

U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs Registration Division (7505P) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460 EPA Registration No.

4822-51

Date of Issuance:

SEP 0 5 2008

NOTICE OF PESTICIDE:

Registration

☑ Reregistration

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

Term of Issuance:

Unconditional

Name of Pesticide Product:

OFF! Insect Repellent Foam Type

Name and Address of Registrant (include ZIP Code):

S.C. Johnson & Son, Inc.

1525 Howe Street

Racine, WI 53403

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 is made to the label:

A copy of your label stamped "Accepted with Comments" is enclosed for your records.

Signature of Approving Official:

Date:

Refer to Page 3.

Richard J. Gebken, Product Manager (10) Registration Division, Insecticide Branch SEP 0 5 2008

1. Page 1 and 2:

- a. Remove the following Unacceptable disease vector claims:
 - i. Mosquitoes
 - 1. Encephalitis
 - a. Japanese
 - b. Venezuelan equine
 - c. Murray Valley
 - 2. Ross River Fever
 - 3. Barmah Forest Disease
 - 4. Dengue Fever
 - 5. Yellow Fever
 - 6. Rift Valley Fever
 - ii. Ticks
 - 1. European Tick Borne Encephalitis
 - iii. Black Flies

Repels Black Flies that carry Onchocerciasis

- 1. Remove the "(spritz)" from the 2nd to the last marketing claim.
- 2. Page 2 and 3:
 - a. Within the ingredient statement, replace the words "Inert Ingredients" with "Other Ingredients"
 - b. Within the "Hazards to Humans" section, revise the statement "Wash thoroughly with soap and water after handling." To "Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco" ¹
 - c. Within the First Aid Section, revise the statement "Skin: If you or your child react to this product, discontinue use, takeoff contaminated clothing, wash treated skin and call a poison control center or doctor for treatment advice." to "If you suspect a reaction to this product, discontinue use, wash treated skin, and call your local poison control center."
 - d. Within the section entitled "TO APPLY TO FACE", move the following DEET statements "Do not apply to children's hands." and "When using on children, apply to your own hands and then put it on the child." to the previous paragraph on page 2. The DEET RED document does not limit this language when applying to the facial area only.
 - e. Add the required header "Storage and Disposal" directly above the Storage and Disposal section. In addition, revise the sentence "Do not reuse this container" to "Do not reuse or refill this container."
- 3. 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.
- 4. 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

¹ Refer to the Label review manual Chapter 7, D, 6, Table 3 and Table 6.

² Refer to the Label review manual Chapter 13, Section IV.

guidelines.

5. 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 Assurance. As an alternative, you may refer consumers to the company's phone number or email address.

If you have any questions, you may contact Carmen Rodia, at (703) 306-0237. Two (2) copies of the finished labeling must be submitted prior to releasing the product for shipment.

Sincerely,

Richard Gebken

Product Manager 10

Insecticide Branch

Registration Division (7505C)

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Enclosure: Label Stamped as "Accepted with Comments"

OFF! Insect Repellent Foam Type [primary name of record]

- SC Johnson A Family Company
- INSECT REPELLENT
- Keeps mosquitoes away from you!
- (Provides protection from) (Protects against) (Fights off Repels) (Works on)
 mosquitoes, biting flies, ticks (including ticks that cause Lyme Disease), gnats,
 no-see-ums, chiggers and fleas
- Repels insects
- Repels bugs, not people
- Non-greasy
- The OFF! repellent you'll want on
- Feels great(!)
- Proven protection against mosquitoes
- Mosquito protection
- Hours of protection from mosquitoes
- (Also) repels deer flies, sand flies, and most other flies, ticks and chiggers
- Repels fleas from treated skin
- Not greasy, won't stain, resists perspiration
- HOLD UPRIGHT WHEN SPRAYING
- Contains DEET (N,N-Diethyl-meta-toluamide)
- Mosquito protection
- Repels mosquitoes that may carry West Nile Virus
- · Repels mosquitoes that may carry diseases
- Repels mosquitoes that may carry (St. Louis) (Eastern equine) (Western equine) (LaCrosse) (Japanese) (Cache Valley) (Venezuelan equine) (Murray Valley) encephalitis
- Repels mosquitoes that may carry (Ross River Fever) (Barman Forest Disease)
 (Dengue Fever) (Yellow Fever) (Rift Valley Fever)
- 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 Onchocerciasis
- Up to 6 hours of mosquito protection
- (OFFI) (products) also available in (aerosol) (spritz) (towelette) (and great fragrances tool)
- Keeps bugs OFF!

KEEP OUT OF REACH OF CHILDREN

WARNING

See additional Precautions on Back Panel

ACCEPTED
with COMMENTS
In EPA Letter Dated

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. Net Wt. 1 - 12 oz.

HOLD UPRIGHT WHEN SPRAYING

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 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.

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

PHYSICAL & CHEMICAL HAZARDS - FLAMMABLE: Contents under pressure. Do not use near heat, sparks or open flame. Do not puncture or incinerate containers. Exposure to temperature 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.

Shake before using. Hold spout next to palm of hand, press valve button and release puff of foam about size of a quarter. Rub hands together; spread evenly with hand to moisten all exposed skin and thin clothing, reapplying as needed to cover all exposed areas. 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 other 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: 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 corresponding graphic below).)



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

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