


4822-362

9/30/08

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 <p>U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Registration Division (7505P) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460</p>	EPA Registration No. 4822-362	Date of Issuance: SEP 30 2008
<p>NOTICE OF PESTICIDE: <input type="checkbox"/> Registration <input checked="" type="checkbox"/> Reregistration (under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)</p>	Term of Issuance: Unconditional	
	Name of Pesticide Product: OFF! Lotion Formula II	
<p>Name and Address of Registrant (include ZIP Code):</p> <p>S.C. Johnson & Son, Inc. 1525 Howe Street Racine, WI 53403-2236</p>		
<p>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.</p>		
<p>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.</p> <p>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.</p> <p>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.</p> <p>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:</p> <ol style="list-style-type: none">1. The following diseases depicted on the labeling should be removed, since the agency is not permitting diseases that are currently not endemic to the United States: Japanese, Venezuelan equine, and Murray Valley mosquito borne encephalitis; European Tick Borne Encephalitis; Ross River Fever; Barmah Forest Disease; Dengue Fever; Yellow Fever; Rift Valley Fever; and; Onchocerciasis.2. 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".3. Remove the word "Skin" from the beginning of the reaction statement. The DEET RED document does not limit allergic reactions strictly to skin.		

4. Remove the letter "s" in the reference to the term "ingredients", where it states "lower level of active ingredients. . ." on your label.

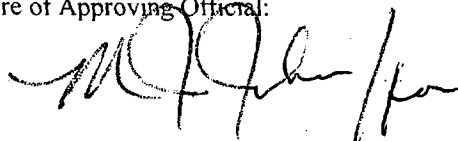
5. The Agency is in the process of developing and improving the current Efficacy Assessment Guidelines for repellent products. The Agency intends to defer the determination of any related efficacy data requirements supporting the claims that may appear on this label until these Efficacy Assessment Guidelines 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 registration for personal repellent products that have not previously submitted efficacy data sufficiently consistent with the revised guidelines.

6. 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 of 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 and email address.

If you have 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.

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

Signature of Approving Official:



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

Date:

9/30/08

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 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 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 diseases**
- **Repels mosquitoes that may carry (St. Louis) (Eastern equine) (Western equine) (LaCrosse) (Japanese) (Cache Valley) (Venezuelan equine) (Murray Valley) encephalitis**
- **Repels mosquitoes that may carry (Ross River Fever) (Barmah Forest Disease) (Dengue Fever) (Yellow Fever) (Rift Valley Fever)**
- **Repels ticks that may carry (Lyme disease) (Rocky Mountain Spotted Fever) (Tick Paralysis) (Ehrlichiosis) (European Tick Borne Encephalitis) (Powassan Encephalitis)**
- **Repels black flies that may carry Onchocerciasis**

ACCEPTED
with COMMENTS
In EPA Letter Dated
September 30, 2008
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No
4022-362

ACTIVE INGREDIENT:
DEET..... 7.5%
INERT 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 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 clothing that may have come in contact with treated skin, wash treated skin and call a poison control center or doctor for treatment advice.

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.**

For best results, spread evenly and completely over all exposed skin. ***Do not apply over cuts, wounds, irritated or sunburned skin.*** Apply to 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 keep product on any longer than necessary. 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: Store away from heat or flame in an area inaccessible to children.

DISPOSAL: ***Before disposing, empty the container by using the product according to the label. Do not reuse 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. ©2004 S.C. Johnson & Son, Inc. Racine, WI 53403-2236 USA. All Rights Reserved

EPA Reg. No. 4822-362

EPA Est. No. 4822-XX

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