4822-396

06-10-2009



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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

June 10, 2009

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

Subject: Amended Reregistration Label Unscented OFF!® Skintastic Insect Repellent, EPA Reg. No. 4822-396 Your Submission Dated March 12, 2009

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 Statement:

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

Precautionary Statements, Hazards to Humans section comment(s):

2. To facilitate inclusion of language from the RED for DEET, insert the following text immediately following the 3rd sentence in this section: "If you suspect a reaction to this product, discontinue use, wash treated skin and call your local poison control center. If you go to a doctor, take this repellent product with you."

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. In addition, current labels on DEET repellent products tend to dissolve from contact with the repellent (usually liquids). All reregistered DEET product labels must use materials that remain permanent and readable for the reasonable life of the product.

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. 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 FIFRA section 6(e). 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 (7505P)

Enclosure: Label stamped "Accepted with Comments" 004822-00396 D407654

Unscented OFF! Skintastic Insect Repellent [primary name of record] OFF! Skintastic VIII [alternate brand name] OFF! FamilyCare Insect Repellent VII [alternate brand name 5/8/06]

- SC Johnson A Family Company
- Low DEET Formula
- The Right Amount of Protection from Mosquitoes, Biting Flies, Gnats, Chiggers and Fleas
- With Aloe Vera
- Non-Greasy
- Unscented
- Insect Repellent
- Get the OFF! mosquito protection that is right for you and your family
- Protect your family with Unscented OFF! Skintastic Spray Insect Repellent
- Specially formulated to feel and smell better on your skin
- Provides Protection from Mosquitoes, Biting Flies, Gnats, No-see-ums, Chiggers and Fleas
- (Great for) (activities such as) (playing in the yard), (barbecuing), (playing and relaxing outdoors), (or) (relaxing on the deck)
- Tropical Fresh (spray) (aerosol)
- Fresh Scent
- Contains (with) Deet (N, N, Diethyl-meta-toluamide)
- Contains (with) Deet (N, N; Diethyl-meta-toluamide) Mosquito Protection
- xx% (MORE) (FREE)
- Bonus (Value) (Size) (Pack)
- xx oz (ounces) at the (same) 6 oz (ounce) price
- xx oz (ounces) for the (same) price of 6 oz (ounce)
- Twin-Pack
- Buy one get one Free (!)
- For Family
- OFF! Family Pack
- (Place) (Carry) (Have) (Unscented OFF! Skintastic Spray Insect Repellent)(one): (everywhere) (in your) (purse) (glove compartment) (glove box) (golf bag) (tennis bag) (tackle box) (tent) (book bag) (backpack) (fanny pack) (beach bag) (boat) (summer cabin) (first-aid kit)
- For use at (;) (home) (or) (on the go) (on a picnic) (picnicking) (camping) (at sporting events) (boating) (fishing) (hiking) (while) (gardening) (playing) (outside)
- Keep(s) Bugs OFF!®
- Take Along (OFF! repellent) (Unscented OFF! Skintastic Spray Insect Repellent) (!)
- On the go (OFF! repellent) (Unscented OFF! Skintastic Spray Insect Repellent) (!)
- (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
- 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

ACCEPTED With COMMENTS In EPA Letter Dated:

Under the Federa Insecticide, Fungicia and Rodenticide Act, As amended, for pesticide Registered under EP//Reg.

4822-

Page 1 of 4

3/12/09

- (A) scent(s) from OFF! Skintastic repellent(s), (so you can enjoy the outdoors)
- Best smelling (product name) ever
- Repels bug(s), not people
- Light, refreshing scent repels bugs, not people
- (Fragrance Name) (Unscented OFF! Skintastic Spray Insect Repellent) 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
- Keeping insects away never felt better
- OFFI: (X)+ years of experience in Mosquito Protection
- Repels mosquitoes that may carry West Nile Virus
- Repels mosquitoes that may carry (St. Louis) (Eastern equine) (Western equine) (Lacrosse) (Cache Valley) encephalitis
- HOLD UPRIGHT WHEN SPRAYING (SPRAYS UPSIDE DOWN TOO)
- OFF! Skintastic Family Insect Repellent is specially formulated with a lower level of active repellent ingredient to feel and smell better on your skin.
- Effectively repels mosquitoes, biting flies, deer flies, no-see-ums, gnats, chiggers and fleas from treated skin and clothing.
- It is effective, dependable protection that does not feel greasy or oily.
- It won't stain and resists perspiration.
- OFF! Skintastic Family Insect Repellent has a fresh, clean fragrance that won't leave you smelling like a bug repellent.
- Contents: ethyl alcohol, DEET, hydrocarbon propellant, fragrance, aloe vera
- Repels ticks that may carry (Lyme disease) (Rocky Mountain Spotted Fever) (Tick Paralysis) (Ehrlichiosis) (Powassan Encephalitis)
- Trial size (aerosol)
- Created by Skintastic
- From Skintastic

[Note to reviewer: Bulleted statements and text within parenthesis are optional]

[Optional labeling for a possible sticker covering the actuator] Remove before (spraying) (using)

KEEP OUT OF REACH OF CHILDREN WARNING See Additional Precautions on Back Panel

Net. Wt. 1-12 oz.

PRECAUTIONARY STATEMENTS

4822-396 (7% DEET aerosol)

Page 2 of 4

3/12/09

6.005

HAZARDS TO HUMANS: WARNING – Causes substantial but temporary eye injury. Do not get in eyes. 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-you-suspect-a-reaction-to-this-product, discontinue-use, wash-treated-skin, and call-your-local-poison---control-center---

PHYSICAL & CHEMICAL HAZARDS – **Extremely flammable**: Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperature above 120°F may cause bursting. 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. 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 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 fire, sparks and heated surfaces. 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 optional graphic below].)



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

EPA Reg. No. 4822-396

EPA Est. No. 4822-XX-X

3/12/09