

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

June 9, 2009

Ms. Jean M. Fugate, Registration Specialist II S.C. Johnson & Son, Inc. 1525 Howe Street Racine, WI 53403-2236

Subject:

**Amended Reregistration Label** 

OFF!® TOWELETTE INSECT REPELLENT, EPA Reg. No. 4822-258 Your Submissions Dated March 12, 2009 and May 19, 2009

Dear Ms. Fugate:

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):

# **General Statement:**

Delete all text throughout the label marked with "strikethrough."

## Precautionary Statements, Hazards to Humans section comment(s):

2. To facilitate inclusion of language from the RED for DEET, insert the following text immediately following the 4<sup>th</sup> sentence in this section: "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."

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,

Richard J. Gebken

Product Manager (10)

Insecticide Branch

Registration Division (7505P)

Enclosure: Label stamped "Accepted with Comments" 004822-00258 D407644

OFF!® TOWELETTE INSECT REPELLENT [primary name of record]
OFF! Deep Woods insect Repellent Towelettes [alternate brand name]
Deep Woods OFF! for Sportsmen Insect Repellent Towelettes [alternate brand name]
OFF! Deep Woods Sportsmen Insect Repellent Towelettes [alternate brand name]

- LONG LASTING PROTECTION from (Mosquitoes) (Ticks) (Biting Flies) (Gnats) (Chiggers) (Fleas)
- S.C. Johnson A Family Company
- X Individual towelette packet(s)
- X (individually wrapped) towelettes
- Easy to apply to face and neck
- (For) easy application to face and neck
- Even application
- Easy application
- Easy to reapply
- Pleasant scent
- Unscented
- Fragrance Free
- · Handy to carry with you
- On the go protection
- Provides (long) lasting protection from (mosquitoes) (biting flies) (gnats) (sand flies) (no-see-ums) (deer flies)
   (stable flies) (black flies).
- Enjoy protection from (mosquitoes) (biting flies) (gnats) (sand flies) (no-see-ums) (deer flies) (stable flies) (black flies) (ticks) (chiggers) (fleas).
- And because it's from the makers of OFF! it's especially formulated to effectively repel (mosquitoes) (biting flies) (gnats) (sand flies) (no-see-ums) (deer flies) (stable flies) (black flies) (ticks) (chiggers) (fleas).
- Also repels (ticks) (chiggers) (fleas) from treated skin.
- (Effective) protection (you can count on) (from mosquitoes that may carry West Nile Virus)
- (Delivers) (Powerful) protection (against mosquitoes)
- (Keeps working) (Proven Shield) against mosquitoes (that may carry West Nile Virus)
- Fights off mosquitoes (that may carry West Nile Virus)
- Contains DEET (N,N-Diethyl-meta-toluamide)
- Mosquito protection (for up to 8 hours)
- Repels mosquitoes (for up to 8 hours)
- Repels-mosquitoes-(that-may-carry-West-Nile-Virus)-
- Won't get in your eyes like sprays can
- Non-aerosol
- Pre-moistened repellent towelettes
- · Repels bugs, not people
- Easy on arms, tough on bugs
- Easy on your skin
- Wipe OFF!
- Unwrap it
- Won't dry out
- Match your protection to the occasion
- Fast and friendly
- Wipe it on, toss it out
- Small package
- OFF! to go

ACCEPTED
With COMMENTS
In EPA Letter Dated:
Tune 9, 2-009
Under the Federal Insecticide, Fungicide
and Rodenticide Act, As amended, for the
pesticide Registered under EPA Reg. No:
4822-258

- Always fresh
- Keeps Bugs OFF!
- Always Carry (Product Name)
- Singles
- (It is individually wrapped so it won't dry out) (and) (it fits anywhere)
- For use at home or on the go!
- Carry one everywhere
- Quick protection
- Protect and Go
- Protection on the Go
- (Product name) convenient to toss in your (Car) (Desk) (Purse) (Bag) (Briefcase) (Gym Bag) (Beach Bag)
   (Back Pack) (Wallet)
- Enjoy the (outdoors) (great outdoors) (backyard) (outside) (park) (woods) (forest) (with protection against mosquitoes)
- (Product name) gives effective protection and is not greasy, won't stain and resists perspiration
- Moist and fresh, anytime, anywhere!
- Trial sample (included)
- (OFF!) (#) (count) Pack
- (#) towelette packets
- (OFF!) (Deep Woods) (Mosquito) (Towelette) (Repellent) Pack
- (OFF!) (Summer) (Value) (Bonus) (Family) (Camping) (Sporting) (Gardening) (Convenient) (All Activity) (All Activities) (Pack)
- OFF! (repellent) has you covered
- (Packaged) for resale (and personal use)
- UPC on each packet
- Open for (individual units) (individually wrapped towelettes) (individual packets)
- Resalable
- OFF! (mosquito) (bug) repellents (to use) at (home) (country clubs) (and) (farms).
- OFF! (mosquito) (bug) repellents (ideal) (for use by) (contractors) (vending machine operators)
- OFF! mosquito repellents for resale in (convenience stores) (retail stores) (vending machines)
- (Great) (Ideal) for camping
- OFF! (Deep Woods) The right protection for your family
- (No matter where you are,) (you) (you've) gotta get your OFF! on!
- Repels mosquitoes that may carry (St. Louis) (Eastern equine) (Western equine) (LaCrosse) (Cache Valley)
  encephalitis (for up to 8 hours)
- Repels ticks that may carry (Lyme disease) (Rocky Mountain Spotted Fever) (Tick Paralysis) (Ehrlichiosis)
   (Powassan Encephalitis)
- (Enjoy) up to 8 hours of protection from (mosquitoes). Also protects against (works on) (repels) (ticks
  (including ticks that may carry/transmit Lyme disease)) (biting flies) (stable flies) (black flies) (sand flies) (deer
  flies) (chiggers) (fleas) (gnats) (no-see-ums)
- Lasts for up to 8 hours against mosquitoes
- Stav protected for up to 8 hours (from mosquitoes that may carry West Nile Virus)
- Maximum protection (keeps working) (for) up to 8 hours against mosquitoes
- (Proven) (Effective) Protection (you can count on for up to 8 hours) (from mosquitoes that may carry West Nile Virus)
- (Delivers) (Powerful) protection (keeps working) for up to 8 hours against mosquitoes
- Proven shield for up to 8 hours against mosquitoes (against mosquitoes that may carry West Nile Virus)
- Fights off (mosquitoes) (mosquitoes that may carry West Nile Virus) for up to 8 hours

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- Up to 8 hours of proven protection from mosquitoes (that may carry West Nile Virus)
- Effective protection up to 8 hours from mosquitoes (that may carry West Nile Virus)
- Enjoy the (outdoors, the great outdoors, backyard, outside, park, woods/forest) with up to 8 hours of protection against mosquitoes

[Note to reviewer: the following label is for individual towelette wrappers and/or outer containers]

#### **ACTIVE INGREDIENT:**

 DEET
 25%

 OTHER INGREDIENTS
 75%

Keep Out of Reach of Children

WARNING

See additional precautions on (side) (back) panel

NET WT: X OZ.

#### PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS: WARNING – Causes substantial but temporary eye injury. Do not get in eyes. Harmful if swallowed. Use of this product may cause skin reactions in rare cases. Wash treated clothing before wearing it again. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

[Note to reviewer: Boxed format or bullets may be used in First aid section if label space permits]

### FIRST AID

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

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.

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 you suspect a reaction to this product, discontinue use, wash treated skin, and call your local poison control—center.

PHYSICAL & CHEMICAL HAZARDS: FLAMMABLE - Do not use near heat or open flame. Keep treated surfaces away from fire or flame until dry.

#### 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 package, remove and unfold towelette. Moisten all exposed skin evenly and completely. Do not apply over cuts, wounds, irritated or sunburned skin. Do not apply near eyes and mouth. Apply sparingly around ears. Use

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just enough repellent to cover exposed skin. Avoid over-application of this product. Frequent reapplication is unnecessary. Do not allow children to handle this product. Do not apply to children's hands. After returning indoors, wash treated skin with soap and water. Do not use under clothing. Will not damage cotton, wool or nylon. DO NOT APPLY ON OR NEAR: acetate, rayon, spandex, or other synthetics (other than nylon), furniture, plastics, leather, watch crystals and painted or varnished surfaces including automobiles.

[Note to reviewer: If any "hours of duration" claims are used on the marketed product label, the following statement will be included: "Some may need more than one towelette for adequate coverage."]

STORAGE AND DISPOSAL

STORAGE: Store away from heat or flame in an area inaccessible to children.

[The following is for individually-wrapped towelettes]

DISPOSAL: Before disposing, empty package by using the product according to the label. Do not reuse towelette or wrapper. Place used towelette and wrapper in trash.

[The following is for outer containers containing individually-wrapped towelettes]

DISPOSAL: Before disposing, empty package using the product according to the label. Do not reuse towelette or wrapper. Place used towelette and wrapper in trash. Place outer container in trash or offer for recycling if available.

[The following is for outer containers containing towelettes that are not individually-wrapped]

DISPOSAL: Nonrefillable container. Before disposing, empty package using the product according to the label. Do not reuse or refill outer container. Do not reuse towelette. Place used towelette in trash. For unused towelettes: Call your local solid waste agency or 1-800-529-3394 for disposal instructions. Place outer container in trash or offer for recycling if available.

Questions? Comments? Call 800-558-5252 or write Helen Johnson. © 2009 S. C. Johnson & Son, Inc. Racine, WI 53403-2236 U.S.A. All rights reserved.

(Made in Canada)

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