

59894-10

09/10/2010

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

SEP 10 2010



Office of Pesticide Programs

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 September 3, 2010

The amendment, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, with the correct wording and correct time frames to the product labeling, is acceptable.

A stamped copy of the "accepted" product labeling is enclosed for your records.

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

Sincerely

A handwritten signature in black ink that reads "M Swindell".

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

Enclosure

EPA Reg. No. 59894-10
KWIKKILL DISINFECTANT/DEODORIZING/CLEANING WIPES
All word(s), phrases, or symbols in [] and bolded are OPTIONAL

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Front panel required statements:

KWIKKILL

DISINFECTING / DEODORIZING/CLEANING WIPES

FOR USE ON ENVIRONMENTAL SURFACES

	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 Fungicidal	Isopropyl Alcohol	41.58%
	OTHER INGREDIENTS+:	<u>58.18%</u>
	TOTAL	100.00%
	+Does not include weight of dry wipe.	

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.

Contents: [160 Presaturated Wipes (6 x 6.75 in.)]
[XXX Presaturated wipes (X x X in.)]

Net Weight: X lb. X ounces

ACCEPTED
with **COMMENTS**
EPA Letter Dated:

SEP 10 2010

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

EPA Reg. No. 59894-10
KWIKKILL DISINFECTANT/DEODORIZING/CLEANING WIPES
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Kwikkill Disinfecting/Deodorizing/Cleaning Wipes are effective against the following pathogens in 2 [two] minutes at 20°C/68°F, on hard, non-porous surfaces when used as directed:

- | | |
|---|--|
| <i>Staphylococcus aureus</i> | <i>Human Hepatitis B virus</i> |
| <i>Pseudomonas aeruginosa</i> | <i>Human Hepatitis C virus</i> |
| <i>Salmonella enterica</i> | * <i>Herpes Simplex virus 2 (genital herpes virus)</i> |
| <i>Escherichia coli</i> O157:H7 | * <i>Influenza A (A2 Japan)</i> |
| <i>Mycobacterium tuberculosis</i> | {* <i>HIV-1 (AIDS virus)**</i> (At an exposure time of 1 min.) |
| Methicillin Resistant <i>Staphylococcus aureus</i> (MRSA) | **See panel for complete HIV-1 (AIDS virus) information.} |
| Vancomycin Resistant <i>Enterococcus faecalis</i> (VRE) | |

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

Trichophyton mentagrophytes (Athlete's foot fungus)

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 [orifice] [tear throat] 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.

DIRECTIONS FOR USE:

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

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 pre-clean 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.

DISINFECTION: Thoroughly wet pre-cleaned, hard, non-porous surface with a wipe, keep wet for 2 minutes (5 minutes if fungus is suspected), and allow to air dry. Use as many wipes as needed for the treated surface to remain wet for the entire contact time. For use as a general disinfectant wipe on hard, non-porous, inanimate surfaces [such as see list of possible surfaces, page 5]. You may use a wipe to pre-clean the surface to be disinfected, but thorough re-wiping with a fresh wipe is required for disinfection. Use on food contact surfaces, must be followed by a potable water rinse.

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 [see list of possible site, page 5.] and [similar areas]. When used to clean a hard non-porous surface prior to disinfection, a second wipe must be used for disinfection.

ACCEPTED
with COMMENTS
EPA Letter Dated:

SEP 10 2010

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

EPA Reg. No. 59894-10

EPA MASTER LABEL

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KWIKKILL DISINFECTANT/DEODORIZING/CLEANING WIPES

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All word(s), phrases, or symbols in [] and bolded are OPTIONAL

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

(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.

Note to reviewer: Box borders optional

STORAGE AND DISPOSAL:

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

Container Disposal:

[Re-fillable container.] Refill this container with Kwikkill Disinfecting /Deodorizing/Cleaning Wipes only. Do not reuse this container for any other purpose. Cleaning of the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. Container should be cleaned, triple rinsed and dried prior to refilling.

or

[Non-refillable container:]

Non-refillable container. Do not reuse or refill this container. Offer for recycling if available.

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. Wear disposable latex gloves, gowns, masks and eye coverings, 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.**

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

EPA Reg. No. 59894-10 EPA MASTER LABEL
 KWIKKILL DISINFECTANT/DEODORIZING/CLEANING WIPES
 All word(s), phrases, or symbols in [] and bolded are OPTIONAL

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[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]

[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 XXXXXXXXXX or visit www.xxxxxxxx.com and request document XXXXX.]

U.S. Patent #4983635 / Additional Patent Pending

Lot Number [Date code]:

ACCEPTED
 with COMMENTS
 EPA Letter Dated:

Please note: The following are optional marketing text

SEP 10 2010

Optional Marketing claims:

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

- [Disinfectant
- Disinfecting
- Deodorizing
- Cleaning
- Wipes
- A non-woven disposable cloth containing a stable, low pH formulated disinfectant and deodorant for use on hard, non-porous surfaces, [see list of use sites], [where control of cross-contamination is required].
- For use on hard non-porous surfaces only, [such as [see list of use areas]]
- 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.
- Kills:

- Staphylococcus aureus* [ATCC 6538]
- Pseudomonas aeruginosa* [ATCC 15442]
- Salmonella enterica* [ATCC 10708]
- Escherichia coli* O157:H7 [ATCC 35150]
- Mycobacterium tuberculosis*
- Methicillin Resistant *Staphylococcus aureus* (MRSA) [ATCC 33591]
- Vancomycin Resistant *Enterococcus faecalis* (VRE) [ATCC 51299]
- Human Hepatitis B virus
- Human Hepatitis C virus
- Herpes Simplex virus 2 (genital herpes virus) [ATCC VR-734]
- Influenza A (A? Japan) [(Strain A/PR/8/34 H1N1)]

EPA Reg. No. 59894-10
KWIKKILL DISINFECTANT/DEODORIZING/CLEANING WIPES
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Note to reviewer: the following are optional marketing text

Areas of use:

[For use in:

hospital
medical offices
dental offices
clinics
physician offices
health care
ambulances
patient rooms
recovery
X-ray
Cat. Lab
anesthesia
surgery
exam rooms
laboratories

emergency medical settings
emergency medical services
emergency rooms
intensive care units
newborn nursery
sickrooms
orthopedics
nursing facilities
respiratory therapy
bathrooms
rusty closets
janitorial
where control of cross-contamination is required
kitchens
or other similar areas

veterinary facilities
commercial
industrial plants
industrial facilities
salons
spas
health clubs
schools
school buses
day care

**ACCEPTED
with COMMENTS
EPA Letter Dated:**

Types of surfaces:

For use on hard non-porous surfaces only, such as

stainless steel
Formica
plastic
glass
glass tables
supplies
equipment
carts
chart racks
exam tables
bedside
bed springs
frames
wheel chairs
walkers
counter tops
counters
cabinets
operating room hard surfaces
ambulance equipment and surfaces

chairs
tubs
sinks
toilets
urinals
basins
laundry hampers
telephones
baskets
wastebaskets
Waste cans
trash carts
light fixtures
switches
door knobs
mirrors
cages
other similar hard surfaces

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.
razors
razor blades
combs
shears
clipper blades
clippers
cutters
cutter blades
tanning beds (hard surfaces)
office furniture
office machinery

[Can be used for] external surface disinfection and/or anesthetic equipment]

**ACCEPTED
with COMMENTS
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. 59894-10

The following labeling is for the Pouch Refill

ACCEPTED
with COMMENTS
EPA Letter Dated:
SEP 10 2010

Pouch Refill

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

ACTIVE INGREDIENTS:	
N-Alkyl (60% C14, 30% C16, 5% C12, 5% C18)	0.12%
Dimethyl Benzyl Ammonium Chloride	
N-Alkyl (68% C12, 32% C14)	0.12%
Dimethyl Ethyl Benzyl Ammonium Chloride	
Isopropyl Alcohol	41.58%
INERT INGREDIENTS+:	<u>58.18%</u>
TOTAL	100.00%

+Does not include weight of dry wipe.

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.

Contents: [160 Presaturated Wipes (6 x 6.75 in.)
[XXX Presaturated wipes (X x X in.)]

Net Weight: X lb. X ounces

DIRECTIONS FOR USE:

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

For refill into Kwikkil Disinfecting/Deodorizing/Cleaning Wipes container only. See outside of this product for complete Directions For Use and Precautions.

DIRECTIONS FOR USE:

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

Cut open pouch at indicator line. Place open pouch into Kwikkil Disinfecting/Deodorizing/Cleaning Wipes container. From center of wipes roll, pull up a wipe corner, twist into a point and thread through the X hole [orifice] [tear throat] 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.

STORAGE AND DISPOSAL:

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

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. 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.**

[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

[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 XXXXXXXXXX or visit www.xxxxxxxx.com and request document XXXXX.]

[U.S. Patent #4983635 / Additional Patent Pending]

Lot Number [Date Code]:

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