



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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

May 12, 2009

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

**Subject: Revised Label, Response to EPA Letter Dated September 13, 2006
IR 25 Water-Based Insect Repellent Formula, EPA Reg. No. 10088-117
Your Submission Dated February 24, 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 revision provision(s):

First Aid Statement comment(s):

1. Delete the existing statement (3rd row of this table) starting with "**IF YOU SUSPECT A REACTION TO THIS PRODUCT:**" since this text has already been replaced/updated with revised text that was added to the Directions for Use section.

Net Contents/Net Weight Statement section comment(s):

2. The net contents must be expressed in terms of liquid measure (fluid ounces) per individual wipe and also total fluid ounces per package.¹

Directions for Use section comment(s): To facilitate inclusion of language from the RED for DEET:

3. In the 1st paragraph of this section, replace the 3rd sentence with: "Avoid over-application of this product."
4. In the 1st paragraph of this section, replace the 7th sentence with: "Do not apply to eyes and mouth. Do not apply to children's hands."
5. In the 2nd paragraph of this section, replace the 2nd sentence with: "Wash treated clothing before wearing it again."

¹ For more detailed information, please refer to Chapter 17, Section III(A)(2) of EPA's Label Review Manual.

Storage and Disposal Statement section comment(s):

6. To facilitate inclusion of language from PR Notice 2007-4, replace this section with:

<p>STORAGE AND DISPOSAL</p> <p>Pesticide Storage: Keep container closed. Store this product in a cool, dry place that is inaccessible to children.</p> <p>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.</p>


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.

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 Rodia.Carmen@epa.gov.

Sincerely Yours,

fol

 Richard J. Gebken
 Product Manager (10)
 Insecticide Branch
 Registration Division (7505P)

Enclosure: Label stamped "Accepted with Comments"
010088-00117 D407141

ACCEPTED
With COMMENTS
In EPA Letter Dated:

May 12, 2009

Under the Federal Insecticide, Fungicide
and Rodenticide Act, As amended, for the
pesticide Registered under EPA Reg. No:

IR 25

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

10088-117

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:	<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, then continue rinsing eyes. • 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 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.
IF YOU SUSPECT A REACTION TO THIS PRODUCT:	<ul style="list-style-type: none"> • Discontinue use. • 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.

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

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%

KEEP OUT OF REACH OF CHILDREN 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 overuse. 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 apply to eyes and mouth and do not apply to hands of young children. Do not allow children to handle this product. 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 reuse. 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

STORAGE: Store in a cool, dry place. Keep container closed.

DISPOSAL:

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

IF PARTLY FILLED: Call your local solid waste agency or (1-800-CLEANUP) for disposal instructions. Never place unused product down any indoor or outdoor drain.

3045

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.

Or

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.

Or

Canister Directions

TO OPEN:

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

Manufactured By:
Althea Laboratories, Inc.
Product Name: IR 25
EPA Reg. No. 10088-117

- Pull up corner of center (towel)(towelette)(wipe), twist to
a point and thread through dispenser hole in lid. DO NOT
PUSH FINGER THROUGH OPENING.
- 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.

Or

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.

Or

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).

Or

(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.

Or

(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.

Or

(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.

Or

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

Or

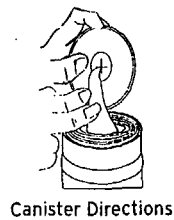
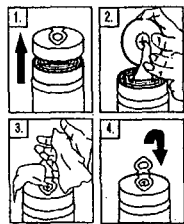
(for the single cloth sample pack)

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

Optional Marketing Text:

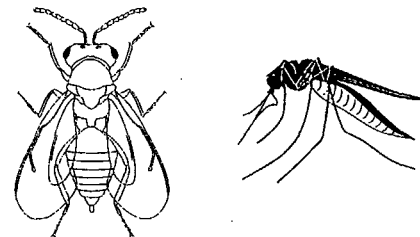
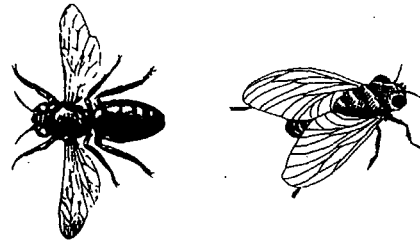
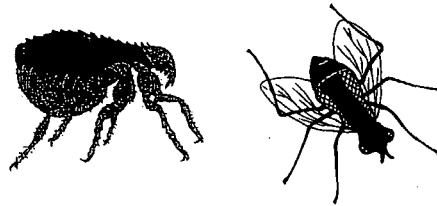
- Repels Mosquitoes that may carry/transmit the West Nile virus.
- Towels apply repellent where you need it most.
- Will not stain clothes or fabric.
- Will not stain clothing or fabric.
- Stain-free formula will not harm clothes.
- Repellent formula will not stain clothes or fabrics.
- No excess spray 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:

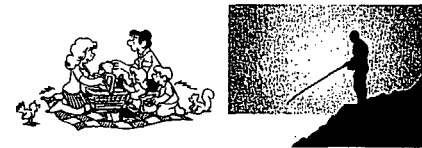
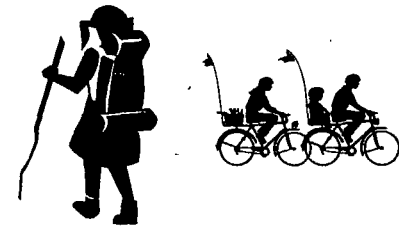


Manufactured By:
Athea Laboratories, Inc.
Product Name: IR 25
EPA Reg. No. 10088-117

Optional Graphics:



Optional Graphics:



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