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

UNITED STATES

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 Unscented OFF!® Insect Repellent, EPA Reg. No. 4822-380 Your Submission Dated March 12, 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:

2.

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

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

To facilitate inclusion of language from the RED for DEET, insert the following text immediately following the 4th 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."

To be eligible for reregistration, 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. In addition, 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 <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"

Unscented OFF! Insect Repellent [master name] OFF! Insect Repellent II [alternate brand name, 8/15/94] OFF! Active Insect Repellent I [alternate brand name, 10/7/04]

- SC Johnson A Family Company
- EFFECTIVE PROTECTION from Mosquitoes, Gnats, No-See-Ums, Biting Flies, Ticks (including ticks that may cause Lyme disease), Chiggers and Fleas
- Repels mosquitoes, gnats, ticks, biting flies, chiggers & fleas
- Long-lasting protection from mosquitoes, ticks, biting flies, gnats, and chiggers
- FRAGRANCE FREE
- UNSCENTED
- NON-GREASY
- Summer Splash
- Outdoor Fresh
- **Tropical Fresh**
- Fresh Scent
- (Fragrance name) scent (!)
- (Fragrance name) fragrance (!)
- Scratch'n'sniff
- Scratch here (to smell fragrance name)
- Refreshing(ly) light scent (of fragrance name) (!)
- Refreshingly light scent your whole family will enjoy
- (OFF!) Family Pack
- Always carry (product name)
- (Travel) (Sample) size
- Try the scent(s) from OFF! Skintastic repellent(s)
- Clean, fresh scent (of fragrance name)
- (Fresh) scent (!)
- A clean, fresh scent your whole family will enjoy
- Visit www.mosquitoes.com for more information
- Keeps bugs OFF!
- Best smelling (product name) ever
- Repels bug(s), not people
- Light, refreshing scent repels bugs, not people
- (Fragrance Name) (Product name) won't leave you smelling like a bug repellent
- The bug repellent that doesn't smell like bug repellent
- A better-smelling way to Keep Bugs OFF!
- Keeping bugs OFF! never smelled (so great) (so good) (better)(!)
- Feels great (!)
- Feels good on. Smells even better (!)
- The OFF! repellent you'll want on
- Contains DEET (N, N-Diethyl-meta-toluamide)
- Proven protection against mosquitoes
- Mosquito protection
- Up to 6 hours of Mosquito Protection
- Repels mosquitoes that may carry West Nile Virus (for up to 6 hours)
- Repels mosquitoes that may carry (St. Louis) (Eastern equine) (Western equine) (LaCrosse)
- (Cache Valley) encephalitis (for up to 6 hours)

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With COMMENTS EPA Letter Dated:

Under the Federal Insecticide, Fungicide

and Rodenticide Act, As amended, for the

pesticide Registered under EPA Reg. No:

922-3RD

- Repels ticks that may carry (Lyme disease) (Rocky Mountain Spotted Fever) (Tick Paralysis) (Ehrlichiosis) (Powassan Encephalitis)
- (Enjoy) up to 6 hours of protection from mosquitoes. Also protects against (ticks) (biting flies) (stable flies) (black flies) (sand flies) (deer flies) (chiggers) (fleas) (gnats) (no-see-ums)
- (Protects against) (Repels) (Works on) (mosquitoes) (mosquitoes that may carry West Nile Virus) (ticks) (biting flies) (stable flies) (black flies) (sand flies) (deer flies) (chiggers) (fleas) (gnats) (no-see-ums)
- Lasts for up to 6 hours against mosquitoes
- Stay protected for up to 6 hours from mosquitoes (that may carry West Nile Virus)
- Maximum protection (keeps working) (for) up to 6 hours
- (Proven) (Effective) Protection (you can count on for up to 6 hours from mosquitoes) (that may carry West Nile Virus)
- ((Delivers) (Powerful) protection) (keeps working) against mosquitoes for up to 6 hours
- Proven shield for up to 6 hours against mosquitoes
- (Fights off) (Protects against) (repels) (mosquitoes (that may carry West Nile Virus)) (ticks) (biting flies) (stable flies) (black flies) (sand flies) (deer flies) (chiggers) (fleas) (gnats) (no-seeums)
- Up to 6 hours of proven (effective) protection from mosquitoes (that may carry West Nile Virus)
- (Effective) (Proven) protection up to 6 hours from mosquitoes (that may carry West Nile Virus)
- Enjoy the (outdoors, the great outdoors, backyard, outside, park, woods/forest) with up to 6 hours of protection against mosquitoes
- HOLD UPRIGHT WHEN SPRAYING (SPRAYS UPSIDE DOWN TOO!)
- Provides hours of effective protection from mosquitoes, gnats, and biting flies (deer flies, sand flies, stable flies, and black flies).
- Also repels ticks, chiggers and fleas from treated skin and clothing.
- OFFI© is not greasy, won't stain and resists perspiration.
- Sweat-Resistant
- Sweat-Resistance
- With resistance to sweat
- Designed for people on the go
- Take-Along
- (Perfect to) take-along with you

[Optional labeling for a possible sticker covering the actuator]

• Remove before spraying

ACTIVE INGREDIENT:

DEET	15%
OTHER INGREDIENTS:	85%

KEEP OUT OF REACH OF CHILDREN

WARNING

See additional Precautions on Back Panel Net Wt. 1 - 12 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 centor.

PHYSICAL & CHEMICAL HAZARDS - FLAMMABLE: Contents under pressure. Do not use near heat, sparks or open flame. Do not puncture or incinerate container. Exposure to temperatures above 120" F may cause bursting. 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 6 to 8 inches from skin or clothing and spray with a slow sweeping motion. 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. Splay shirts, parts, socks, and hats. For ticks and chiggers also spray cuffs, socks and around other openings in outer clothing. Will not damage cotton, wool, or nylon. Do not apply on or near: acetate, rayon, spendex or other synthetics (other than nylon), furniture, plastics, watch crystals, leather and painted or varnished surfaces including automobiles.

STORAGE AND DISPOSAL

STORAGE: Store in a cool, dry place away from heat, sparks and open flame.

4822-380 (15% DEET aerosol)

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DISPOSAL: Do not puncture or incinerate!

If empty: This container may be recycled in the few but growing number of communities where aerosol can recycling is available. Before offering for recycling, empty the container by using the product according to the label. If recycling is not available, place in trash.

If partially filled: Call your local solid waste agency or 1-800-529-3394 for disposal instructions.



[Note to reviewer: The STEEL recycle symbol might be used on final printed label if space allows.]

(Contains no CFCs or Other Ozone Depleting Substances. Federal Regulations Prohibit CFC Propellants in Aerosols [or optional graphic below])



Questions? Comments? Call 800-558-5252 or write Helen Johnson. ©2009 S.C. Johnson & Son,Inc. Racine, W I 53403-2236 USA. All Rights Reserved

EPA REG. NO. 4822-380

EPA EST. NO. 4822-XX-X