

U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs Registration Division (7505P) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460-0001

EPA Registration No.

Date of Issuance:

4822-399

SEP 2 5 2008

NOTICE OF PESTICIDE: □ Registration

☑ Reregistration

(under the Federal Insecticide, Fungicide and Rodenticide Act, as amended)

Term of Issuance: Conditional

Name of Pesticide Product:

Unscented Deep Woods OFF! Insect Repellent II

Name and Address of Registrant (include ZIP Code):

S.C. Johnson & Son, Inc.

1525 Howe Street

Racine, WI 53403-2236

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This action is taken under the authority of section 4(g)(2)(c) of the Federal Insecticide, Fungicide and Rodenticide Act, as amended. Reregistration under this section does not eliminate the need for continual reassessment of pesticides. EPA may require submission of data at any time to maintain the registration of your product.

Based on your response to the Reregistration Eligibility Document(s), EPA has reregistered the product listed above provided that the following change(s) is(are) made to the label:

General Statement:

- 1. Delete all text throughout the label marked with "strikethrough."
- The words "INSECT REPELLENT" must be displayed prominently on the front panel of this label as well as on the alternate brand name(s), immediately after the brand name, in capital lettering, with large, contrasting, bold-faced type.

(continued on page 2)

Signature of Approving Official:

Date:

Refer to Page #3.

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

SEP 2 5 20008

J. 10 10

Marketing Claims section comment(s):

- 3. Delete the 3rd marketing claim listed as "New." This statement is permitted for a period of 6 months following initial registration only.
- 4. In the 29th marketing claim, insert the word "may" immediately preceding the word "cause."
- 5. Delete the 30th, 31st, 32nd, 33rd, 34th and 35th marketing claims. These claims are considered comparative claims.
- 6. In the 37th marketing claim, delete Japanese, Venezuelan equine and Murray Valley encephalitis since these diseases do not occur within the continental United States and/or its territories.
- 7. Delete the 38th marketing claim since Ross River Fever, Barmah Forest Disease, Dengue Fever, Yellow Fever and Rift Valley Fever do not occur within the continental United States and/or its territories.
- 8. In the 39th marketing claim, delete European Tick Borne encephalitis since this disease does not occur within the continental United States and/or its territories.
- 9. Delete the 40th marketing claim since Onchocerciasis does not occur within the continental United States and/or its territories.
- 10. In the 51st marketing claim, delete the word "(Powerful)" since its use implies heightened efficacy.

<u>Ingredient Statement section comment(s)</u>:

11. The 3rd line of the Ingredient Statement should be revised to read as follows:

OTHER INGREDIENTS...... 75.00%

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

12. To facilitate inclusion of revised language from the acute toxicity review completed for this product, replace this section with: "Causes substantial but temporary eye injury. Harmful if swallowed. Do not get in eyes. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse."

First Aid Statement comment(s):

- 13. In the First Aid statement starting with "If swallowed: ...," replace the 3rd sentence with: "Do not induce vomiting unless told to do so by a poison control center or doctor."
- 14. To facilitate inclusion of revised language from the acute toxicity review completed for this product, replace the statement starting with "For additional information ..." with: "Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-xxx-xxxx."

<u>Directions for Use section comment(s)</u>:

- 15. The statement "Read and follow all directions and precautions on this product label." should be CAPITALIZED and bolded to increase its prominence.
- 16. The statements "Do not apply to children's hands. When using on children, apply to your own hands and then put it on the child." should be relocated from the end of the 2nd paragraph to immediately following the 9th sentence in the 1st paragraph.
- 17. To facilitate inclusion of required language from the DEET RED, insert the statements "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." immediately following the 10th sentence in the 1st paragraph.

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

Storage and Disposal Statement section comment(s):

18. To facilitate inclusion of language from PR Notice 2007-1, replace this section with:

STORAGE AND DISPOSAL

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

Pesticide Storage: Store this product away from open heat or flame in an area inaccessible to children. Pesticide Disposal: Do not puncture or incinerate! If empty: Offer for recycling if available. If partially filled: Call your local solid waste agency [or toll free number or website which meets the criteria in paragraph II.E., P.R. Notice 20007-1] for disposal instructions.

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.

S.C. Johnson & Son, Inc. should note that 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 FIFRA 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) lists 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 be 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 EPA's Office of Enforcement and Compliance Assurance (OECA). As an alternative, you may refer consumers to the company's phone number or e-mail address.

A-copy-of-your-label-stamped "Accepted-with Comments" for this product 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 Rodia at (703) 306-0327 or via e-mail at <u>Rodia Carmen(wepa, gov.</u>

Sincerely yours,

Richard J. Gebken Product Manager (10) Insecticide Branch

niscetteride Branch

Registration Division (7505P)

Enclosure: Label stamped "Accepted with Comments"

Unscented Deep Woods OFF! Insect Repellent II [primary name of record]
OFF! Deep Woods Insect Repellent VII [alternate brand name, 6/2/03]
Deep Woods OFF! for Sportsmen Insect Repellent VIII [alternate brand name, 7/2/03]
OFF! Deep Woods Sportsmen Insect Repellent III [alternate brand name, 10/07/04]
OFF! Active Insect Repellent IV [alternate brand name, 12/16/04]

SC Johnson A Family Company

Protection from Mosquitoes, Ticks, Biting Flies, Gnats, Chiggers and Fleas

- Now-

- Unscented
- Fragrance Free
- Tropical Fresh
- Fresh scent
- Get the OFF! mosquito protection that is right fo you and you
- OFF! Family Pack
- Contains (with) Deet (N. N. Diethyl-meta-toluamide)
- Contains (with) Deet (N, N, Diethyl-meta-toluamide) Mosquito Protection
- xx% (MORE) (FREE)
- Bonus (Value) (Size) (Pack)
- xx oz (ounces) at the (same) 6 oz (ounce) price
- xx oz (ounces) for the (same) price of 6 oz (ounce)
- Twin-Pack
- Buy one get one Free
- (Place) (Carry) (Have) (product name)(one): (everywhere) (in) (your) (purse) (glove compartment) (glove box) (golf bag) (tennis bag) (tackle box) (tent) (book bag) (backpack) (fanny pack) (beach bag) (boat) (summer cabin) (first-aid kit)
- For use at (;) (home) (or) (on the go) (on a picnic) (picnicking) (camping) (at sporting events) (boating) (fishing) (hiking) (while) (gardening) (playing) (outside)
- Camping
- Fishing
- Hunting
- Boating
- Hiking
- ----Picnic−
- Gardening
- Taking a walk
- Keep(s) Bugs OFF!®
 LONG LASTING PROTECTION from mosquitoes, ticks (including ticks that cause Lyme disease), biting flies, gnats and chiggers
- From the #1 brand of insect repollents
- --- From (the makers of) OFF), the #1-brand of insect repellents
- From America's #1 brand of insect repellents
- - (From the) (America's) #1 trusted brand of insect repellents -
- --- OFFI: 40+ years of experience in Mesquite Protection
 - Families have trusted the OFF! protection for more than 40 years.
 - Repels mosquitoes that may carry (West Nile Virus) (diseases)
 - Repels mosquitoes that may carry (St. Louis) (Eastern equine) (Western equine) (Lacrosse) (Japanese) (Cache Valley) (Venezuelan equine) (Murray-Valley) encephalitis (for up to 8 hours)

ACCEPTED
with COMMENTS
In EPA Letter Dated

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

- 5/7
- Repels mosquitoes that may carry (Ross River Fever) (Barmah Forest Disease) (Dengue-Fever) (Yellow Fever) (Rift Valley Fever) (for up to 8 hours)
 - Repels ticks that may carry (Lyme disease) (Rocky Mountain Spotted Fever) (Tick Paralysis)
 (Ehrlichiosis) (European Tick Borne Encephalitis) (Powassan Encephalitis)
- Repels black flies that may carry Onchoccreiasis
 - Provides hours of effective protection from mosquitoes and biting flies: deer flies, sand flies, stable flies, black flies.
 - Repels gnats and biting flies: deer flies, sand flies, stable flies, black flies.
 - · Also repels ticks, chiggers, and fleas from treated skin and clothing.
 - (Product name) is not greasy, won't stain, resists perspiration.
 - Mosquito protection (for up to 8 hours)
 - Repels mosquitoes (for up to 8 hours)
- Lasts for up to 8 hours against mosquitoes
- Stay protected for up to 8 hours (from mosquitoes that may carry West Nile Virus) (from mosquitoes that may carry disease(s))
- 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) (from mosquitoes that may carry disease(s)
- (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) (disease(s)).
- Fights off (mosquitoes) (mosquitoes that may carry West Nile Virus) for up to 8 hours
- 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) (that may carry disease(s))
- Enjoy the (outdoors, the great outdoors, backyard, outside, park, woods/forest) with up to 8 hours of protection against mosquitoes
- HOLD UPRIGHT WHEN SPRAYING
- Sweat-Resistant
- Sweat-Resistance
- With resistance to sweat
- Designed for people on the go_
- Take-Along
- (Perfect to) take-along with you

[Note to reviewer; Bulleted statements and text within parenthesis are optional].

ACTIVE INGREDIENT:

DEET 25.00%

INERT INGREDIENTS ...75.00%

KEEP OUT OF REACH OF CHILDREN WARNING

See additional precautions on back label

NET WT. 3.5 to 12 OZ.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS: 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 thoroughly with soap and water after handling.

[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. Do not give anything by mouth to an unconscious person.

- Skin: If you suspect a reaction to this product, discontinue use, take off contaminated clothing, wash-treated skin and call a poison control center or doctor for treatment advice.

For additional information in case of emergency call toll free 800-558-5252.

PHYSICAL & CHEMICAL HAZARDS - Combustible: Do not use or store 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. Hold container 4 to 6 inches from skin or clothing and spray. Do not apply over cuts, wounds, irritated or sunburned skin. Do not spray in enclosed areas. Use just enough repellent to cover exposed skin and/or clothing. Avoid over-application of this product. Frequent reapplication and saturation are unnecessary. Do not allow children to handle this product. After returning indoors, wash treated skin with soap-and-water. FOR—MAXIMUM PROTECTION: Spread evenly with hands to moisten all exposed skin.

TO APPLY TO FACE: Spray palm of hand first and then apply sparingly and avoid eyes. Do not spray directly onto face. Do not apply near eyes and mouth. Apply sparingly around ears. Do not apply to children's hands. When using on children, apply to your own hands and then put it on the child.

WORKS ON CLOTHING TOO: Do not use under clothing. Spray shirts, pants, socks, and hats. For ticks and chiggers also spray cuffs, socks and around openings in outer 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, watch crystals, leather and painted or varnished surfaces including automobiles.

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

DISPOSAL: Before disposing, empty the container by using the product according to the label. Do not reuse this container. Place in trash or offer for recycling if available.

If partially filled: Call your local solid waste agency or 1-800-529-3394 for disposal instructions. Never place unused product down any indoor or outdoor drain.

Questions? Comments? Call 800-558-5252 or Write Helen Johnson ©2004 S.C. Johnson & Son, Inc. Racine, WI 53403-2236 U.S.A. All Rights Reserved

EPA Reg. No. 4822-399

EPA Est. No. 4822-WI-1