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# U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs Registration Division (7505P) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460 EPA Registration No.

4822-396

Date of Issuance:

SEP 0 5 2008

NOTICE OF PESTICIDE: ☐ Registration

☑ Reregistration

(under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)

Term of Issuance:

Unconditional

Name of Pesticide Product:

**Unscented OFF! Skintastic Insect Repellent** 

Name and Address of Registrant (include ZIP Code):

S.C. Johnson & Son, Inc.

1525 Howe Street

Racine, WI 53403

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.

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.

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.

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.

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:

A copy of your label stamped "Accepted with Comments" is enclosed for your records.

Signature of Approving Official:

Date:

Refer to Page 3.

SEP 0 5 2008

Richard J. Gebken, Product Manager (10) Registration Division, Insecticide Branch

EPA Form 8570-6

## 1. Page 1 and 2:

- a. If the alternate trade name "OFF! Skintastic VIII" or any additional name without the words "Insect Repellent" in conjunction with this product. The words "INSECT REPELLENT" must be displayed prominently on the front panel of all product labels, immediately after the brand name, in capital lettering, with large, contrasting, bold-faced type.
- b. Remove the statements "New", "and improved", and "introducing" from all locations. These terms are reserved for new products, and or fragrance changes permitted for a period of 6 months from a stamped approved label. <sup>1</sup>
- c. Remove the following comparative claims: "New (consumer) preferred fragrance (or scent)", "Best smelling (product name) ever "From the Ill brand of insect repellents", "From (the makers of) OFF!, the #1 brand of insect repellents", "From America's #1 brand of insect repellents", "(From the) (America's) #1 trusted brand of insect repellents", "OFF!: 40+ years of experience in Mosquito Protection", and "Families have trusted the OFF! protection for more than 40 years"
- d. Revise the following claim by removing the "s" from ingredients: "OFF! Skintastic Family Insect Repellent is specially formulated with a lower level of active repellent ingredients to feel and smell better on your skin."
- e. The word "fragrance" within the statement "Contents: ethyl alcohol, DEET, hydrocarbon propellant, fragrance, aloe vera." should be placed in brackets to denote its use only for formulations that do not contain any type of fragrance. SCJ should also clearly indicate on the label when this statement is and is not going to be used.

# 2. Page 3:

- 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" <sup>2</sup>
- 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.
- c. Add the required header "Storage and Disposal" directly above the Storage and Disposal section.<sup>3</sup> In addition, revise the sentence "Do not reuse this container" to "Do not reuse or refill this container."
- 3. 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.
- 4. 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

<sup>1</sup> These statements appear on all previous labels back to May 19, 2003.

<sup>2</sup> Refer to the Label review manual Chapter 7, D, 6, Table 3 and Table 6.

<sup>3</sup> Refer to the Label review manual Chapter 13, Section IV.

- have not previously submitted efficacy data sufficiently consistent with the revised guidelines.
- 5. 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 Assurance. As an alternative, you may refer consumers to the company's phone number or email address.

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"

# Unscented OFF! Skintastic Insect Repellent [primary name of record] OFF! Skintastic VIII [alternate brand name]

- 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
- New
- 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) (!)
- New (and improved) (fragrance name) scent (!)
- New (and improved) (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 new scent(s) from OFF! Skintastic repellent(s)
- Clean, fresh scent (of fragrance name)
- (Fresh) (new) scent (!)
- A clean, fresh scent your whole family will enjoy

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

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- Visit <u>www.mosquitoes.com</u> for more information
- Introducing (a) new scent(s) from OFF! Skintastic repellent(s), (so you can enjoy the outdoors)
- New (consumer) preferred fragrance (or scent)
- Best smelling (product name) ever
- Repels bug(s), not people
- New light, refreshing scent repels bugs, not people
- (Fragrance Name) (Unscented OFF! Skintastic Spray Insect Repellent) won't leave you smelling like a bug repellent
- (Introducing) 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. Now smells even better (!)
- The OFF! repellent you'll want on
- Keeping insects away never felt better
- From the #1 brand of insect repellents
- From (the makers of) OFF!, the #1 brand of insect repellents
- From America's #1 brand of insect repellents
- (From the) (America's) #1 trusted brand of insect repellents
- OFF!: 40+ years of experience in Mosquito Protection
- Families have trusted the OFF! protection for more than 40 years
- Repels mosquitoes that may carry West Nile Virus
- HOLD UPRIGHT WHEN SPRAYING (SPRAYS UPSIDE DOWN TOO)
- o OFF! Skintastic Family Insect Repellent is specially formulated with a lower level of active repellent ingredients 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
- 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 c	overing the actuator	* * * * *
Remove before (spraying) (using) ACTIVE INGREDIENT:		
DEET	*****	6 4 8 6 7 11 11 11
KEEP OUT OF REACH OF CHILDREN WARNING See Additional Precautions on Back Panel		
bee Hadrichal Freeditions on Back I and		* *

Net. Wt. 1-12 oz.

#### PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS: WARNING – Causes substantial but temporary eye injury. Do not get in eyes. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. 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.

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 – 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. 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 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.

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[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. ©2006 S.C. Johnson & Son, Inc. Racine, WI 53403-2236 USA. All Rights Reserved.

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