

75459-1

1/13/2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Mr. J. Michael Kelley, Ph.D.
Consultant for Albaad
toXel, LLC
7140 Heritage Village Plaza
Gainesville, VA 20156

JAN 13 2010

Subject: Antibacterial Wipe
EPA Registration No. 75459-1
Amendment Date: August 27, 2009
EPA Receipt Date: August 27, 2009

Dear Mr. Kelley,

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), section 3(C)(7)(A) is acceptable with the conditions below.

Proposed Amendment

- Addition of microorganisms and marketing claims

Conditions

Revise the label as follows:

- 1.) Revise the following phrase by deleting all brackets as follows: "...including the Pandemic 2009 H1N1 Influenza A virus."
- 2.) Revise the directions for use to be in agreement with PR Notice 2000-5 and to provide additional clarification by stating:

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SYMBOL	7510P						
SURNAME	J. Kelly						
DATE	1/12/2010						

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- a. "...For surfaces that *come in contact with food as well as children's toys, rinse with potable water prior to reuse.*"
 - b. "...Always follow the manufacturer's use & care instructions for any item."
- 3.) As per 40 CFR 156.10 (6) (d) the weight of this product must be expressed in pounds and ounces. Add this information to the label following the statement regarding the size of the towelettes.

Data Matrix

The Agency has corrected the typographical error on your data matrix. On page five, the study in support of *S. enterica* is MRID # 47469703. Make the same correction to the matrix in your files.

Efficacy Data

The following data may be used to support this product. The review of this data is attached.

Data Requirement	Means of Support	Status
Virucidal Efficacy of pre-saturated wipes: Influenza A	Submitted study, MRID 478408-01	Acceptable, contact time of 5 minutes
Pre-Saturated Towelettes for disinfection – Methicillin Resistant <i>Staphylococcus aureus</i>	Submitted study, MRID 478408-02	Acceptable, contact time of 5 minutes

General Comments

A stamped copy of the accepted labeling with conditions is enclosed. Submit 1 copy of your final printed label before distributing or selling the product bearing the revised labeling.

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3 (c) (5) and section 4 (a) when the Agency requires all registrants of similar products to submit such data.

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If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6 (e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions. Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415 or Velma Noble at (703) 308-6233.

Sincerely,



Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510P)

7510P:T.Lantz:1/11/2010:75459-1 relying on new data

Enclosure: Stamped Label

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{All text in brackets [xxx] is optional & may or may not be included on a final label.}

[7" x 7.9" (178 mm X 200 mm)] or [6.9" x 7.9" (175 mm X 200 mm)]

Antibacterial Wipe (402962, modified 401253)

Disinfecting wipes for One Step Cleaning and Disinfecting

Lemon Fresh

Bleach Free

[Made with Bamboo]

Active Ingredients:

n-Alkyl (C14, 60%; C16, 30%; C12, 5%; C18, 5%) Dimethyl Benzyl Ammonium Chloride.....	0.5%
n-Alkyl (C12, 68%; C14, 32%) Dimethyl Ethylbenzyl Ammonium Chloride.....	0.5%
Other Ingredients.....	99.0%
Total.....	100.0%

Keep Out of Reach of Children

CAUTION

SEE BACK PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

One Step Cleaning and Disinfecting

This product [is effective against] [kills] Staphylococcus aureus [(ATCC 6538)], Pseudomonas aeruginosa [(ATCC 15442)], Salmonella enteric [(ATCC 10708)], Methicillin Resistant Staphylococcus aureus – MRSA [(ATCC 33592)], and Influenza A virus [(ATCC VR-544)], [including] [the Pandemic 2009][H1N1][Influenza A virus].

Disinfects Household kitchen and bathroom bacteria

Convenient and Quick way to clean and disinfect household hard non-porous surfaces

SUITABLE for use in KITCHENS on: counter tops, sinks, faucets, and exterior surfaces of refrigerators, stoves, and appliances

SUITABLE for use in BATHROOMS on: toilet seats and rims, tubs, showers, glazed tiled walls.

Other Uses: doorknobs, glazed tiled floors, children's toys, animal crates and cages.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read and follow all directions and precautions on this product label.

To Open Package: Open cap lid. Remove lid by pulling it up firmly. Insert a corner of a center wipe through the opening in the lid. Do not push finger through the opening. Replace lid and pull wipe out at an angle. Always close lid flap between uses to retain moisture.

To Disinfect: Use to disinfect hard, non-porous surfaces. Thoroughly wet surface using a fresh wipe, enough for the surface treated to remain visibly wet for 5 minutes. Let surface dry. For highly soiled surfaces, clean excess dirt first. For surfaces that may come in contact with food, rinse with potable water.

To Clean: Wipe surface clean.

Not for personal use. Do not use on untreated or painted wood. The cleaning performance of this product may not be optimal for some modern surfaces; streaking may occur. Please always follow the manufacturer's use & care instructions for any item.

EPA Reg. No. 75459-1

EPA Est. No. [82051-NC-001][75459-ISR-001]

AFG Wipes Inc.
129 Technology Drive
Reidsville, NC 27323

A Subsidiary of:

Albaad Massuot Yitzhak Ltd
Massuot Yitzhak, M.P.
Sde Gat 79858, Israel

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

PHYSICAL OR CHEMICAL HAZARDS

Do not apply this product around electrical devices or outlets

Combustible. Do not use or store near heat or open flame.

FIRST AID	
If on skin:	<ul style="list-style-type: none"> - Take off contaminated clothing. - Rinse skin immediately with plenty of water for 15-20 minutes. - Call a poison control center or doctor for further treatment advice.
If in eyes:	<ul style="list-style-type: none"> - Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, and then continue rinsing. - Call a poison control center or doctor for treatment advice.
If swallowed:	<ul style="list-style-type: none"> - Call a poison control center or doctor immediately for treatment advice. - Have person sip a glass of water if able to swallow. - Do not induce vomiting unless told to by a poison control center or doctor. - Do not give anything to an unconscious person.
-Have the product container or label with you when calling a poison control center or doctor or going for treatment. For emergencies, contact Chemtrec at 800-348-1811	

STORAGE AND DISPOSAL

Store product in original container in a cool, dry place. Keep containers tightly closed. Do not flush non-reusable container. Do not reuse or refill this container. Dispose of wipes with contents in the trash. Offer for recycling, if available.

ACCEPTED
with COMMENTS
in EPA Letter Dated:
JAN 13 2010

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 75459-1

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