


4822-368

9/16/2008

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	U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Registration Division (7505P) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460	EPA Registration No. 4822-368	Date of Issuance: SEP 16 2008
NOTICE OF PESTICIDE: <input type="checkbox"/> Registration <input checked="" type="checkbox"/> Reregistration (under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)		Term of Issuance: Unconditional Name of Pesticide Product: OFF! Insect Repellent Formula 1990 #3	
Name and Address of Registrant (include ZIP Code): S.C. Johnson & Son, Inc. 1525 Howe Street Racine, Wisconsin 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.			
<p>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.</p> <p>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.</p>			
<p>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.</p> <p>Based on your response to the Reregistration Eligibility Decision document(s), EPA has reregistered the product listed above provided that the changes listed on page 2 of this Notice of Reregistration are made to your label. A copy of your label stamped "Accepted with comments" is enclosed for your records.</p>			
Signature of Approving Official: <i>Refer to Page 3.</i> Richard J. Gebken, Product Manager (10) Registration Division, Insecticide Branch		Date: SEP 16 2008	

List of Label Changes for EPA Reg. No. 4822-368:

1. In the bullets on page 1,
 - a. change the following sentence as shown by strikeout "OFF! Insect Repellent Formula 1990 #3 is specially formulated with a lower level of active ingredients to feel and smell better on your skin"; and
 - b. remove any reference to following diseases from the product label as they have been identified not to occur in the United States:
 - Japanese Encephalitis,
 - Cache Valley Encephalitis,
 - Venezuelan Equine Encephalitis,
 - Murray Valley Encephalitis,
 - Ross River Fever,
 - Barmah Forest Disease,
 - Dengue Fever,
 - Yellow Fever,
 - Rift Valley Fever,
 - European Tick Born Encephalitis, and
 - Onchocerciasis.
2. On page 2 under Precautionary Statements, change the sentence "Wash thoroughly with soap and water after handling" to "Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet."
3. On page 2 in the First Aid statements, remove the word "Skin:" prior to the sentence that begins "If you suspect a reaction to this product..." because the suspected reaction may not be limited to dermal symptoms; and
4. On page 2 under the Directions for Use, add the sentence "When using on children, apply to your own hands then put it on the child" to the main Directions for Use section, per the DEET RED. This sentence appears in the "To apply to face" section of the directions for use, but the RED does not limit this statement to facial applications.
5. On page 3, please include the header "Storage and Disposal" directly above the storage and disposal language per 40 CFR §156.10(i)(2)(ix). In addition, please change the sentence "Do not reuse this container" to "Nonrefillable container. Do not reuse or refill this container" per 40 CFR §156.140(a)(1) and (a)(2).

Also, to meet the requirements of the DEET RED, the product must be packaged in containers with a concave trigger to help aim the product, or another comparable mechanism that will ensure that the product will not be inadvertently sprayed in the eyes.

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

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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.

In addition, 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 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) 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 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)

Enclosure: Label stamped "Accepted with comments."

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OFF! Insect Repellent Formula 1990 #3 [primary name of record]

OFF! Skintastic Spray [alternate brand name]

OFF! Skintastic V [alternate brand name]

- **SC Johnson A Family Company**
- Insect Repellent
- Provides protection from Mosquitoes, Ticks (including ticks that cause Lyme Disease), Biting Flies, Gnats, No-see-ums, Chiggers and Fleas
- Repels insects
- Fresh Scent
- Baby powder fresh scent
- Non-greasy
- With Aloe vera
- Low DEET formula
- OFF! Insect Repellent Formula 1990 #3 is specially formulated with a lower level of active repellent ingredients to feel and smell better on your skin.
- Repels mosquitoes, biting flies, ticks (including ticks that cause Lyme Disease), deer flies, gnats, no-see-ums, chiggers and fleas up to 2 hours from treated skin and clothing.
- OFF! Insect Repellent Formula 1990 #3 is effective, dependable protection that does not feel greasy or oily.
- It won't stain and resists perspiration.
- OFF! Insect Repellent Formula 1990 #3 has a fresh, clean (baby powder fresh) fragrance that won't leave you smelling like a bug repellent.
- Keeping insects away never felt so good.
- Contents: Ethyl alcohol, DEET, Fragrance, Aloe
- 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) (Barmah 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**

ACTIVE INGREDIENT:

DEET..... 7%

INERT INGREDIENTS:..... 93%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See additional precautions on back panel

ACCEPTED
with COMMENTS
In EPA Letter Dated

9-16-08
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.

4822-360

NET WT. 1 - 12 fl. oz.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS - CAUTION: Causes *moderate* eye irritation. Avoid contact with eyes. *Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. 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.

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.

PHYSICAL & CHEMICAL HAZARDS – FLAMMABLE: Do not use near heat or open flames. Keep treated surfaces away from fire, sparks, 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.** 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

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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

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EPA Est. No. 4822-XX