

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460-0001

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

August 19, 2009

Mr. Adam Swader, Regulatory Compliance Specialist ATHEA Laboratories, Inc. P.O. Box 240014 Milwaukee, WI 53224-9001

Subject:

Amended Labeling, Response to EPA Letter Dated May 12, 2009

IR 25 Water-Based Insect Repellent Formula, EPA Reg. No. 10088-117

Your Submission Dated May 30, 2009

Dear Mr. Swader:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable with the following label revisions:

<u>First Aid Statement section comment(s)</u>:

Revise the 2nd sentence in the "**HOT LINE NUMBER**" subsection to read "For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-xxx-xxxx." ¹

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 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.

A copy of your label stamped "Accepted with Comments" is enclosed for your records. Please submit two (2) copies of the final printed labeling, incorporating the above changes, before releasing the product for shipment. If these 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 amended labeling constitutes accepting of these conditions.

Please note that the "1-800-xxx-xxxx" phone number must be available twenty-four (24) hours per day, seven (7) days per week for answering and responding to any medical emergencies or health concerns.

If you have any questions about this label review, please contact Mr. Carmen J. Rodia, Jr. at (703) 306-0327 or via e-mail at <u>Rodia.Carmen@epa.gov</u>.

Sincerely Yours,

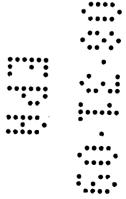
Richard J. Gebken

Product Manager (10)

Insecticide Branch

Registration Division (7505P)

Enclosure: Label stamped "Accepted with Comments"



With COMMENTS
In EPA Letter Dated
August 19,2009
Under the Federal Insecticide, Fungicide
and Rodenticide Act, As amended, for the

pesticide Registered under EPA Reg

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING

Causes substantial but temporary eye injury. Harmful if swallowed. Do not get in eyes. Use of this product may cause skin reactions in rare cases. Wash treated clothing before wearing it again. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

FIRST AID	
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 eyes. Call a poison control center or doctor for treatment advice.
IF SWALLOWED:	 Call a poison control center or doctor immediately for treatment advice. Have a 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 a doctor. Do not give anything by mouth to an unconscious person.

Have the product container or label with you when calling a poison control center or dector or going for treatment. For information regarding medical emergencies or pesticide incidents, call the Poison Control Center at 1-800-222-1222.

IR 25

Water-Based Insect Repellent Formula

Non-VOC Formula

No Strong/Offensive Odor

Leaves No Sticky Residue

With Effective DEET Repellent

Repels Biting Insects For Up To 4 Hours/ Provides Up To 4 Hours Protection

Repels Mosquitoes, Black Flies, Ticks, and Fleas

ACTIVE INGREDIENT:

 DEET
 .25.00%

 OTHER INGREDIENTS:
 .75.00%

 TOTAL
 100.00%

WARNING

See side panel for additional precautionary statements.

EPA REG. NO. 10088-117 EPA EST. NO. 10088-WI-2

Net Contents: (x) ounces

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

Manufactured By:

ATHEA LABORATORIES, INC. P.O. Box 240014 Milwaukee, WI 53224

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

IR 25 provides up to 4 hours of protection from Mosquitoes, Black Flies, Stable Flies, Sand Flies, Gnats, Chiggers, Fleas, and Ticks

Convenient, easy to use (Towel)(Towelette)(Wipe) allows quick and thorough application to skin, hair, and clothing for maximum protection.

Read and follow all directions and precautions on this product label.

Wipe and spread evenly to moisten all exposed skin. Use just enough repellent to cover exposed skin and/or clothing. Avoid over-application of this product. Frequent reapplication and saturation of clothing are unnecessary for effectiveness. When using on face, apply sparingly, avoiding eyes and mouth. Apply sparingly around ears. Do not allow children to handle this product. Do not apply to eyes and mouth. Do not apply to children's hands. When using on children, apply to your own hands and then put it on the child. Do not apply over cuts, wounds, or irritated skin. Also apply to clothing such as shirt, pants, hat, and socks. Do not use under clothing. For Chiggers and Ticks, apply to shirt and pant cuffs and socks.

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 repellent product with you.

NOTE: Will not damage cotton, wool, or nylon. Do not apply on or near acetate rayon, Spandex or synthetics other than nylon, furniture, plastics, watch crystals, leather and painted or varnished surfaces (including automobiles).

DIRECTIONS FOR DISPENSING:

Remove lid. Pull towel from center of the roll and thread through underside of lid. Do not push finger through lid opening. Pull towel at 90° angle. Snap hinged cap back into place so towels stay moist.

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Keep container closed. Store this product in a cool, dry place that is inaccessible to children.

CONTAINER DISPOSAL:

IF EMPTY: Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available.

IF PARTLY FILLED: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

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Optional text imprinted on label:

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

Golf Outing
Golf Camp
Day Camp
Summer Camp
Summer Carnival
Summer Picnic
Grand Opening
Grand Opening Fair
Best Year Ever
Compliments of
Keeping you protected

Optional Package Direction/Directions for Dispensing (may be bulleted, numbered or in sentence form):

Resealable package instructions (used with product supplied in resealable pouches/packages):

To Open Package: Peel back resealable label. Remove (towel)(towelette)(wipe)(cloth) from the center of the pack. Reseal package to the closed position to keep (towels)(towelettes)(wipes)(cloths) moist.

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Tear open envelope, remove towel; open, and wipe or rub liberally on all exposed skin areas avoiding eyes and mouth. 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.

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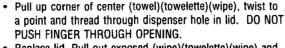
Canister Directions

EPA Reg. No. 10088-117

TO OPEN:

- · Remove lid from canister.
- . Lift flap in center of lid.

Manufactured By: Athea Laboratories, Inc. Product Name: IR 25



- Replace lid. Pull out exposed (wipe)(towelette)(wipe) and snap off. The next (towel)(towelette)(wipe) pops up automatically. Dispose of used (towels)(towelettes) (wipes) in trash receptacle. Snap center flap down when finished to retain moisture.
- . Do not flush.

Or

TO OPEN PACKAGE:

Flip open dispensing cap and remove lid by pulling upward. Thread center (towel)(towelette)(wipe) corner through slits in lid center. DO NOT PUSH FINGER THROUGH OPENING. Replace lid. Dispense (towels)(towelettes)(wipes) by pulling out at an angle. Snap flip lid down when finished, to retain moisture. Dispose of used (towels)(towelettes)(wipes) in trash. Do not flush.

Or

TO OPEN PACKAGE:

Pop open dispensing cap and remove top by lifting upward. Pull up corner of center (towel)(towelette)(wipe), twist to a point and thread through slits on top. DO NOT PUSH FINGER THROUGH SLITS. Replace top and pull (towels)(towelettes)(wipes) at a slight angle. The next (towel)(towelette)(wipe) pops up automatically. Snap tab closed to retain moisture. Do not flush.

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DISPENSER: To start feed. Remove large cover and discard seal from container. From center of (towel)(towelette)(wipe) roll, pull up (towel)(towelette)(wipe) corner, twist into a point and thread it through the hole in the container cover. DO NOT PUSH FINGER THROUGH HOLE. Pull through about one inch. Replace cover. Pull out first (towel)(towelette)(wipe) and snap off at a 90 degree angle. Remaining (towel)(towelette)(wipe) feed automatically ready for next use. When through using, keep small center cap closed to prevent moisture loss. Do not flush.

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Resealable Package Instructions:

TO OPEN PACKAGE: Slowly peel back label. (Pull out)(Remove) (towels)(towelettes)(wipes) as needed. To retain moisture, reseal (pouch)(package) by firmly pressing label back on (pouch)(package).

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(For canister)

To Open Package: Remove cover. Pull up (towel)(towelette)(wipe) corner from center of roll. Thread through hole in the cover. Replace cover. Open center cap to cover to remove wipe. When not in use (When not using), close center cap (securely) to prevent moisture loss.

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(For carton or tub)

To Open Package: Open cover and slowly peel back label on pouch. Remove (Pull out) (towel)(towelette)(wipe) as needed. To retain moisture, reseal (pouch)(bag) by firmly pressing seal back on the (pouch)(bag) and close (carton or tub) cover.

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(for the Travel Pack size)

To Open Package: Slowly peel back label. (Pull out)(Remove) (towels)(towelette)(wipes) as needed. Reseal label to retain moisture.

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To Open Package: Open ziplock (Tear edge of pack). (Pull out)(Remove) (towels)(towelette)(wipes) as needed. Reseal ziplock to retain moisture.

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(for the single cloth sample pack)

To Open Package: Tear edge of pack. (Pull out)(Remove) (towels)(towelette)(wipe).

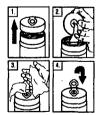
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Optional Marketing Text:

- · Repels Mosquitoes that may carry/transmit the West Nile virus.
- · Towels apply repellent where you need it most.
- . Will not stain clothes or fabric.
- . Will not stain clothing or fabric.
- · 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 (X)-count canister can be taken anywhere.
- . Portable (X)-count canister easily fits into pockets
- · Use towels at work or at play.
- Soft, durable (X") x (X") (towelette)(towel)(wipe).
- · Non-greasy insect repellent.
- · Portable, resealable packaging.

Optional Graphics:











Optional Graphics:



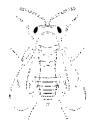














Optional Graphics:

























