

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAY 12 1997

Palmero Sales Company, Inc.
c/o SRA International, Inc.
1850 M Street, NW, Suite 290.
Washington, D. C. 20036

Attention: Frederick T. Smith
Regulatory Scientist

Subject: Isotex 70 Disinfecting Towelettes
EPA Registration No. 10492-4
Amendment Dated August 21, 1996 and
May 9, 1997

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to include claims against Methicillin Resistant Staphylococcus aureus (MRSA) and Vancomycin Resistant Enterococcus faecalis (VRE) to the product labeling, is acceptable, provided that you make the following changes listed below:

1. The use of the words VIRUCIDAL and HERPECIDAL in the front panel must be changed to VIRUCIDAL* and HERPECIDAL**. The asterisk must denote the specific viruses that have been tested.
2. On the front panel, in the paragraph ending "...Single-Use Towelettes in 1 minute at 23°C."; modify the last sentence to read "...Single-Use Towelettes in 1 minute at 23°C on pre-cleaned, hard, non-porous, environmental surfaces".
3. Delete the two use sites "food service and consumer use". These two sites are too broad, and may lead to confusion. However, the term "non-food contact surfaces" is acceptable.
4. Our records indicate that the product name for this registration is "Isotex 70 Disinfecting Towelettes" and not "DisCide Disinfecting Towelettes". For future reference, please include the basic product name on all your product labeling when submitting for review.

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

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(BACK PANEL)

DIRECTIONS FOR USE

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

[dispenser]

TO START FEED: Remove large cover from container. From center of towelette roll, pull up a towelette corner, twist into a point and thread through hole in 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 not in use, keep small center cap closed to prevent moisture loss.

TO DISINFECT: Completely preclean surfaces to be disinfected. An Isotex 70 Disinfecting Towelette can be used for this purpose. Then, thoroughly wet the surfaces with another towelette and allow to remain wet for 6 minutes.

[foil packages]

Completely preclean surfaces to be disinfected. An Isotex 70 Disinfecting Towelette can be used for this purpose. Then, open, unfold and use another towelette to thoroughly wet the surfaces and allow to remain wet for 6 minutes.

For disinfection of inanimate, precleaned, hard, non-porous surfaces such as chairs, counter tops, drawer pulls, carts, baskets, tables, cabinets, telephones and other related hard surfaces in hospitals, operating rooms, intensive care and emergency units, dental or veterinary offices, surgery, recovery, anesthesia, X-Ray, Cat. Lab, orthopedics, newborn nursery, respiratory therapy, radiology, central supply, emergency medical vehicles, police and fire vehicles, correctional facilities, schools and school medical facilities, school buses, day care, ~~use on stainless steel, glass, formica and other similar surfaces.~~ Use on stainless steel, glass, formica and other similar surfaces. Do not use on plexi-glass as discoloration may occur. Discard towelette after use.

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (AIDS VIRUS) FOR SURFACES OR OBJECTS SOILED WITH BLOOD OR BODY FLUIDS

PERSONAL PROTECTION: When using the towelettes, wear disposable latex gloves, protective gown, face mask and eye covering, 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 application of the disinfectant. An Isotex 70 Disinfecting Towelette can be used for this purpose.

CONTACT TIME: Thoroughly wet surface with a new Isotex 70 Disinfecting Towelette. Allow to dry. Although the efficacy of a 1 minute contact time has been shown to be adequate against HIV-1 (AIDS virus), this time would not be sufficient for control of other organisms.

DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluids should be autoclaved and disposed of according to Federal, State, and local regulations for infectious waste disposal.

PRECAUTIONARY STATEMENTS

Hazards to humans and domestic animals: WARNING. 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.

Physical or chemical hazards: Flammable. Keep away from heat or open flame.

[dispenser] **DISPOSAL:** Do not reuse towelette or empty container. Wrap towelette container and discard in trash.

[foil packages] **DISPOSAL:** Do not reuse towelette or empty packet. Dispose of used towelette and packet in trash.

For product emergency, contact Chem•Tel Inc. at 1-800-255-3924, 24 hours.

PALMERO HEALTH CARE, 120 GOODWIN PLACE, STRATFORD, CT 06497
For technical information, call 1-800-344-6424.

ACCEPTED
with COMMENTS
in EPA Letter Dated:
MAY 12 1997
The Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
10492-4

BEST AVAILABLE COPY

(FRONT PANEL)

ISOTEX 70 DISINFECTING TOWELETTES*

A dual chain quaternary ammonium and high level alcohol impregnated towelette

TUBERCULOCIDAL VIRUCIDAL BACTERICIDAL FUNGICIDAL HERPECIDAL

ACTIVE INGREDIENTS

n-alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈) dimethyl benzyl ammonium chloride	0.12%
n-alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl ethyl benzyl ammonium chloride	0.12%
Isopropyl alcohol	63.25%

INERT INGREDIENTS

36.51%

TOTAL INGREDIENTS

100.00%

Inert Ingredients do not include towelette

For use in: HEALTH CARE & ALTERNATE CARE SETTINGS such as hospitals, intensive care units, emergency medical settings, central supply, laboratories, clinics, nursing homes and dental suites.

Kills HIV-1 (AIDS Virus) on precleaned environmental surfaces or objects previously soiled with blood or body fluids in 1 minute at room temperature (20-25°C) in health care settings 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).

Isotex 70 is tuberculocidal against Mycobacterium bovis BCG by the Tuberculocidal Activity test within 1 minute at 20°C; virucidal against Herpes Simplex Virus type 2 and Adenovirus type 2 by an EPA approved virucidal test in 1 minute at 20°C; fungicidal against Trichophyton mentagrophytes by the AOAC Germicidal Spray Products as Disinfectants Test Modified for Single-Use Towelettes in 1 minute at 22°C and bactericidal against Staphylococcus aureus, Pseudomonas aeruginosa, and Salmonella choleraesuis by the AOAC Germicidal Spray Products as Disinfectants Test Modified for Single-Use Towelettes in 1 minute at 22°C, and Methicillin Resistant Staphylococcus aureus (MRSA) and Vancomycin Resistant Enterococcus faecalis (VRE) by the AOAC Germicidal Spray Products as Disinfectants Test Modified for Single-Use Towelettes in 1 minute at 23°C.

WARNING

KEEP OUT OF REACH OF CHILDREN

See back panel for additional precautionary statements

NET CONTENTS:

EPA REG. NO. 10492-4
EPA EST. NO. 56952-AR-01

*alternate brand name is Isotex 70 Disinfecting Towelettes

ACCEPTED
with COMMENTS
in EPA Letter Data

MAY 12 1997

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

10492-4

BEST AVAILABLE COPY

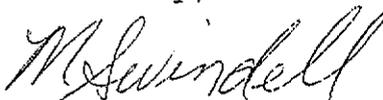
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A stamped copy of the labeling is enclosed for your records. Submit one (1) copy of the final printed labeling before you release the product for shipment.

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely,



Marshall Swindell
Acting Product Manager (31)
Regulatory Management Branch I
Antimicrobial Division (7505W)

Enclosure