

1 PML 34

46851-10

9-23-98

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U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (H7505C)
401 "M" St., S.W.
Washington, D.C. 20460

EPA Reg. Number:

46851-10

Date of Issuance:

SEP 23 1998

NOTICE OF PESTICIDE:
 X Registration
 Reregistration

Term of Issuance: **Until Reregistration**

Name of Pesticide Product:

ProSpray™ Wipe, Disinfectant Toweletts

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Cottrett, LTD.
7399 South Tucson Way
Englewood, CO 80112

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistration under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data or other material required for registration/reregistration of your product under FIFRA sec. 3(c)(5) or FIFRA sec. 4 when the Agency requires all registrants of similar products to submit such data.

2. Make the labeling changes listed below before you release the product for shipment:

Signature of Approving Official:

Adam Heyward, Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510W)

Date:

SEP 23 1998

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- a. Add the phrase, "EPA Registration No. 46851-10".
- b. Revise the Herpes virus types 1 & 2, to read "Herpes simplex virus type 1 and type 2."

3. Submit five (5) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for a further description of final printed labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

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

Sincerely,



Adam Heyward
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510W)

Enclosure

ACCEPTED
with COMMENTS
in EPA Letter Dated:

SEP 23 1998

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

46851-10 COTTRELL

ProSpray wipe™

Disinfectant Towelettes

Tuberculocidal, Virucidal,
Bactericidal, Fungicidal

Active Ingredients	
o-phenylphenol	0.28%
o-benzyl-p-chlorophenol	0.03%
Inert Ingredients	99.69%
Total	100.00%

60 Pre-moisten Towelettes
10 x 11.75 in. (25.4 x 29.85 cm)
Packet Net Contents:
38.1 oz/1185 grams
Reorder No. PSWP60

See back for additional
precautionary statements

CAUTION: Keep Out of Reach of Children

PSWP60 FL01

A BISYNTHETIC PHENOL SOLUTION IMPREGNATED IN A PATENTED* UNIFORM RELEASE TOWELETTE

ProSprayWipes™, Disinfectant Towelettes are intended for use in hospitals, medical, dental and veterinary offices, laboratories, industrial clean rooms, nursing homes, ambulances, police, hotels, schools, homes, health spas, boats autos, and toilet seats. Use on inanimate surfaces and equipment such as stainless steel, formica, glass tables, carts, baskets, counters, cabinets, telephones and other hard non-porous surfaces.

Preparation of Dispenser: Lift up tab and pull back to expose the entire opening. Do not Remove Peel & Seal Tab. Grasp exposed edge of towelette and pull out. Close Peel & Seal tab to prevent evaporation, by returning it to its original position and press down firmly.

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING.

DIRECTIONS FOR USE: Remove one ProSprayWipes, Disinfectant Towelette, unfold, wipe surface to remove gross filth. Use a second towelette to thoroughly wet surface. Ensure surface remains wet for 10 minutes to destroy or inactivate bacteria including *Escherichia Coli 0113*, *Staphylococcus aureus*, *Salmonella typhosa*, *Pseudomonas aeruginosa*, *Mycobacterium tuberculosis*, fungi including *Trichophyton mentagrophytes*; and the following viruses* Polio virus 1, Herpes virus types 1 & 2, Vaccinia virus, Influenza virus types A 1 (New Jersey) and Influenza B (Maryland).

This product is not to 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 blood stream or normally sterile areas of the body, (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise 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.

*KILLS HIV 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 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).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 OF SURFACES OR OBJECTS SOILED WITH BLOOD OR BODY FLUIDS.

- **PERSONAL PROTECTION:** When handling items soiled with blood or body fluids or when conducting procedures which might lead to contact with blood or body fluids always wear items such as heavy-duty Nitrile gloves, gowns, masks, and eye coverings.
- **CLEANING PROCEDURES:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects prior to disinfection. Apply ProSprayWipes, Disinfectant Towelette directly to the surface to be cleaned and then discard.
- **DISPOSAL OF INFECTIOUS MATERIAL:** Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

PRECAUTIONARY STATEMENTS:

- **CAUTION:** Avoid contact with eyes and clothing. Protective gloves should be worn.
- **STATEMENT OF PRACTICAL TREATMENT:** If in eyes - flush with plenty of water. Seek medical attention if irritation persists.
- **STORAGE AND DISPOSAL:** Store at room temperature. Do not reuse towelettes. Dispose of used towelettes and empty packets in regular trash.

* U.S. Patent No. 4,775,582

EPA Reg. No. 46851-
EPA Est. No. 46851-CO-3

MANUFACTURED BY:
COTTRELL, LTD.
7399 South Tucson Way
P.O. Box 112, CO. #0112 USA
1 800 THE EDGE



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