



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 20155

JAN 10 2012

Subject: Antibacterial Wipe
EPA Registration No. 75459-1
Amendment Date: August 25, 2011
EPA Receipt Date: August 26, 2011

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
- Addition of marketing claims
- Revised Confidential Statements of Formula

Conditions

Revise the label as follows:

- 1) The following three bullets on page one must be clarified by adding the statement "when used as a non food contact sanitizer." Add this phrase to bullets 17, 19, 20. Since *Staphylococcus aureus* is the test organism for both non food contact sanitization and disinfection for clarity in your labeling it is important to include the contact time. The level of kill differs for the same organism under the two claims. A sanitizing claim accounts for the kill of approximately 1000 organisms in 45 seconds while the disinfection claim accounts for the kill of approximately 100,000 to 1,000,000 organisms in 5 minutes. This clarification is critical.

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

- 2) Correct the ATCC number for Respiratory syncytial virus to read VR-26.
- 3) Should you wish to retain a reference to the company's website on your label, (page 2) then please be aware that such a reference transforms the website into labeling under the Federal Insecticide Fungicide and Rodenticide Act sec 2 (p) (2) and then the website is subject to review by the Agency. If the website content is false or misleading, the product would be misbranded and its sale or distribution unlawful to sell or distribute under FIFRA section 12(a)(1)(E). In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Although EPA has not yet determined the extent to which it will routinely review company websites, if the Agency finds or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from claims approved through the registration process, the website may be referred to the EPA's Office of Enforcement and Compliance Assurance.

Chemistry Data

The submitted Basic and Alternate Confidential Statements of Formula (CSFs) dated 8/25/11 have been reviewed and found acceptable. Please note the comment in the attached review. These formulations will supersede all previously submitted CSFs.

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: Respiratory syncytial virus	Submitted study, MRID 485856-01	Acceptable, 5% soil load, contact time of 5 minutes
Non-Food contact sanitizer, Staphylococcus aureus, Enterobacter aerogenes	Submitted study, MRID 485856-02	Acceptable, 5% soil load, contact time of 45 seconds

Please be advised that although we are not requiring confirmatory data to support the change in formulation at this time, we will likely require this information for future amendments. In addition, be advised that we may require that this testing be done at the lower certified limit as specified on the Confidential Statement of Formulations.

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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.

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)

Enclosure: Stamped Label, DERs D393814 and D393849
7510P:T.Lantz:1/10/2012:75459-1 a relying on new data efficacy and chem

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{MASTER LABEL}

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

{All text in braces {xxx} is administrative communication & will not appear on a printed label.}

{XXXXX (capitalized) is a placeholder for web site names or alternate trade names for this product or associated non-pesticidal products and xxxxx (lower case) – indicate values/numbers}

Antibacterial Wipe (402962, modified 401253)

Disinfecting Wipes [for One Step Cleaning and Disinfecting]

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

ACCEPTED
with COMMENTS
Letter Dated:
JAN 10 2012
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide
registered under EPA Reg. No.

75459-1

{Optional Marketing Claims}

- Lemon Fresh
- Bleach Free
- Fabric made from Bamboo fiber
- One Step Cleaning and Disinfecting
- [Now] for use on Sealed Stone [and Glazed Ceramic] Surfaces
- Sealed Granite · Marble · Travertine · Limestone · Glazed Ceramic
- Disinfects without Damaging Sealed Stone Surfaces
- One Step Cleaning and Disinfecting
- XXXXX [Stone Care] products are designed by stone care experts with more than 40 years experience in the natural stone industry. This product is a convenient way to clean and disinfect sealed stone surfaces
- This product [is effective against] [kills] *Staphylococcus aureus* [(ATCC 6538)], including Methicillin Resistant *Staphylococcus aureus* (MRSA) [(ATCC 33592)], *Pseudomonas aeruginosa* [(ATCC 15442)], *Salmonella enterica* [(ATCC 10708)], and Influenza A virus [(ATCC VR-544)], including the Pandemic 2009 H1N1 Influenza A virus.
- Disinfects Household kitchen and bathroom bacteria
- Convenient way to clean and disinfect household hard non-porous surfaces
- Material Safety Data Sheets are available online at www.XXXXX.com
- QUESTIONS? COMMENTS? Call xxx-xxx-xxxx or visit www.XXXXX.com
- Made In the USA
- Use to sanitize hard non-porous non-food contact surfaces
- Kills 99.9% of Bacteria in (just) 45 seconds(!)**
- ***Staphylococcus aureus* (Staph), *Enterobacter aerogenes*
- Kills 99.9% of *Staphylococcus aureus* (Staph) (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048) in (just) 45 seconds (!)
- 99.9% effective in 45 seconds against *Staphylococcus aureus* (Staph) (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048)
- 99.9% effective in killing common (household) (kitchen) (bathroom) bacteria
- This product is effective against (kills) Respiratory syncytial virus (RSV virus) (ATCC VR-25)
- This product is virucidal in the presence of organic soil (5% blood serum) against Respiratory syncytial virus (RSV virus) at 5 minutes contact time.

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

SUITABLE for use in BATHROOMS on: sealed stone surfaces, counter tops, sinks, faucets, toilet seats and rims, tubs, showers, glazed tiled walls.

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

EPA Reg. No. 75459-1

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

Albaad USA
129 Technology Drive
Reidsville, NC 27323

A Subsidiary of:

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

[35 Wet Wipes]

[7" x 7.9" (178 mm X 200 mm)] [6.9" x 7.9" (175 mm X 200 mm)] [7" x 8"]

[Net Weight 0.46 lbs (7.3 oz)]

{MASTER LABEL}

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{XXXXX (capitalized) is a placeholder for web site names or alternate trade names for this product or associated non-pesticidal products and xxxxx (lower case) – indicate values/numbers}

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 Sanitize: Use to sanitize hard non-porous non-food contact surfaces [including sealed natural stone]. Thoroughly wet surface using a fresh wipe, enough for the surface treated to remain visibly wet for 45 seconds. Let surface dry. [the stone will have visible streaks]. For highly soiled surfaces, clean excess dirt [with XXXXX] first and rinse with potable water. [Use XXXXX for a streak free shine.] [Do not apply XXXXX until surface has been completely rinsed with potable water and cleaned with XXXXX or streaking may occur.]

To Disinfect: Use to disinfect hard, non-porous surfaces [including sealed natural stone]. Thoroughly wet surface using a fresh wipe, enough for the surface treated to remain visibly wet for 5 minutes. Let surface dry. [The stone will have visible streaks]. For highly soiled surfaces, clean excess dirt [with XXXXX] first. For [children's toys and] surfaces that come in contact with food, rinse with potable water prior to reuse. [Use XXXXX for a streak free shine.] [Do not apply XXXXX until surface has been completely rinsed with potable water and cleaned with XXXXX or streaking may occur.]

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. Always follow the manufacturer's use & care instructions for any item.

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, using tobacco, or using the toilet.

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.

{Note: Since the product is classified as tox category IV for Oral the "If Swallowed" statement is considered optional}

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.
[Contact Number:] -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. Nonrefillable container. Do not reuse or refill this container. Dispose of wipes and container in the trash. Offer for recycling, if available.