



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

February 17, 2016

Dan Hollas  
S.C. Johnson & Son, Inc.  
1525 Howe Street  
Racine, WI 53403

Subject: Label Amendment – Add Claims against Mosquitoes That May Carry Zika Virus  
Product Name: OFF! INSECT REPELLENT FORMULA V  
EPA Registration Number: 4822-167  
Application Date: January 27, 2016  
Decision Number: 513697

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.

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 Maggie Rudick by phone at 703-347-0257, or via email at [rudick.maggie@epa.gov](mailto:rudick.maggie@epa.gov).

Sincerely,

A handwritten signature in black ink, appearing to be 'J S' with a long horizontal stroke extending from the 'S'.

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

Enclosure

## OFF! INSECT REPELLENT FORMULA V [EPA base file name]

OFF! Deep Woods Insect Repellent V [alternate brand name, 4-18-97]

OFF! Explore Insect Repellent | *[alternate brand name 3-29-13]*

OFF! Explore Insect Repellent | Refills [alternate brand name 3-29-13]

ACTIVE INGREDIENT:

DEET..... 25%

OTHER INGREDIENTS:.....75%

KEEP OUT OF REACH OF CHILDREN

## CAUTION

See Additional Precautions on Back Panel

(Contains)

(X Refillable (holder(s)) (unit(s)) (cartridge system(s)) (carabiner(s)) (case(s)) (carabiner case(s)) (cartridge sprayer(s)) (personal repellent(s)) (spray(s)))

(X (Repellent) refill(s))

(Net WT.) ((Net) Contents) X OZ. (X g)

([X (cans) (aerosols)(refills) @ X OZ. (X g) each])

## PRECAUTIONARY STATEMENTS

**HAZARDS TO HUMANS - CAUTION:** Causes moderate eye irritation. Avoid contact with 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.

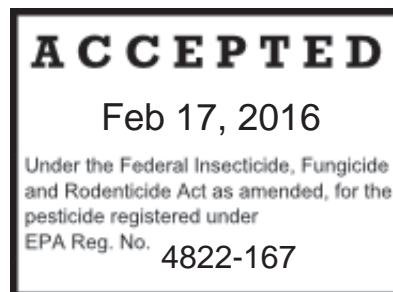
If swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

If you suspect a reaction to this product, discontinue use, wash treated skin, and call your local poison control center.

**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.**



*[Note to reviewer: Table A shows options for terms used to identify an aerosol can holder in the optional directions or other statements that follow]*

(Table A) Options for aerosol can holder terms	
<ul style="list-style-type: none"><li>• Holder</li><li>• Unit</li><li>• Cartridge system</li><li>• Carabiner</li></ul>	<ul style="list-style-type: none"><li>• Case</li><li>• Carabiner case</li><li>• Cartridge sprayer</li></ul>

((Product name) (OFF!) (insert holder term from Table A) Set-Up)

*[Optional holder set up - Option 1]*

To prepare (product name) (OFF!) (insert holder term from Table A) (To insert repellent (refill)):

1. Remove one (mosquito) (insect) repellent (refill) from its packaging (and remove (the) (dust) cap).
2. (Squeeze) (pinch) (buttons) (tabs) (and) (twist) (to) remove (detach) (separate) (the) top of (the) (insert holder term from Table A)
3. (Insert) (place) (refill) into (the) (bottom of) (the) (insert holder term from Table A)
4. (Reattach) (snap) the (top of) (insert holder term from Table A) to the (bottom of) (the) (insert holder term from Table A)
5. Clip the (insert holder term from Table A) to your belt, pants/short(s) waistband, backpack, gear, or store in any other convenient location.

*[OR]*

*[Optional holder set up - Option 2]*

Remove dust cap from (aerosol) (can) (bottle) (refill). (Press buttons) (pinch buttons) (squeeze) (twist) (rotate) (to) Remove the (base) (bottom) from the top and insert (aerosol/can/bottle) refill into the (base) (bottom). Reattach the top to the (base) (bottom).

*[Optional section for holder use]*

To (access) (use) repellent:

1. (Squeeze) (pinch) (buttons) (tabs) (and) (twist) (to) remove the bottom of (insert holder term from Table A) from the (top of the) (insert holder term from Table A)
2. Spray repellent as (indicated) (directed)
3. After applying repellent, (reattach) (snap) the bottom of the (insert holder term from Table A) to the top of the (insert holder term from Table A)

*[Optional clarifying text for pictograms for holder directions, if used:]*

1. Remove (refill).
2. (Twist to) (Separate) (Remove) the top of (insert holder term from Table A) from the bottom of (insert holder term from Table A).
3. Insert refill into the bottom of (insert holder term from Table A).
4. (Reattach) (snap) the top (insert holder term from Table A) to the bottom of (insert holder term from Table A)
5. Attach to a convenient location (on you or your gear).
6. To use, (twist to) remove the bottom of (insert holder term from Table A) from the top of (insert holder term from Table A)
7. Spray repellent.

(To Apply Spray) (To Apply Repellent) (When Applying Repellent)

(Shake well before each use.) ((Squeeze tabs and) pull cap to remove.) 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. 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 AND DISPOSAL

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

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 labels of steel can if space allows.]

(Aluminum can, please recycle)

[Note to reviewer: The aluminum recycle symbol might be used on final printed label of aluminum can 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 (Sold by:) © 2014 S. C. Johnson & Son, Inc., Racine, WI 53403-2236 U.S.A. All Rights Reserved

EPA Reg. No. 4822-167

EPA Est. No. 4822-XX-X

(Made in [insert country])  
([Insert holder term from Table A] made in [insert country])  
((Refill) (Aerosol) made in [insert country])

*[For small size aerosol cans with a peel-out label, a referral statement will be utilized]*

[Language on optional holder]  
Read the label inside before use.  
(Made in [insert country])

[Optional marketing statements for all label options]

- SC Johnson A Family Company
- A family company since 1886. Fisk Johnson
- 25% DEET
- Unscented
- LONG LASTING PROTECTION from mosquitoes, ticks (including ticks that may cause Lyme disease), biting flies, gnats and chiggers
- Keeps bugs off!®
- BUG-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)
- Mosquito protection that you can feel confident will last 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)
- [\*\*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) (Cache Valley) encephalitis (for up to 8 hours)
- 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)
- Repels ticks that may carry (Lyme disease) (Rocky Mountain Spotted Fever) (Tick Paralysis) (Ehrlichiosis) (Powassan Encephalitis)
- TICKS-OFF®
- Up to 8 hours of (effective) mosquito protection
- (Enjoy) up to 8 hours of protection from (mosquitoes). Also protects against (works on) (repels) (ticks (including ticks that may 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)
- Maximum protection (keeps working) (for) up to 8 hours against mosquitoes
- (Proven) (Effective) Protection (you can count on for up to (8) hours hours) (from mosquitoes that may carry West Nile Virus)
- (Delivers) (Powerful) protection (keeps working) for up to 8 hours hours against mosquitoes
- Proven shield for up to 8 hours against mosquitoes (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)
- Enjoy the (outdoors, the great outdoors, backyard, outside, park, woods/forest) with up to 8 hours of protection against mosquitoes
- SPRAYS UPSIDE DOWN TOO!
- Turn (top of) nozzle counterclockwise to unlock
- Provides long lasting protection from mosquitoes, ticks (including ticks that may 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)
- Dries quickly
- Sprays evenly
- Fine (aerosol) mist (spray)
- Fine (aerosol) spray
- Light (aerosol) mist (spray)
- Light (aerosol) spray
- Provides (quick) (fast) (easy) (aerosol) protection
- Provides (even) (broad) (full) (aerosol) coverage
- (For) you
- For (more) active outdoor adventures
- For (hiking) (fishing) (hunting) (camping) (backpacking)
- (Contains) Deep Woods (formula)
- (Secure) snap-on cap (attaches to caribiner)
- Portable (protection)
- Light & compact

[Optional marketing statements for refillable holder system]

- (Multiple) (OFF!) Refills available
- Attaches securely to gear
- (Accessible) (Refillable) (Personal) (Mosquito) (Portable) Spray
- (Accessible) (Refillable) (Portable) Personal repellent



Table B [Note to reviewer: information in Table B is to be used for insertion in the statements that follow]

Holder Descriptor	Options for aerosol can holder terms
<ul style="list-style-type: none"> <li>• Rugged adventure</li> <li>• Crush-resistant</li> <li>• Leak-Resistant</li> <li>• Water-Resistant</li> <li>• Durable</li> <li>• Accessible</li> <li>• Refillable</li> <li>• Personal</li> <li>• Portable</li> <li>• Light</li> <li>• Compact</li> <li>• Aluminum</li> </ul>	<ul style="list-style-type: none"> <li>• Holder</li> <li>• Unit</li> <li>• Cartridge system</li> <li>• Carabiner</li> <li>• Case</li> <li>• Carabiner case</li> <li>• Cartridge sprayer</li> </ul>

- [Insert holder descriptor(s) from Table B] [insert holder term from Table B]
- Always carry your (OFF!) [Insert holder descriptor(s) from Table B] [insert holder term from Table B]
- Works with (name of starter kit) (OFF!) [Insert holder descriptor(s) from Table B] [insert holder term from Table B]
- Compatible with (name of starter kit) (OFF!) [Insert holder descriptor(s) from Table B] [insert holder term from Table B]
- Fits (name of starter kit) (OFF!) [Insert holder descriptor(s) from Table B] [insert holder term from Table B]
- Refill(s) in [insert holder term from Table B]
- Refill in [insert holder term from Table B]

[Note to reviewer: Alternate Segmentation Options: to be used in conjunction with a reference to another OFF! Product appropriate to the claim.

“You” will be used in conjunction with a reference to an approved personal repellent.

“Your gear” & “Your tent” will be used in conjunction with a reference to an approved repellent product for use on tent.

“Your area” & “Your campsite” will be used in conjunction with a reference to an approved area repellent product.]

- For a (full) (complete) (range) (line) of (mosquito) (protection) (OFF! Outdoor) options, choose products for:  
 (you) (your gear) (tent))(your (area) (campsite))
- For you, for your (gear) (tent), for your (area) (campsite)