

FEB 07 2002

M & S Research
11500 W. Hill Drive
Rockville, MD 20852

AGENT: Kyle H. Sibinovic
Shaldra, Inc.
4327 Reels Mill Road
Frederick, MD 21704-7759

Subject: KWIKKILL
EPA Registration No. 59894-10
Amendment Dated October 3, 2001

The amendment, submitted in connection with registration under the FIFRA sec. 3(c)(7)(A), to add the HIV (AIDS Virus) and Mycobacterium tuberculosis claims to the label, is acceptable, provided that you:

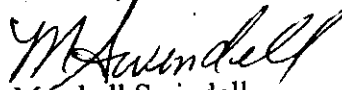
1. Submit and/or cite all data required for registration/ reregistration of your product under FIFRA sec. 3(c)(5) and sec. 4 when the Agency requires all registrants of similar product to submit such data.
2. Submit five (5) copies of final printed labeling before you release the product for shipment.

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.

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

Sincerely,



Marshall Swindell
Product Manager 33

CONCURRENCES Regulatory Management Branch 1

SYMBOL					Antimicrobial Division (7510C)		
SURNAME							
DATE							

DRAFT LABEL

KWIKKILL DISINFECTANT DEODORIZING WIPES

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ACCEPTED
with COMMENTS
in EPA Letter Dated:

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KWIKKILL

DISINFECTING / DEODORIZING/CLEANING WIPES FOR USE ON ENVIRONMENTAL SURFACES

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

59894-10

A non-woven disposable cloth containing a stable, low pH formulated disinfectant and deodorant for use on hard, non-porous surfaces, in hospitals, intensive care units, surgery, recovery, anesthesia, X-ray, Cat. Lab., orthopedics, newborn nursery, respiratory therapy, emergency medical settings, day care, schools, school buses, laboratories, clinics, nursing facilities, medical offices, dental offices, veterinary facilities, janitorial, commercial, industrial facilities, spas and health clubs where control of cross-contamination is required. For use on hard non-porous surfaces only, such as stainless steel, Formica, glass tables, carts, baskets, counters, cabinets, telephones.

ACTIVE INGREDIENTS		
Virucidal*	N-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) Dimethyl Benzyl Ammonium Chloride	0.12%
Bactericidal	N-Alkyl (68% C12, 32% C14) Dimethyl Ethyl Benzyl Ammonium Chloride	0.12%
Pseudomonocidal Tuberculocidal	Isopropyl Alcohol	41.58%
Fungicidal	Inert Ingredients+	<u>58.18%</u>
TOTAL		100.00%

+Does not include weight of dry wipe.

Contents: 160 Presaturated Wipes (6 x 6.75 in.)

KEEP OUT OF REACH OF CHILDREN

CAUTION

DO NOT USE AS A BABY WIPE

See side panel for additional precautionary statements.

PREPARATION OF DISPENSER: Remove cover from canister and discard covering seal. From center of wipes roll, pull up a wipe corner, twist into a point and thread through the X hole in the underside of the lid cover. Pull wipe through about one (1) inch. Replace the lid cover on container, assuring a secure fit. Pull out first wipe and snap at a 90° angle. Remaining wipes feed automatically for next use. Always reseal hinged cap after each use to insure moisture retention.

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 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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

Manufactured by: Multi Pack
5700 W. Hemlock
Milwaukee, WI 53223

For: M & S Research, Inc.
11500 W. Hill Dr.
Rockville, MD 20852

EPA Reg. No. 59894-10

EPA Est. No. 73027-WI-01

DIRECTIONS FOR USE:

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

DISINFECTION: Thoroughly wet pre-cleaned, hard, non-porous surface with a wipe, keep wet for 5 minutes, and allow to air dry. For use as a general disinfectant wipe on hard, non-porous, inanimate surfaces such as chairs, baskets, counter tops, exam tables, cages, toilets, basins, tubs, bed springs, frames, bedside and office furniture, chart racks and equipment, cabinets, door knobs, office machinery, sinks, mirrors, light fixtures and switches, supply, dressing, and trash carts, telephones, waste cans and laundry hampers, wheel chairs, and walkers, urinals, plastic and other similar hard surfaces. You may use a wipe to pre-clean the surface to be disinfected, but thorough rewiping with a fresh wipe is required for disinfection. Not to be used on food contact surfaces.

Kwikkill Disinfecting / Deodorizing/Cleaning Wipes are effective against the following pathogens in 5 minutes at 20°C/68°F, on hard, non-porous surfaces when used as directed:

- | | |
|--|--|
| <i>Staphylococcus aureus</i> | <i>Trichophyton mentagrophytes</i> (Athlete's foot fungus) |
| <i>Pseudomonas aeruginosa</i> | <i>Mycobacterium tuberculosis</i> |
| <i>Salmonella choleraesuis</i> | Methicillin Resistant <i>Staphylococcus aureus</i> (MRSA) |
| <i>Escherichia coli</i> 0157:H7 | Vancomycin Resistant <i>Enterococcus faecalis</i> (VRE) |
| *Herpes simplex virus 2 (genital Herpes virus) | *HIV-1 (AIDS virus)**(At an exposure time of 1 min.) |
| *Influenza A (A ₂ Japan) | |
| **See panel for complete HIV-1 (AIDS virus) information. | |

DEODORIZING: Wipe hard, non-porous surface thoroughly to eliminate odors from bathrooms, industrial plant processes, fecal matter, urine, burns, smoke, mildew and mold, decay, stale air, tobacco, sickrooms and musty closets.

CLEANING: To clean surfaces, wipe thoroughly with a fresh wipe, which may be used to deodorize at the same time as cleaning. Use in bathrooms, industrial plants, kitchens (non-food use surfaces), sickrooms, musty closets and similar areas. When used to clean a hard non-porous surface prior to disinfection, a second wipe must be used for disinfection.

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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. Wear safety glasses and rubber gloves, as appropriate, when handling HIV-1 infected blood or body fluids. Avoid contamination of food.

FIRST AID:

If in eyes, hold eye open and rinse slowly and gently with water for at least 15 - 20 minutes. Remove contact lenses, if present, after first 5 minutes, then, continue rinsing eye. Call a poison control center or doctor for treatment advice. If on skin or clothing, Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 to 20 minutes. Call a poison control center or doctor for treatment advice. Wash contaminated clothing before reuse. **WASH THOROUGHLY AFTER HANDLING WIPES.**

STORAGE AND DISPOSAL:

Store in cool area. Keep away from heat or open flame. Do not reuse wipes. Dispose of used wipe and wrapped empty dispenser in trash.

THE ACTIVITY OF KWIKKILL DISINFECTING / DEODORIZING/CLEANING WIPES AGAINST THE HIV -1 (AIDS VIRUS):

Kwikkill Disinfecting/Deodorizing/Cleaning Wipes completely inactivate the HIV-1 (AIDS virus) on hard, non-porous surfaces when used at a contact time of 1 minute at room temperature (20-25°C). **Kwikkill Disinfecting/Deodorizing/Cleaning Wipes** kill HIV-1 on pre-cleaned environmental surfaces/objects soiled with blood/body fluids, 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).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

Personal Protection: Specific barrier protection items to be used when handling items soiled with blood or body fluids are disposable latex gloves, gowns, masks or eye coverings.

Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of **Kwikkill Disinfecting/Deodorizing/Cleaning Wipes**.

Contact Time: HIV-1 virus is inactivated in 1 minute.

Disposal of Infectious Materials: Materials that may contain blood or other body fluids should be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.

For product emergency, contact Chem-Tel at 1-800-377-8988. For technical information call 1-414-760-9000 or fax 1-414-760-9900

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