

4822-362

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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
OFF!® Lotion Formula II, EPA Reg. No. 4822-362
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."

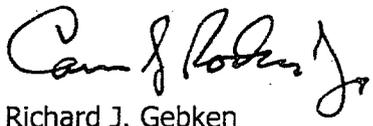
Current labels on DEET repellent products tend to dissolve from contact with the repellent (usually liquids). All reregistered DEET product labels must use materials that remain permanent and readable for the reasonable life of the product.

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 Rodia.Carmen@epa.gov.

Sincerely Yours,

For


Richard J. Gebken
Product Manager (10)
Insecticide Branch
Registration Division (7505P)

Enclosure: Label stamped "Accepted with Comments"

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OFF! Lotion Formula II [primary name of record]

- SC Johnson A Family Company
- Insect repellent
- Provides protection from mosquitoes, Biting Flies, Ticks (including ticks that may cause Lyme Disease), Gnats, No-see-ums and Fleas
- Repels insects
- Light, pleasant scent
- Clean Fresh Scent
- Baby powder fresh scent
- Lotion
- Non-Greasy
- Leaves your skin feeling smooth and natural
- With aloe vera
- Moisturizes with aloe vera
- Feels so good you'll forget you've got it on!
- OFF! Insect screen lotion
- Insect screen lotion
- Low DEET formula
- OFF! Lotion Formula II is a pleasant (baby powder fresh) smelling lotion specially formulated to repel mosquitoes, biting flies, ticks (including ticks that may cause Lyme disease), gnats, no-see-ums and fleas for up to two hours.
- OFF! Lotion Formula II also moisturizes your skin.
- It contains aloe vera to leave skin feeling smooth and natural, never sticky or greasy.
- Keeping insects away never felt so good.
- CONTENTS: Deionized water, DEET, Distearyltrimonium chloride, Petrolatum USP, Glycerin USP, Isopropyl palmitate, Cetylalcohol, Aloe, Dimethicone, Titanium dioxide USP, Methyl paraben, Propyl paraben, Sodium chloride, Fragrance
- Contains DEET (N,N-Diethyl-meta-toluamide)
- 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
- Repels ticks that may carry (Lyme disease) (Rocky Mountain Spotted Fever) (Tick Paralysis) (Ehrlichiosis) (Powassan Encephalitis)
- Repels black flies

ACCEPTED
 With COMMENTS
 In EPA Letter Dated:
June 10, 2009
 Under the Federal Insecticide, Fungicide
 and Rodenticide Act, As amended, for the
 pesticide Registered under EPA Reg. No:
4822-362

ACTIVE INGREDIENT:

DEET..... 7.5%
 OTHER INGREDIENTS:.....92.5%

KEEP OUT OF REACH OF CHILDREN

WARNING

See additional precautions on back label

NET WT. 0.4 - 12 fl. oz.

PRECAUTIONARY STATEMENTS

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 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.~~

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.**

Spread evenly and completely over all exposed skin. Do not apply over cuts, wounds, irritated or sunburned skin. Apply hand for application to face and neck and rub on. Do not apply near eyes and mouth. Apply sparingly around ears. Use just enough repellent to cover exposed skin. 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. Do not use under clothing. Do not apply on or near: acetate, rayon, spandex, dynel fabrics or other synthetics (other than nylon), furniture, plastics, leather, watch crystals and painted or varnished surfaces including automobiles.

STORAGE AND DISPOSAL

STORAGE: Store away from heat or flame in an area inaccessible to children.

DISPOSAL: Nonrefillable container. Before disposing, empty the container by using the product according to the label. Do not reuse or refill this container. Place in trash or offer for recycling if available.

If partially filled: Call your local solid waste agency or 1-800-529-3394 for disposal instructions. Never place unused product down any indoor or outdoor drain.

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. 4822-362

EPA Est. No. 4822-XX-X

This product may be sold in individual pouches. The following additional labeling may be added to container.

Single Use Pouches

Directions For Use:

- 1) Cut (or tear) corner where indicated at top of pouch.

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- 2) Apply lotion to hand for application to face and neck.
- 3) Spread evenly and completely over all exposed skin.
- 4) Dispose in trash.