


4822-167

9/5/2008

16

 <p>U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Registration Division (7505P) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460</p>	EPA Registration No. 4822-167	Date of Issuance: SEP 05 2008
<p>NOTICE OF PESTICIDE: <input type="checkbox"/> Registration <input checked="" type="checkbox"/> Reregistration (under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)</p>	Term of Issuance: Unconditional	
	Name of Pesticide Product: OFF! INSECT REPELLENT FORMULA V	
<p>Name and Address of Registrant (include ZIP Code): S.C. Johnson & Son, Inc. 1525 Howe Street Racine, WI 53403</p>		
<p>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>		
<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 Document(s), EPA has reregistered the product listed above provided that the following change is made to the label:</p> <ol style="list-style-type: none">1. Page 1:<ol style="list-style-type: none">a. Remove the following unacceptable vector/disease claims:<ol style="list-style-type: none">i. Mosquitoes<ol style="list-style-type: none">1. Encephalitis<ol style="list-style-type: none">a. Japaneseb. Venezuelan equinec. Murray Valley <p>A copy of your label stamped "Accepted with Comments" is enclosed for your records.</p>		
Signature of Approving Official: <i>Refer to Page 2.</i> Richard J. Gebken, Product Manager (10) Registration Division, Insecticide Branch	Date: SEP 05 2008	

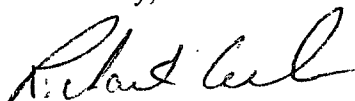
2. Barmah Forest Disease
3. Ross River Fever
4. Dengue Fever
5. Yellow Fever
6. Rift Valley Fever
- ii. Ticks
 1. European Tick Borne Encephalitis
- iii. Black Flies
 1. Repels Black Flies that carry Onchocerciasis
2. Page 2:
 - a. Within the "Hazards to Humans" section, revise the statement "Wash thoroughly 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
3. Page 3:
 - a. Remove the word "Skin:" from the beginning of the reaction statement. The DEET RED document did not limit allergic reactions strictly to skin.
 - b. 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 directly above. The DEET RED document does not limit this language when applying to the facial area only.
4. Page 4:
 - a. Add the required header "Storage and Disposal" directly above the Storage and Disposal section.²

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.

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.

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 as "Accepted with Comments"

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.

OFF! INSECT REPELLENT FORMULA V [master name]
OFF! Deep Woods Insect Repellent V [alternate brand name, 4-18-97]
Deep Woods OFF! Insect Repellent V [alternate brand name, 6-21-91]

- Unscented
- LONG LASTING PROTECTION from mosquitoes, ticks (including ticks that cause Lyme disease), biting flies, gnats and chiggers
- Keeps bugs off!®
- (OFF!) Family Pack
- Always carry [product name]
- (Travel) (Sample) size
- Contains DEET (N,N-Diethyl-meta-toluamide)
- Proven protection against mosquitoes
- Mosquito protection (for up to 8 hours)
- Repels mosquitoes (for up to 8 hours)
- x% (MORE) (FREE)
- (Bonus) (Value) Size
- x (oz) (ounces) at the (same) x (oz) (ounce) price
- x (oz) (ounces) for the (same) price of x (oz) (ounces)

ACCEPTED
with COMMENTS
In EPA Letter Dated
9-5-08
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
4822-167

Note to reviewer: In the claims directly above x is used to represent any number between 1 and 100

- Repels mosquitoes that may carry West Nile Virus
- 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)
- 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)
- **TICKS-OFF®**
- Repels black flies that may carry Onchocerciasis
- (Enjoy) up to 8 hours of protection from (mosquitoes). Also protects against (works on) (repels) (ticks (including ticks that cause Lyme disease)) (biting flies) (stable flies) (black flies) (sand flies) (deer flies) (chiggers) (fleas) (gnats) (no-see-ums)
- (Protects against) (Fights off) (Repels) (Works on) (mosquitoes) (ticks (including ticks that cause Lyme disease)) (biting flies) (stable flies) (black flies) (sand flies) (deer flies) (chiggers) (fleas) (gnats) (no-see-ums)
- 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
- SPRAYS UPSIDE DOWN TOO!
- Provides long lasting protection from mosquitoes, ticks (including ticks that cause Lyme disease) and biting flies: stable flies, black flies, sand flies, and deer flies.
- Also repels chiggers, fleas, gnats, no-see-ums from treated skin and clothing.
- OFF! Insect Repellent Formula V gives effective protection and is not greasy, won't stain and resists perspiration.
- (OFF!) (Deep Woods) (products) also available in a (pump) (towelette)

ACTIVE INGREDIENT:

DEET..... 25%

INERT INGREDIENTS:.....75%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Additional Precautions on Back Panel

NET WT.

OZ.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS - CAUTION: Causes moderate eye irritation. Harmful if swallowed. Avoid contact with 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 unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

5/6

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: Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 120° F may cause bursting. Do not expose treated surfaces near 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. 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].)



EPA Est. No. 4822-XX