

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460-0001

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

November 6, 2012

Ms. Jean M. Fugate, Registration Specialist II S.C. Johnson & Son, Inc. 1525 Howe Street Racine, WI 53403-2236

Subject:

Amended Labeling; Addition of New Optional Marketing Statements & Addressing of Potential

Packaging-Related Changes to Directions for Use

Unscented OFF!® INSECT REPELLENT, EPA Reg. No. 4822-380

Your Submission Dated August 8, 2012

Dear Ms. Fugate:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable with the following label revision provision(s):

#### General Comment(s):

1. Delete all text throughout the subject label that are marked with "strikethrough."

#### Net Weight/Contents Statement section comment(s), page 1 of 7:

2. Net weight or contents for multi-pack products must be stated on a pesticide label in accordance with section (2)(q)(2)(C)(iii) of FIFRA and 40 CFR §156.10(a)(1)(iii). EPA interpretation of the statutory and regulatory requirements is that the label must state the total weight for the entire contents as sold and distributed. In addition, the label may indicate the net weight and quantity of individual units within the carton. For example, "Net Weight 6.25 lbs. (20 - 5oz. packets)." For additional information regarding the "Net Weight/Contents" statement, please refer to Chapter 17 of the Agency's Label Review Manual under "Miscellaneous" at <a href="http://www.epa.gov/oppfead1/labeling/lrm/chap-17.htm">http://www.epa.gov/oppfead1/labeling/lrm/chap-17.htm</a>. As such, you must revise the "Net Contents" statement to read as follows:

"[For individually packaged sprayers:

Net Weight (NET WT.) ((Net) Contents): \_\_ fluid oz.]

[For multi-packs containing a number of individually packaged sprayers:

Net Weight: \_X\*\_ fl. oz. (\_XX\*\*\_ mL) XXX\*\*\* - \_\_ fl. oz. (\_XXXX\*\*\*\*\_ mL containers)

Contains [\_\_ (holder(s)) (unit(s)) (cartridge system(s)) (carabiner(s)) (case(s)) (carabiner case(s)) (cartridge sprayer(s)) (personal repellent(s)) (spray(s)) \_\_ oz. Total)]'

<sup>\*</sup>The net weight of the entire multipack must be displayed in fluid ounces.

<sup>\*\*</sup> The net weight in ml is optional.

<sup>\*\*\*</sup> The total count of the multi-pack must be displayed

<sup>\*\*\*\*</sup> The fluid ounces of each container within the multi-pack must be identified.

Optional Marketing Claims section comment(s), bottom of page 7 of 7:

3. You must delete the newly added optional marketing statements that have been marked with "strikethrough." The Agency is not really sure how the addition of these added optional marketing statements relate to a DEET repellent product that is typically applied to skin or clothing. In addition, there are no added graphics for us to review and/or consider.

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 FIFRA 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 section 12(a)(1)( E) of FIFRA. 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 be 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 EPA's Office of Enforcement and Compliance Assurance (OECA). As an alternative, you may refer consumers to the company's phone number or e-mail address.

A copy of your label stamped "Accepted with Comments" is enclosed for your records. Please submit two (2) copies of the final printed labeling, incorporating the above changes, before releasing the product for shipment. If these conditions are not complied with, the registration will be subject to cancellation in accordance with section 6(e) of FIFRA. Your release for shipment of the product bearing amended labeling constitutes accepting of these conditions. If you have any questions about this label review, please contact Mr. Carmen J. Rodia, Jr. at (703) 306-0327 or via e-mail at <u>Rodia.Carmen@epa.gov</u>.

Sincerely Yours,

Richard J. Gebken Product Manager (10) Insecticide Branch

Registration Division (7504P)

Enclosure: 004822-00380 D468620

Label stamped "Accepted with Comments," dated November 6, 2012

# Unscented OFF! Insect Repellent [EPA base file name] OFF! Active Insect Repellent I [alternate brand name, 10/7/04]

**ACTIVE INGREDIENT:** 

KEEP OUT OF REACH OF CHILDREN WARNING

See additional Precautions on Back Panel

(Net Wt.) ((Net) Contents) 1-12 X oz

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:

4322-380

(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))

#### PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS - WARNING: Causes substantial but temporary eye injury. Do not get in 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. Do not use near heat, sparks or open flame. Do not puncture or incinerate container. Exposure to temperatures above 120°F may cause bursting. Keep treated surfaces away from fire or flame until dry.

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#### 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 that follow]

#### (Table A)

#### Options for aerosol can holder terms

- Holder
- Unit
- Cartridge system
- Carabiner
- Case
- Carabiner case
- Cartridge sprayer

((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 repellent (refill) from its packaging (and remove (the) (dust) cap).
- 2. (Squeeze) (pinch) (buttons) (tabs) (and) (twist) (to) remove (detach) (separate) (the) top of (insert holder term from Table A)
- 3. (Insert) (place) (refill) into (the) (bottom of) (insert holder term from Table A)
- 4. (Reattach) (snap) the (top of) (insert holder term from Table A) to the (bottom of) (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)

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### [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 label 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 optional graphic below])



Questions? Comments? Call 800-558-5252 or write Helen Johnson. ©2009 S.C. Johnson & Son, Inc. Racine, W I 53403-2236 USA. All Rights Reserved

EPA REG. NO. 4822-380 XX-X EPA EST. NO. 4822-

[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.

### [Optional marketing statements for all label options]

- SC Johnson A Family Company
- A family company since 1886. Fisk Johnson
- 15% DEET
- EFFECTIVE PROTECTION from Mosquitoes, Gnats, No-See-Ums, Biting Flies, Ticks (including ticks that may cause Lyme disease), Chiggers and Fleas
- Repels mosquitoes, gnats, ticks, biting flies, chiggers & fleas
- Long-lasting protection from mosquitoes, ticks, biting flies, gnats, and chiggers
- FRAGRANCE FREE
- UNSCENTED
- NON-GREASY
- Summer Splash
- Outdoor Fresh
- Tropical Fresh
- Fresh Scent
- (Fragrance name) scent (!)
- (Fragrance name) fragrance (!)
- Scratch'n'sniff

- Scratch here (to smell fragrance name)
- Refreshing(ly) light scent (of fragrance name) (!)
- · Refreshingly light scent your whole family will enjoy
- (OFF!) Family Pack
- Always carry (product name)
- (Travel) (Sample) size
- Try the scent(s) from OFF! Skintastic repellent(s)
- Clean, fresh scent (of fragrance name)
- (Fresh) scent (!)
- · A clean, fresh scent your whole family will enjoy
- Visit www.mosquitoes.com for more information
- Keeps bugs OFF!
- Best smelling (product name) ever
- Repels bug(s), not people
- · Light, refreshing scent repels bugs, not people
- (Fragrance Name) (Product name) won't leave you smelling like a bug repellent
- The bug repellent that doesn't smell like bug repellent
- A better-smelling way to Keep Bugs OFF!
- Keeping bugs OFF! never smelled (so great) (so good) (better)(!)
- Feels great (!)
- Feels good on. Smells even better (!)
- The OFF! repellent you'll want on
- Contains DEET (N, N-Diethyl-meta-toluamide)
- Proven protection against mosquitoes
- Mosquito protection (that you can feel confident will last up to 6 hours)
- Up to 6 hours of (effective) Mosquito Protection
- Repels mosquitoes that may carry West Nile Virus (for up to 6 hours)
- Repels mosquitoes that may carry (St. Louis) (Eastern equine) (Western equine)
   (LaCrosse)
  - (Cache Valley) encephalitis (for up to 6 hours)
- Repels ticks that may carry (Lyme disease) (Rocky Mountain Spotted Fever) (Tick Paralysis) (Ehrlichiosis) (Powassan Encephalitis)
- (Enjoy) up to 6 hours of protection from mosquitoes. Also protects against (ticks) (biting flies) (stable flies) (black flies) (sand flies) (deer flies) (chiggers) (fleas) (gnats) (no-see-ums)
- (Protects against) (Repels) (Works on) (mosquitoes) (mosquitoes that may carry West Nile Virus) (ticks) (biting flies) (stable flies) (black flies) (sand flies) (deer flies) (chiggers) (fleas) (gnats) (no-see-ums)
- Lasts (for) up to 6 hours against mosquitoes
- Stay protected for up to 6 hours from mosquitoes (that may carry West Nile Virus)
- Maximum protection (keeps working) (for) up to 6 hours
- (Proven) (Effective) Protection (you can count on for up to € hours from mosquitoes) (that may carry West Nile Virus)
- ((Delivers) (Powerful) protection) (keeps working) against mosquitoes for up to 6 hours
- Proven shield for up to 6 hours against mosquitoes
- (Fights off) (Protects against) (repels) (niosquitoes (that may carry West Nile Virus))
   (ticks) (biting flies) (stable flies) (black flies) (sand flies) (deer flies) (chiggers) (fleas)
   (gnats) (no-see-ums)

- Up to 6 hours of proven (effective) protection from mosquitoes (that may carry West Nile Virus)
- (Effective) (Proven) protection up to 6 hours from mosquitoes (that may carry West Nile Virus)
- Enjoy the (outdoors, the great outdoors, backyard, outside, park, woods/forest) with up to 6 hours of protection against mosquitoes
- HOLD UPRIGHT WHEN SPRAYING (SPRAYS UPSIDE DOWN TOO!)
- Turn (top of) nozzle counterclockwise to unlock
- New can design
- Provides hours of effective protection from mosquitoes, gnats, and biting flies (deer flies, sand flies, stable flies, and black flies).
- · Also repels ticks, chiggers and fleas from treated skin and clothing.
- · OFF!© is not greasy, won't stain and resists perspiration.
- Sweat-Resistant
- Sweat-Resistance
- With resistance to sweat
- · Designed for people on the go
- Take-Along
- · (Perfect to) take-along with you
- New propellant [Note: only to be used for first 6 months of marketing product containing formulas reflecting CSFs identified as GEN\_SOFs 11535 and 11533]
- New formula [Note: only to be used for first 6 months of marketing product with formulas reflecting CSFs identified as GEN\_SOFs 41535 and 415337
- 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)
- (Secure) snap-on cap (attaches to caribiner)
- Portable (protection)
- Light & compact

#### [Optional labeling for a possible sticker covering the actuator]

Remove before spraying

#### [Optional marketing statements for refillable holder system]

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

Table B [Note to reviewer: information in Table B is to be used for insertion in the

| Holder Descriptor   | Options for aerosol can holder terms   |
|---|--|
| <ul> <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>Reloadable</li> <li>Personal</li> <li>Portable</li> <li>Light</li> <li>Compact</li> <li>Aluminum</li> </ul> | <ul> <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)) relead(s) in [insert holder term from Table B]
- Refill in [insert holder term from Table B]

## {Text describing OFFI line segmentation to be used with or without graphics}

- For complete protection, choose products for: (you) (your gear) (your tent) (your world) (your area) (your campsite)
- For the most complete protection options, choose products for: (you) (your gear) (your tent) (your world) (your area) (your campsite)

[Text to be used in conjunction with graphics to describe alternate OFF! segmentation available]

For you, for your (gear) (tent), for your (area) (world) (campsite)