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





OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

September 15, 2008

Mr. Patrick Rego, Director of Technical Services & Regulatory Affairs Athea Laboratories, Inc. PO. Box 240014
Milwaukee, WI 53224

Subject: Amended Reregistration Label For: Insect Repellent Towel. **EPA Registration No.** 10088-97

Dear Mr. Padovani;

The Agency in accordance with the Federal Fungicide and Rodenticide Act as Amended (FIFRA) has completed reviewing all of the information submitted with your application to support the reregistration of the aforementioned product in connection the MGK 326 RED, and has concluded that your submission is acceptable with the following label revision provisions:

Page 1:

- 1. Within the ingredient statement, revise the statement "Inert Ingredients" to "Other Ingredients"
- 2. Per the Acute Toxicology review, revise in all locations, the signal word from CAUTION to "WARNING".
- 3. Remove the box from the section titled "Precautionary Statements"
- 4. Revise the statements within the section entitled "HAZARDS TO HUMANS AND DOMESTIC ANIMALS" as follows:
 - "WARNING: Causes substantial but temporary eye injury. Harmful if swallowed. Do not get in eyes. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash clothing before reuse.
- 5. Within the FIRST AID section, reverse the statements to state"

"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, then continue rinsing eye. Call a poison control center or doctor for treatment active.

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. Go not give anything by mouth to an unconscious person.

¹ Note: The text within the existing section "Instruct older children in the proper use of this product" is contradictory to the DEET and MGK 326 required language. The statement "Do not apply to lips or get into eyes." Has been moved to the directions for use, and changed to adhere to the language in the DEET and MGK 326 REDS. The statement "In case of contact with eyes, flush with water" is expressed in the First Aid section.

If you suspect a reaction to this product: Discontinue use. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-XXX-XXXX² for emergency medical treatment information."

6. Directions for Use:

a. Revise and or relocate all of the language within the Directions for Use as follows: "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.

Do not apply over cuts, wounds, or irritated skin. Do not apply near eyes and mouth. Apply sparingly around ears. Do not apply to children's hands. Do not allow children to handle this product. Do not apply more than 3 times per day to children ages twelve (12) and under. When using on children, apply to your own hands and then put it on the child. Use just enough repellent to cover exposed skin and/or clothing. Do not use under clothing. Avoid over-application of this product. After returning indoors, wash treated skin with soap and water. Wash treated clothing before wearing it again. Use of this product may cause skin reactions in rare cases. If you suspect a reaction to this product, discontinue use, wash treated skin, and call your local poison control center. If you go to a doctor, take this product with you.

{Open} {unfold} {Towel[s]}. Wipe or rub sparingly on all exposed skin areas. {Repeat when insects become annoying.} {For ticks and chiggers, apply to shoe tops, socks and around openings of clothing.}

Avoid contact with plastics, such as eyeglass frames, and such fabrics as acetate rayon."

- 7. Net Contents: The net contents must be expressed in fluid ounces. Please refer to 40 CFR 156.10(d).
- 8. Remove the claim "No excess spray with towels to harm decorative plants. This is an implied safety claim.

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1. Remove the following Optional Text from the label³:

"Optional text imprinted on label:

Date and/or company name and/or company logo, preceded or followed by:

Golf Outing

Golf Camp

Day Camp

Summer Camp

Summer Picnic

Grand Opening

² The XXX-XXXX should be replaced with a toll-free telephone number for consumers to call for additional product information and to report incidents.

³ The Agency would require you to submit as an amendment all logos and promotional information for review and approval prior to use.

Health Fair
Grand Opening Fair
Best Year Ever
Compliments of
Keeping you protected
or other similar type text."

Current labels on DEET repellent products tend to dissolve from contact with the repellent (usually liquids). All reregistered DEET product labels must use materials that remain permanent and readable for the reasonable life of the product. The Agency determined in the DEET RED document that all aerosol and pump spray formulations must be packaged in containers utilizing a concave trigger to help aim product or other comparable mechanism that will ensure that the product will not be inadvertently sprayed in the eyes.

The Agency is in the process of developing and improving the current Efficacy Assessment Guidelines for repellent products. The Agency intends to defer the determination of any related efficacy data requirements supporting the claims that may appear on this label until these Efficacy Assessment Guidelines are complete. When the guidelines are finalized, the Agency expects to issue a Data Call-In to address the revised guidelines to all registrants with registrations for personal repellent products that have not previously submitted efficacy data sufficiently consistent with the revised guidelines.

Should you wish to add/retain a reference to the company's website on your label, please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. 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. Therefore should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance. As an alternative, you may refer consumers to the company's phone number or email address.

NOTE: This product is not being re-registered under FIFRA Sec. 4(g) at this time.

You must submit two copies of the final printed label revised in accordance with the comments listed above before the product is released for shipment under this label. If you have any questions, you may contact Carmen Rodia at (703)-306-0327 or rodia.carmen@epa.gov.

A copy of your label stamped "Accepted with Comments" is enclosed for your records.

Sincerely,

Richard J. Gebken, Product Manager (10) Registration Division, Insecticide Branch

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION KEEP OUT OF REACH OF INFANTS AND YOUNGER CHILDREN

Instruct older children in the proper use of this product. Do not apply to lips or get into eyes. In case of contact with eyes, flush with water,

PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame.

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.

{Open} {unfold} {towel[s]}. Wipe or rub liberally on all exposed skin areas.

{Repeat when insects become annoying.} {For ticks and chiggers, also apply liberally to shoe tops, socks and around openings of clothing.} {Repeat using a fresh towel when necessary.}

Do not allow children to handle this product. Do not apply over cuts, wounds or irritated skin. Do not apply to eyes and mouth and do not apply to the hands of young children. Do not apply directly on face. Apply sparingly around ears. Use just enough repellent to cover exposed skin and/or clothing. After returning indoors, wash treated skin with soap and water. Wash treated clothing. Use of this product may cause skin reactions in rare cases. If you suspect that you or your child is reacting to this product, wash treated skin and call your local poison control center. Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency information, call the National Pesticide Information Center at 1-800-858-7378.

Avoid contact with plastics, such as eyeglass frames, and such fabrics as acetate rayon.

STORAGE AND DISPOSAL

Do not contaminate vrater, food, or feed by storage and disposal.

STORAGE: 4Do nocistore where children or animals may gain access.

IF EMPTY: Do not reuse this container. Place in trash or offer for pecycling if available.

IF-PARTLY FILLED: "Call your local solid waste agency for disposal instructions: Never plage unused product down and indoor or outdoor drain."

ATHEA LABORATORIES, INC.

Product: Insect Repellent Towel

EPA #10088-97

INSECT REPELLENT TOWEL



with Aloe

- Repels Mosquitoes, Biting Flies, Chiggers, Ticks, Deer Flies, Stable Flies, Black Flies, Gnats and Fleas on Exposed Skin Surfaces.
- Repels Most Biting Insects.
- Repels Insects For Hours.
- · Made with aloe to keep skin smooth and soft.
- Formulated with aloe to keep skin smooth and soft.
- Contains aloe to keep skin smooth and soft.
- · Made with aloe, a skin softening agent.
- · Formulated with aloe, a skin softening agent.
- · Contains aloe, a skin softening agent.

ACTIVE INGREDIENTS:

DEET	.12.33%
N-Octyl bicycloheptene dicarboximide	3.52%
Di-n-propyl Isocinchomeronate	1.76%
INERT INGREDIENTS:	82.39%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN CAUTION

FIRST AID:

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 do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

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, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

EPA REG. NO. 10088-97 EPA EST. NO. 10088-WI-2

Contains: (X) • (X)" x (X)" ((X) cm x (X) cm)
Premoistened (Towelettes) (Towels) (Wipes)

Words in italics are for reference only Words in [] are alternate wording Words in { } are optional wording

- · Towels apply repellent where you need it most.
- · Will not stain clothes or fabric.
- · Will not stain clothing or fabrics.
- · Stain-free formula will not harm clothes.
- · Repellent formula will not stain clothes or fabrics.
- · No excess spray with towels to harm decorative plants.
- · Easy-to-use towels apply repellent in one-step.
- · Apply repellent in one easy step tear off towel and wipe.
- · Portable canister goes anywhere.
- · Portable canister goes anywhere bugs are found.
- · Portable 18-count canister can be taken anywhere.
- Portable 18-count canister easily fits in pockets.
- · Portable 40-count canister can be taken anywhere.
- · Portable 40-count canister easily fits in pockets.
- · Use towels at work or at play.
- Soft, durable 12" x 12" towelette.
- · Non-greasy insect repellent.
- · Portable, resealable packaging.



Manufactured By:

P. O. Box 240014 Milwaukee, WI 53224

ACCEPTED with COMMENTS In EPA Letter Dated

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

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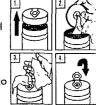


DIRECTIONS FOR DISPENSING:

(may be bulleted, numbered, in sentence form; may also be used with pictorials):

Canister Directions:

- 1. Remove lid by lifting upward.
- Pull towel from center of the roll and thread through "X" on the underside of the lid.
- 3. Close lid. Pull towel at 90° angle.
- 4. Snap hinged cap back into place to ensure towels stay moist.



{Resealable package instructions:}

Peel back re-sealable label. Remove towel from the center of the pack. Reseal package to the closed position to keep towels moist.



Non-resealable packaging:

Tear open envelope, remove towel.

OPTIONAL TEXT IMPRINTED ON LABEL:

Date and/or company name_and/or company logo, preceded or followed by:

Golf Outing

Golf Camp

Day Camp

Summer Camp

Summer Carnival

Summer Picnic

Grand Opening

Health Fair

Grand Opening Fair

Best Year Ever

Compliments of

Keeping you protected

or other similar type text.

ÁTHEÀ LARORATÓRIES, INC. Product: Insect Repellent Towel

EPA #10088-97

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