

59894-10

01/07/2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

JAN - 7 2010

Dr. S. Kyle H. Sibinovic, PhD
Agent for,
c/o M & S Research, Inc.
11500 West Hill Road
Rockville, MD 20852

Subject: Kwikkill Disinfectant Deodorizing Cleaning Wipes
EPA Registration Number 59894-10
Your Notification Dated November 10th, 2009
EPA Received Date December 8th, 2009

The notification referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended, to add H1N1 Influenza A virus to the product labeling, is acceptable.

The notification has been made part of the file.

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

Sincerely,

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



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 59894-10	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Kwikkill Disinfectant Deodorizing Cleaning Wipes	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) Dr. Kyle Sabinovic c/o M & S Research, Inc. 11500 W. Hill Road Rockville, MD 20852 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This notification is consistent with the provisions of PR Notice 95-2 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 95-2 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

NOTIFICATION of addition of H1N1 claims per Guidance for Testing and Labeling Claims against Pandemic 2009 H1N1 Influenza A Virus per PR Notice 95-2. shaldra@verizon.net; fax 401/ 834-3006

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No			
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> on label	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Dr. Kyle Sabinovic	Title Authorized Agent	Telephone No. (Include Area Code) (240) 308-0273

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received
(Stamped)

Signature 	3. Title Authorized Agent
Typed Name Dr. Kyle H Sabinovic, PhD	5. Date 11/10/2009

SarahKyle H Sibinovic, PhD
Shaldra

4004 Petersville Rd – Knoxville, MD 21758-9205
Ph: 301-834-3555 Fax: 401-834-3006 CP: 240-308-0273
Email: shaldra@verizon.net

November 10, 2009

Document Processing Desk (NOTIF-H1N1)
Registration Division
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

5-11-09

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ATTN: Marshall Swindell
Product Manager 33
Insecticide Branch

SUBJECT: APPLICATION FOR PESTICIDE LABEL NOTIFICATION
Submission of Revised Labeling Per:
Guidance for Testing and Labeling Claims Against Pandemic 2009
H1N1 Influenza a Virus (Formerly called Swine Flu)
Kwikkill Disinfectant Deodorizing Cleaning Wipes; EPA Reg. No. 59894-10

Dear Mr. Swindell:

This application for label notification for the above subject product is being submitted to comply with the Agency's letter of October 21, 2009 Guidance for Testing and Labeling Claims against Pandemic 2009 H1N1 Influenza a Virus (Formerly called Swine Flu).

M & S Research, recently re-submitted a label amendment to the Agency (Nov. 2, 2009) for additional efficacy claims based on review of data submitted. The labeling submitted with this notification dated November 10, 2009 is not to supersede the efficacy submission of November 2, 2009.

Two (2) copies of revised draft labeling with changes clearly marked are enclosed. Additions are noted in underlined, highlighted italics. Deletions (if any) are shown struck through.

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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	
Pseudomonocidal	Isopropyl Alcohol	41.58%
Tuberculocidal		
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.)
[XXX Presaturated wipes (X x X in.)]
Net Weight: XX lb. X oz.

**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}

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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 24-25°C, 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 enterica</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 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.

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

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 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 XXXXXXXXXX or visit www.xxxxxxxx.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.