

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

April 23, 2019

Dan Hollas Registration Specialist S.C. Johnson and Son, Inc. 1525 Howe St., M.S. 149 Racine, WI 53403

Subject: Notification per PRN 98-10 – Addition of marketing claims.

Product Name: OFF!® Insect Repellent Formula V

EPA Registration Number: 4822-167 Application Date: March 14, 2019

Decision Number: 549497

Dear Mr. Hollas:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped "Notification" and will be placed in our records.

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.

If you have any questions, you may contact please contact Jennifer Gaines at 703-305-5967 or via email at gaines.jennifer@epa.gov.

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Sincerely,

Elizabeth Fertich

Product Manager 04

Invertebrate & Vertebrate Branch 1

Registration Division (7505P)

Office of Pesticide Programs

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 I [alternate brand name 3-29-13]

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

OFF!® Sportsmen Insect Repellent 4 [alternate brand name 2-20-2019]

OFF!® Sportsmen Insect Repellent 4 Tick [alternate brand name 2-20-2019]

NOTIFICATION

4822-167

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

04/23/2019

ACTIVE INGREDIENT:

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		
 Holder 	Case	
• Unit	 Carabiner case 	
 Cartridge system 	 Cartridge sprayer 	
 Carabiner 		

((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].)



[Optional graphic]



Questions? Comments? Call 800-558-5252 or write Helen Johnson (Sold by:) © 2019 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
- SC Johnson A family company at work for a better world
- 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
- BUZZ OFF!TM
- (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!
- Works Upside Down
- Sprays Upside Down
- 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 chiqqers, 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
- EvenSpray (Technology)
- EvenCover (Technology)
- SoftCover (Technology)
- SmoothCover (Technology)
- 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
- Precision spray
- Even application
- Full reach spray
- Provides (uniform) (consistent) (even) (spray) 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
- Shoplifting is a crime (!)

[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
 Rugged adventure 	Holder
 Crush-resistant 	Unit
 Leak-Resistant 	Cartridge system
 Water-Resistant 	Carabiner
 Durable 	Case
 Accessible 	Carabiner case
 Refillable 	Cartridge sprayer
 Personal 	
 Portable 	
Light	
Compact	
Aluminum	

- [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)