UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Mr. J. Michael Kelley, Ph.D. Authorized Representative for Albaad (*toXcel*, LLC) 7140 Heritage Village Plaza Gainesville, VA 20155-3061

JAN 15 2013

SUBJECT:

Antibacterial Wipe (402962, modified 401253)

EPA Registration Number: 75459-1 Application Dated: December 21, 2012 Receipt Date: December 21, 2013

Dear Mr. Kelley:

This letter acknowledges receipt of the notification identified above submitted under the provisions of section 3 (c) 9 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended and PR Notice 98-10 and 40 CFR 152.46.

- To add optional language for use on supplemental distributor labels.
- To add container sizes per request of supplemental distributors.
- To change the brand name "Antibacterial Wipe (402962, modified 401953)" to "Antibacterial Wipe".

Based on a review of the submitted information, this notification is acceptable. A copy has been inserted in your file for future reference.

General Comments

Should you have any questions concerning this letter, please contact Emilia Oiguenblik at (703) 347-0199 or Velma Noble at (703) 308-6233.

Sincerely,

Velma Noble

Product Manager (31)

Regulatory Management Branch I Antimicrobials Division (7510P)

				CONCURRENC	ES.			
YMBOL								
URNAME	0000000000000000			99999999999999	99998 # 1000000000000		000000000000000000000000000000000000000	
ATE	09000000000000	***************	4 4 4 4 6 7 4 6 4 6 6 6 6 6 6 6 6	~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~	######################################	000000000000000000000000000000000000000	000000000000000000	**************************************

Form Approved. UMB No. 2070-0060, Approval expires 05-31-9

SEPA		Environme Wa	United State	ection Ag		□ R	egistra mendn ther	tion	OPP Identifie	
			Applicat	tion for P	esticide – Se					
1. Company/Product Albaad N 4. Company/Product	assı	uot Yitzhak Lt	d. / 7545	9-1	2. EPA Product M Velm PM#	anager Ia Nob	le		3. Proposed Clas	ssification Restricted
Antibacterial	Wip	9			31					
Albaad Massu Sde G	d Ma uot Y at 79	plicant (Include ZIP C ssuot Yitzhak itzhak, M.P. 1858, Israel s a new address	•		6. Expedited R (b)(i), my producto: EPA Reg. No Product Name _	ct is simi	lar or ide	ntical in	composition ar	nd labeling
				Sec	ction II					
Amendment – E	n respo	nse to Agency letter d	ated		Final Printe Agency lett "Me Too" A Other – Ex	ter dated _c application	1.			
This notification is been made to the la to willfully make a	consistations consisted the consisted consiste	al page(s) if necessar stent with the provis g or the confidential se statement to EPA & 152.46, this produ of FIFRA.	sions of PR statement o I further u	Notice 98-2 of formula conderstand to a violation of	10 and EPA regul of this product. I u hat if this notifica of FIFRA and I m	inderstar	nd that it ot consis	is a viol tent wit	lation of 18 U.S h the terms of I	S.C. Sec. 1001 PR
				Sec	tion III				<u> </u>	
1. Material This Produ	uct Will	Be Packaged In:								
Child Resistant Packaging Yes* No No			□ Y			2. Type	e of Cont Metal Plasti Glass	l ic		
* Certification m be submitted	ust	If "Yes" Unit Packaging wgt. 3 -16 ounces	No. per Container 3 to 75 wipe			. per ntainer		Paper	r	Foil
3. Location of Net Co		nformation tainer		Retail Contair 75 wipes	per container	5.		n Label (Directions on silkscreened on silkscreened on grand or gr	
6. Manner in Which L	abel is <i>i</i>	Affixed to Product	Lithogra Paper (Stencil	glued ed		Other			9 9 9 9 9 9 9 9	
	*				tion IV				<u>ຸ້</u> ລັງລູງ	
1. Contact Point (Con	nplete it	ems directly below for	identification	of individual Title	to be contacted, if r	necessary	, to proces			Aron Code'
J. Michael Kelley, Ph.D.				Authorized Representative			i elebiid	phone No. փոշխմբ Area Code)		
I certify that	the sta	tements I have made any knowingly false o	Certification this form a r misleading	ation and all attach	ments thereto are tr	ue, accur	ate and co	ວກplete. nt or ວ່ວ	6. Dete Appli	cation
2. Signature	ηά	llan		Title Authorized Representative for Albaad (toXcel, LLC)) 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3	1
4. Typed Name J. Mich	ael K	Celley, Ph.D.		5. Date	December 21	l, 2012	2			•

toXcel

Toxicology & Regulatory Affairs 7140 Heritage Village Plaza Gainesville, VA 20155-3061

Phone: (703) 754-0248 Fax: (703) 310-6950

HAND DELIVERED

December 21, 2012

Velma Noble, PM-31
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U. S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

RF.

Label Notification for Albaad's Antibacterial Wipe;

EPA Reg. No. 75459-1

Dear Ms. Noble:

On behalf of Albaad Massuot Yitzhak Ltd. (Albaad), we are submitting this notification to add optional language to the master label of the above mentioned product for use on supplemental distributor labels. No other changes have been made to the product labeling.

Albaad's supplemental distributor will be marketing this product for use with their specific applicator. The optional statement "For use with XXXX and XXXX in accordance with manufacturer's instructions" will be used to specify the specific model of the applicator (see example graphic to be included on selected labels).

The container sizes on the 8570-1 form have also been revised to accommodate the supplemental distributor's packaging requirements.

Albaad would also like to take this opportunity to change the primary product name on file with the agency from "Antibacterial Wipe (402962, modified 401253)" to just "Antibacterial Wipe".

As required, one clean copy and a Microsoft Word track-changes copy of the label are enclosed. An electronic copy (CD) of the label is also being submitted in order to facilitate review.

If you have any questions or require additional information, please do not hesitate to contact me by email at mike.kelley@toxcel.com, or by phone at (703) 754-0248 ext. 112,

Sincerely,

J. Michael Kelley, Ph.D.

Authorized Representative for Albaad Massuot Yitzhak Ltd.

Enclosures

CC: M. Fitzgerald (Albaad)

{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.}

Xs (capitalized) are a placeholder for web site names or alternate trade names for this product and x's (lower case) indicate values/numbers; Ys (capitalized) are a placeholder for associated non-pesticidal products such as cleaners or application devices.}

Antibacterial Wipe

[Disinfecting] [Sanitizing] [Wipes] [for One Step Cleaning] [and Disinfecting]

Active Ingredients:

n-Alkyl (Č14, 60%; C16, 30%; C12, 5%; C18, 5%) Dimethyl Benzyl

NOTIFICATION IS NOTIFICATION I

Keep Out of Reach of Children CAUTION

SEE BACK PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

(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 <u>www.XXXXX.com</u>
- QUESTIONS? COMMENTS? Call xxx-xxx-xxxx or visit <u>www.XXXXX.com</u>
- Made In the USA
- Use to sanitize hard non-porous non-food contact surfaces
- Kills 99.9% of Bacteria in (just) 45 seconds(!)** when used as a non food contact sanitizer
- **Staphylococcus aureus (Staph), Enterobacter aerogenes
- Kills 99.9% of Staphylococcus aureus (Staph) (ATCC 6538) and Enterobacter aerogenes (ATCC 13048) in (just) 45 seconds (!) when used as a non food contact sanitizer
- 99.9% effective in 45 seconds against Staphylococcus aureus (Staph) (ATCC 6538) and Enterobacter aerogenes (ATCC 13048) when used as a non food contact sanitizer
- 99.9% effective in killing common (household) (kitchen) (bathroom) bacteria
- This product is effective against (kills) Respiratory syncytial virus (RSV virus) (ATCC VR-26)
- This product is virucidal in the presence of organic soil (5% blood serum) against Respiratory syncytial virus (RSV virus) at 5 minutes contact time.
- To purchase more XXXXX wipes please go to www.XXXXX.com

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

{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.}

{Xs (capitalized) are a placeholder for web site names or alternate trade names for this product and x's (lower case) indicate values/numbers; Ys (capitalized) are a placeholder for associated non-pesticidal products such as cleaners or application devices.}

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.

[For use with YYYYY in accordance with manufacturer's instructions.]

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 YYYYY] first and rinse with potable water. [Use YYYYY for a streak fee shine.] [Do not apply XXXXX until surface has been completely rinsed with potable water and cleaned with YYYYY 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 YYYYY] first. For [children's toys and] surfaces that come in contact with food, rinse with potable water prior to reuse. [Use YYYYY for a streak fee shine.] [Do not apply XXXXX until surface has been completely rinsed with potable water and cleaned with YYYYY or streaking may occur.]

To Clean: Wipe surface clean.

Not for personal use. [Test on an inconspicuous area before 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.

Octo Reviewed: (Note: Since the product is classified as tox category IV for Oral the "If Swallowed" statement is considered optional)

	FIRST AID
If on skin:	 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:	 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:	 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

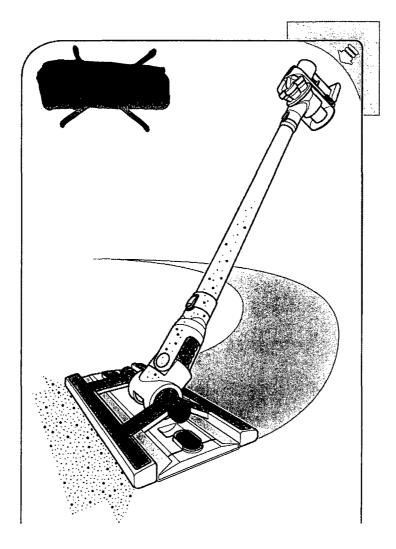
STORAGE AND DISPOSAL

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.

{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.}
{Xs (capitalized) are a placeholder for web site names or alternate trade names for this product and x's (lower case) indicate values/numbers; Ys (capitalized) are a placeholder for associated non-pesticidal products such as cleaners or application devices.}

{Optional Graphic}



NOTIFICATION Date Reviewed: SAMERIED BY -