

59894-10

05/05/2010

1/4

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



Office of Pesticide Programs

MAY - 5 2010

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

Attention: Kyle H. Sibinovic, Ph.D., Agent

Subject: Kwikkill Disinfecting Deodorizing Cleaning Wipes
EPA Registration No. 59894-10
Amendment Dated November 3, 2009

The amendment, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, to correct exposure temperatures and to add efficacy claims, is acceptable, provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3©(5) and sec. 4 when the Agency requires all registrants of similar products to submit such data.
2. Submit two (2) 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 "accepted" product labeling is enclosed for your records. A copy of the Efficacy review is also enclosed for your files.

If you have any questions concerning this letter, please contact Karen Leavy-Munk at (703) 308-6237.

Sincerely

Marshall Swindell
Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510P)

Enclosures

All word(s), phrases, or symbols in { } and bolded are OPTIONAL

KWIKKILL

DISINFECTING / DEODORIZING/CLEANING WIPES FOR USE ON ENVIRONMENTAL SURFACES

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], [physician(s) office(s)], [exam room(s)], [dental offices], [veterinary facilities], [janitorial], [commercial], [industrial facilities], [salons], [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], [shears], [razors], [razor blades], [combs], [clippers], [clipper blades], [cutters], [cutter blades], [tanning beds (hard surfaces)], [wastebaskets].

	ACTIVE INGREDIENTS	
Virucidal*	N-Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈)	0.12%
	Dimethyl Benzyl Ammonium Chloride	
Bactericidal	N-Alkyl (68% C ₁₂ , 32% C ₁₄)	0.12%
	Dimethyl Ethyl Benzyl Ammonium Chloride	
Pseudomonicidal	Isopropyl Alcohol	41.58%
Tuberculocidal		
Fungicidal	Inert Ingredients+	58.18%
	TOTAL	100.00%

+Does not include weight of dry wipe.

ACCEPTED
with COMMENTS
EPA Letter Dated:
MAY 15 2010

Contents: [160 Presaturated Wipes (6 x 6.75 in.)
[XXX Presaturated wipes (X x X in)]
Net Weight: XX lb. X oz.

Under the Federal Insecticide,
Fungicide and Rodenticide Act as
registered for the pesticide,
registered under EPA Reg. No. 59894-10

KEEP OUT OF REACH OF CHILDREN WARNING

DO NOT USE AS A BABY WIPE

See [side], [rear] , [back], [attached] [panel] [label] 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. This product is not for use on the inhalation therapy and/or pulmonary diagnostic equipment.

Manufactured} {Sold} {Distributed} {in the U.S.A.} {by} {for}
[MultiPack,LLC]
8372 N. Steven Rd.]
Milwaukee, WI 53223]

[M & S Research, Inc.]
[11500 W. Hill Dr.]
[Rockville, MD 20852]

EPA Reg. No. 59894-10 -{XXXXX}

EPA Est. No. 73027-WI-[01]

3/4

All word(s), phrases, or symbols in { } and bolded are OPTIONAL

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 2 minutes at 20°C to 22°C, on hard, non-porous surfaces when used as directed:

Staphylococcus aureus	Pseudomonas aeruginosa	Salmonella enterica
Escherichia coli 0157:H7	Herpes simplex virus 2 (genital Herpes virus)	Influenza A (A2 Japan)
Mycobacterium tuberculosis	Human Hepatitis B Virus	Human Hepatitis C Virus
Methicillin Resistant Staphylococcus aureus (MRSA)	Vancomycin Resistant Enterococcus faecalis (VRE)	
{HIV-1 (AIDS virus)**(at an exposure time of 1 min) **See panel for complete HIV-1 (AIDS virus) information}		

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:

Trichophyton mentagrophytes (Athlete's foot fungus)

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.

{ Box borders optional }

PRECAUTIONARY STATEMENTS:

Hazards to Humans and Domestic Animals

WARNING: Causes substantial, but temporary eye injury. Do not get in eyes or on clothing. Wear (specific appropriate protective eyewear such as goggles, face shield or safety glasses) Wash thoroughly with soap and water after handling and before eating drinking chewing gum, or using tobacco. 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. Remove and wash contaminated clothing before reuse.

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.

ACCEPTED
with COMMENTS
EPA Master Label Dated:

MAY 15 2010

4/4

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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 and 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, *however, other pathogens require 5 minutes exposure for complete kill. See disinfection directions.*

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

{For an MSDS, call XXXXXXXXXXXX or visit www.xxxxxxxxxx.com and request document XXXXX.}

U.S. Patent #xxxxxxxxxxxxxxxx / Additional Patent Pending

{ } HIV notations may be removed from label only if all references to HIV efficacy are removed as well.

{Optional Marketing claims:

- Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by influenza A virus. This product (Kwikkill Disinfecting/Deodorizing/Cleaning) is a broad-spectrum hard surface disinfectant that has been shown to be effective against (influenza A virus tested and listed on label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- This product has demonstrated effectiveness against influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus.
- This product has demonstrated effectiveness against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu).
- Kills Pandemic 2009 H1N1 influenza A virus.

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(Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 59894-10