

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

February 18, 2016

Dan Hollas Sr. Associate Regulatory Affairs – Registration S.C. Johnson & Son, Inc. 1525 Howe St, M.S. 149 Racine, WI 53403

Subject: Label Amendment – Adding a claim against mosquitoes that may carry Dengue virus and Zika virus.
Product Name: Unscented Deep Wood OFF! Insect Repellent II EPA Registration Number: 4822-399
Application Date: February 3, 2016
Decision Number: 513707

Dear Mr. Hollas

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then 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.

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Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Jennifer Gaines at 703-305-5967 or via email at gaines.jennifer@epa.gov.

Sincerely,  $\int ($ 

Jennifer Urbanski Saunders, Product Manager 4 Invertebrate & Vertebrate Branch 1 (IVB1) Registration Division (7505P) Office of Pesticide Programs

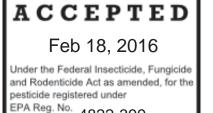
Enclosure

# Unscented Deep Woods OFF! Insect Repellent II [EPA base file name]

OFF! Deep Woods Insect Repellent VII [alternate brand name, 6/2/03] OFF! Deep Woods Sportsmen Insect Repellent III [alternate brand name, 10/07/04] OFF! Active Insect Repellent IV [alternate brand name, 12/16/04]

KEEP OUT OF REACH OF CHILDREN WARNING See additional precautions on back label

NET WT. 0.5 to 12 FL. OZ.



4822-399

#### 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. Do not apply to children's hands. When using on children, apply to your own hands and then put it on the child. After returning indoors, wash treated skin with soap and water. 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.

WORKS ON OUTER SURFACES OF CLOTHING: 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 AND DISPOSAL

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

DISPOSAL: Nonrefillable container. Before disposing, empty the container by using the product according to the label. Do not reuse or refill 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.

## 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.

[Information in brackets is notes to Reviewer] (Information in parentheses is optional language)

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 - Combustible: Do not use or store near heat or open flame. Keep treated surfaces away from fire or flame until dry.

Questions? Comments? Call 800-558-5252 or Write Helen Johnson ©2016 S.C. Johnson & Son, Inc. Racine, WI 53403-2236 U.S.A. All Rights Reserved

EPA Reg. No. 4822-399

EPA Est. No. 4822-XX-X

[Note to reviewer: All marketing claims below are optional]

- SC Johnson A Family Company
- A family company since 1886. Fisk Johnson
- Protection from Mosquitoes, Ticks, Biting Flies, Gnats, Chiggers and Fleas
- Unscented
- Fragrance Free

- Tropical Fresh Fresh scent
- Get the OFF! mosquito protection that is right for you and your family
- 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
- (Take)(Take along)(Bring)(Carry) (product name)(one): (in) (your) (purse) (golf bag) (tennis bag) (tackle box) (book bag) (backpack) (fanny pack) (beach bag) (boat) (car) (first-aid kit)
- (Have) (Take)(Bring)(Carry) (product name)(one): (ready) (in)(to)(for)(your)(tent)(boat)(summer cabin)
- 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
- Keep(s) Bugs OFF!<sup>®</sup>
- LONG LASTING PROTECTION from mosquitoes, ticks (including ticks that may cause Lyme disease), biting flies, gnats and chiggers
- OFF!: (X)+ years of experience in Mosquito Protection
- Repels mosquitoes that may carry West Nile Virus

- Hiking
- Picnic
- Gardening
- Taking a walk

- 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)
- Repels mosquitoes (for up to 8 hours)
- Mosquito protection (for up to 8 hours)
- Lasts for up to 8 hours against mosquitoes
- Stay protected (for up to 8 hours) from mosquitoes
- Maximum protection (keeps working) (for up to 8 hours) against mosquitoes
- (Effective) Protection (you can count on) (for up to 8 hours) from mosquitoes
- (Delivers) protection (keeps working) for up to 8 hours against mosquitoes
- Fights off mosquitoes (for up to 8 hours)
- Up to 8 hours of protection from mosquitoes
- Effective protection (up to 8 hours) from mosquitoes
- Enjoy the (outdoors, the great outdoors, backyard, outside, park, woods/forest) (with up to 8 hours of protection against mosquitoes)
- Repels ticks (for up to 4 hours)(for up to 2 hours).
- Lasts for (up to 4 hours)(up to 2 hours) against ticks.
- Repels black flies
- 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.
- Stay protected for up to 8 hours (from mosquitoes that may carry West Nile Virus)
- (Proven) (Effective) Protection (you can count on for up to 8 hours) (from mosquitoes that may carry West Nile Virus)
- Proven shield (for up to 8 hours) against mosquitoes (that may carry West Nile Virus)
- 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)
- Repels mosquitoes that may carry (the) Dengue (virus)
- Provides (long lasting) protection from mosquitoes that may carry (the) Dengue (virus)
- Effective protection from mosquitoes that may carry (the) Dengue (virus)
- Repels mosquitoes that may carry (the) Zika (virus)
- Provides (long lasting) protection from mosquitoes that may carry (the) Zika (virus)
- Effective protection from mosquitoes that may carry (the) Zika (virus)
- 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