

59894-10

8/26/2008

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

AUG 26 2008

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Dr. Kyle Sibinovic
Regulatory Agent for,
M & S Research, Inc.
11500 W. Hill Road
Rockville, MD 20852

Subject: Kwikkil Disinfectant Deodorizing Cleaning Wipes
EPA Registration Number 59894-10
Your Amendment Dated April 7th, 2008
EPA Received Date April 9th, 2008

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended, to reduce the exposure time for Mycobacterium tuberculosis and add claims for effectiveness as a disinfectant against hepatitis B virus and Hepatitis C virus, is acceptable.

The efficacy data support the use of the product, KWIKKILL Disinfecting/ Deodorizing/ Cleaning Wipes as a disinfectant against Mycobacterium bovis BCG on hard, non-porous surfaces in the presence of a 5% organic soil load for a contact time of 2 minutes at 22 degrees Celsius. Please note that the basic efficacy testing was conducted at a temperature of 22 degrees Celsius, not the labeling specified 20 degrees Celsius.

The proposed label claims that the product, is an effective disinfectant on pre-cleaned, hard, non-porous surfaces against Human hepatitis B virus and hepatitis C virus at 20 degrees Celsius with at 2- minute contact time. These claims are acceptable as they are supported by the submitted data; however, the label-specified temperature of 20 degrees Celsius must be revised to read 24-25 degrees Celsius.

The submitted efficacy data support the use of the product, as a disinfectant with virucidal activity against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load with a contact time of 2 minutes:

- Bovine viral diarrhea virus(a surrogate for Hepatitis C virus)
- Duck hepatitis B virus (a surrogate for Human hepatitis B virus)

Recoverable virus titers of at least 10⁴ were achieved. Complete inactivation (no growth) was indicated in all dilutions tested. The confirmatory studies used one lot of the product, not the standard two.

Please note that the basic efficacy testing was conducted at temperatures of 24-25 degrees Celsius, not the labeling specified 20 degrees Celsius.

The proposed label claims that the product is an effective disinfectant on pre-cleaned, hard, non-porous, surfaces against Human hepatitis B virus and hepatitis C virus at 20 degrees Celsius with a 2 minute contact time. These claims are acceptable as they are supported by the submitted data; however, the label-specified temperature of 20 degrees Celsius must be revised to read 24-25 Celsius.

The proposed label (page 2) has changed "Salmonella choleraesuis" to read "Salmonella enterica". This change is acceptable, as ATCC's nomenclature for this organism has been changed to S. enterica.

The proposed label refers to use of the product to disinfect "equipment" in hospital environments (i.e., unidentified medical equipment). In accordance with DIS/TSS-6 guidelines, the proposed label must be revised to include the following statement: "This product is not for use on the inhalation therapy and/or pulmonary diagnostic equipment."

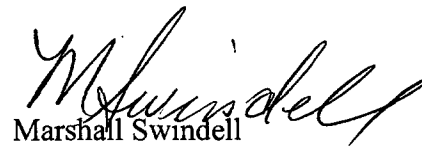
The following changes are required on the proposed label:

- On page 2 of the proposed label under the Disinfection section, change "inanimate surfaces" to read "inanimate surfaces."
- On page 2 of the proposed label under the Cleaning section, change "When used to clean a had non-porous surface" to read "When used to clean a hard non-porous surface."

A stamped label is enclosed for your records.

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

Sincerely,



Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobial Division(7510C)

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], [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], [clipper blades], [tanning beds (hard 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	Isopropyl Alcohol	41.58%
Fungicidal	Inert Ingredients+	58.18%
	TOTAL	100.00%

+Does not include weight of dry wipe.

ACCEPTED
with COMMENTS
in EPA Letter Dated:
AUG 26 2008

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

KEEP OUT OF REACH OF CHILDREN

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

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.

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]

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/68°F, on hard, non-porous surfaces when used as directed:
Mycobacterium tuberculosis Human Hepatitis B Virus Hepatitis C Virus

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> | Methicillin Resistant <i>Staphylococcus aureus</i> (MRSA) |
| <i>Salmonella choleraesuis</i> | Vancomycin Resistant <i>Enterococcus faecalis</i> (VRE) |
| <i>Escherichia coli</i> 0157:H7 | *Influenza A (A ₂ Japan) |
| *Herpes simplex virus 2 (genital Herpes virus) | {*HIV-1 (AIDS virus)**(At an exposure time of 1 min.) |
| **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 had non-porous surface prior to disinfection, a second wipe must be used for disinfection.

ACCEPTED
with COMMENTS
 to EPA Letter Dated:
AUG 26 2008
 Under the Federal Insecticide,
 Fungicide, and Rodenticide Act as
 amended, for the pesticide,
 registered under EPA Reg. No.
 59894-10

5/5

ACCEPTED
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EPA MASTER LABEL

KWIKKILL DISINFECTING/DEODORIZING/CLEANING WIPES

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{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.

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

59894-10

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, *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 XXXXXXXXXX or visit www.xxxxxxxx.com and request document XXXXX.}

U.S. Patent #xxxxxxxxxxxxxx / Additional Patent Pending

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