

9480-4

3/13/2002

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAR 13 2002

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

Subject: Sani-Cloth Germicidal Wipes
EPA Reg. No. 9480-4
Your Submission Dated 9/28/01; Responding to EPA Letter of 8/14/2001

The re-submission referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided you make the following label changes, and submit two copies of a final printed label with these exact changes.

1. In the "Directions For Use", you must change "Allow to remain wet for five (5) minutes", to "Treated surface must remain visibly wet for a full five minutes." This revised label statement more precisely reflects the actual use conditions required to achieve the claimed efficacy levels.
2. The label does not clarify which use sites are intended for food contact. Therefore, in the interim, you must add the following statement in the use directions for food contact, "Use only for the following food contact applications listed on this label; tables, baskets, and counters".
3. To add additional food contact use sites, you must submit an amendment and revised label which clearly distinguishes these sites. The Agency may require a restriction statement against use on any food contact sites requiring total immersion (ie., tableware, glasses, cookware, etc.).
4. Because your "Master Label" does not note it otherwise, all the words on the proposed label, including the changes in this letter, must appear on the final production label (ie., no deletions).

A copy of the label stamped "accepted 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, or myself at 703-308-6341.

Sincerely,



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

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

SANI-CLOTH GERMICIDAL WIPES**GERMICIDAL DISPOSABLE CLOTH**

Disinfects Hard Non Porous Environmental Surfaces

ACTIVE INGREDIENTS:n-Alkyl (68% C₁₂, 32% C₁₄) dimethyl ethylbenzyl ammonium chlorides..... 0.25%n-Alkyl (60% C₁₄, 30% C₁₆, 5% C₁₂, 5% C₁₈) dimethyl benzyl ammonium chloride. . . 0.25%

Isopropyl Alcohol.....55.00%

OTHER INGREDIENTS.....44.50%**TOTAL** 100.00%ACCEPTED
with COMMENTS
in EPA Letter Dated:

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KEEP OUT OF REACH OF CHILDREN**CAUTION**Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.

See back panel for additional precautionary statements

NET WT

NET CONTENTS # OF CLOTHS SIZE

EPA Reg. No.: 9480-4

EPA Est. No.: 9480-NY-001

Manufactured by:

PDI Healthcare Division of Nice Pak 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.

STORAGE AND DISPOSAL: Towel: 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.

For use in: CRITICAL CARE AREAS

Where control of the hazards of cross contamination is of prime importance.

Effective against a wide range of bacteria including *Staphylococcus aureus*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*.

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 dangerous viruses such as Influenza A2/Hong Kong and Herpes Simplex II.

*Kills Rhino virus.

*Kills Vaccinia virus and Adeno virus Type 5.

*Kills Pseudorabies virus.

Kills *Candida albicans*.

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Effective in five (5) minutes against: *Staphylococcus aureus*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Klebsiella pneumoniae*, *Mycobacterium bovis* BCG (Tuberculosis), Methicillin-resistant *Staphylococcus aureus* (MRSA), Vancomycin resistant *Enterococcus* (VRE), *Escherichia coli* (E. Coli), *Candida albicans*.

*Kills viruses in five minutes: Influenza A2/Hong Kong, Herpes Simplex II, Rhino virus, Vaccinia virus, Adeno virus Type 5, Pseudorabies virus.

***KILLS HIV-1 ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS**

PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in healthcare settings or other settings in which there is an expected likelihood of soiling of inanimate environmental surfaces with blood or body fluids, and in which the environmental surfaces 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).

Convenient - Premeasured - Premoistened

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

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. Organisms are removed from the surface by thoroughly wiping the surface with the towel. Remaining organisms are killed within five minutes by exposure to the liquid in the towel.

Areas of Use: Hard surfaces in: surgery, recovery, anesthesia, x-ray CAT lab, emergency room, new-born nursery, respiratory therapy, radiology and 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 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.

Dispenser Directions:

To start feed: Remove large cover and discard seal from container. From center of towel roll, pull up towel corner, twist it into a point and thread it through the hole in the container cover. Pull through about one (1) inch. Replace cover. Pull out first towel and snap off at a 90° angle. Remaining towels feed (pop-up) automatically ready for next use. When not in use, (When through using) keep small center cap closed to prevent moisture loss.

TOWEL

TO DISINFECT:

NON FOOD CONTACT SURFACES

Open, unfold, wipe to remove gross filth. Use a second towel to wet surface thoroughly. Allow to remain wet for five (5) minutes. Let air dry.

FOOD CONTACT SURFACES

Open, unfold, wipe to remove gross filth. Use a second towel to wet surface thoroughly. Allow to remain wet for five (5) minutes. Let air dry, followed by a potable water rinse.

***Special Instructions for Cleaning and Decontamination Against HIV-1 for Surfaces or Objects Soiled with Blood or Body Fluids:**

PERSONAL PROTECTION: When using the disinfectant cloth, wear disposable protective gloves, protective gowns, face masks, or eye coverings as appropriate when handling *HIV-1 infected blood or body fluids.

CLEANING PROCEDURES: All blood and other body fluids must be thoroughly cleaned from surface and objects before disinfection by the cloth. Open, unfold first disinfectant cloth to remove gross filth.

CONTACT TIME: Use second disinfectant cloth to thoroughly wet surface. Allow to remain wet 1 minute. Let air dry. Although efficacy at a 1 minute contact time has been shown to be adequate against *HIV-1 (AIDS VIRUS), this time would not be sufficient for other organisms.

DISPOSAL OF INFECTIOUS MATERIALS: Dispose of used towel in accordance with local regulations for infectious waste disposal.

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