and mildew

*Kills Rhinovirus 13 in 3 minutes

Bactericidal, Tuberculocidal, and Virucidal*

Kills many common household germs

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

Kill *Trichophyton mentagrophytes*, *Aspergillus niger* and *Candida albicans* in 5 minutes at 20°C.

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Under the Federal Insecticide,
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9488-5

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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

Some 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

Kills common household germs such as *Staphylococcus aureus* (Staph) and *Salmonella choleraesuis*. Also effective against cold and flu viruses such as Rhinovirus 13 and 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 *Mycobacterium bovis* BCG (Tuberculosis) in 10 minutes at 20°C

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

*Kills Rhinovirus 13 in 3 minutes

Cleans and disinfects common hard non-porous surfaces

Effectively disinfects common hard non-porous household surfaces

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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.

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

Some 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 water is required for surfaces in direct contact with food.

Use wipes to kill Influenza A2/Hong Kong, Rhinovirus 13, Salmonella, Staphylococcus and other harmful germs on most bath and kitchen hard, non-porous surfaces.

Do not flush in toilet.

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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.

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 (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 heavy soil. 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.

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 (10 minutes for Mycobacterium bovis BCG-tuberculosis), let air dry.

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