

MAR 31 1998

Palmero Health Care  
120 Goodwin Place  
Stratford, CT 06497

Attention: Frederick T. Smith  
Regulatory Scientist

Subject: Isotex 70 Disinfecting Towelettes  
EPA Registration No. 10492-4  
Letters Dated February 25, 1998  
And March 30, 1998

The labeling 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 changes listed below:

1. Delete the term "Human" from the phrase "Kills a Wide Range of Human Pathogens in One Minute". The term denotes application to the living body. Since the intent of use for this product is limited to inanimate environment, this word must be replaced by an appropriate descriptive term for the effects claimed in the inanimate applications recommended.

2. On the front panel, revise the statement "Isotex 70 Disinfecting Towelettes are effective against the following human pathogens when used as directed" to read "Isotex 70 Disinfecting Towelettes are effective against the following pathogens on hard non-porous surfaces when used as directed".

3. On the back panel, include the following HIV-1 statement above the "Special Instructions" for the HIV-1 claims.

"Kills HIV-1 ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings (Hospitals, Nursing Homes) 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).

CONCURRENCES

SYMBOL							
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4. On the back panel, under the "TO DISINFECT" heading, revise the the last sentence to read "When used as a tuberculocidal disinfectant, allow the surface to remain wet for 5 minutes at 20°C.

5. The term "Virucidal" and the two viruses on the front panel must be keyed with an double "Asterisk" or some other symbol to denote the specific viruses that have been tested.

6. On the back panel, include a "Storage and Disposal" heading.

The additional brand name "TelAseptic Disinfecting Towelettes" is unacceptable. The term "Aseptic" associated with your brand name denotes application to the living body. Please note that all labeling bearing the brand name will be identical to the primary or basic labeling in all other respects.

A stamped copy of the labeling is enclosed for your records. Submit two (2) 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,

*Martha Swindell* / 703

Marshall Swindell  
Product Manager (33)  
Regulatory Management Branch 1  
Antimicrobial Division (7510W)

Enclosure

# Isotex 70 Disinfecting Towelettes

**Kills A Wide Range of Human Pathogens In One Minute\***

**Bactericidal ♦ Tuberculocidal ♦ Virucidal ♦ Fungicidal ♦ Herpeccidal**

Isotex 70 Disinfecting Towelettes are herbal scented, non-woven disposable towelettes impregnated with a dual chain quaternary ammonium/high level alcohol solution.

**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.

Isotex 70 Disinfecting Towelettes are effective against the following human pathogens when used as directed (see back panel):

- ♦ HIV-1 (AIDS virus)
- ♦ Methicillin Resistant Staphylococcus aureus (MRSA)
- ♦ Vancomycin Resistant Enterococcus faecalis (VRE)
- ♦ Staphylococcus aureus (Staph)
- ♦ Pseudomonas aeruginosa
- ♦ Salmonella choleraesuis
- ♦ Escherichia coli (E. coli)
- ♦ Adenovirus type 2
- ♦ Herpes Simplex Virus type 2 (genital herpes virus)
- ♦ Mycobacterium bovis (Tuberculosis bacteria) (5-minute contact time required)\*
- ♦ Trichophyton mentagrophytes (Athlete's Foot fungus)

## ACTIVE INGREDIENTS

n-alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chloride . . . . . 0.12%

n-alkyl (68% C12, 32% C14) dimethyl ethyl benzyl ammonium chloride . . . . . 0.12%

Isopropyl alcohol . . . . . 63.25%

**INERT INGREDIENTS** . . . . . **36.51%**

**TOTAL INGREDIENTS** . . . . . **100.00%**

Inert ingredients do not include towelettes

## WARNING

**KEEP OUT OF REACH  
OF CHILDREN**

See back panel for additional  
precautionary statements

EPA Reg. No. 10492-4  
EPA Est. No. 56952-AR-01

## Isotex 70 Disinfecting Towelettes

meet the disinfection requirements of  
OSHA's Bloodborne Pathogen Standard (29 CFR §1910.1030).

## NET CONTENTS:

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

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

10492-4

(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 and discard seal. 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 surface with another towelette and allow to remain wet for 1 minute. When used as a tuberculocidal disinfectant, allow the surface to remain wet for 5 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 and non-food contact surfaces. Use on stainless steel, glass, formica and other similar surfaces. Use care when using on varnished surfaces, plexi-glass or leather.

DO NOT USE AS A BABY WIPE. 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 this disinfecting towelette, 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 this 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 air dry. The efficacy of a 1 minute contact time has been shown to be adequate against HIV-1 (AIDS virus).

**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.

For technical information on this and other fine PHC spray disinfectants, antimicrobial hand asepsis products and other infection control products, call 1-800-344-6424 or fax 203-377-8938.

PALMERO HEALTH CARE, 120 GOODWIN PLACE, STRATFORD, CT 06497

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