

APR 14 2004

Jill C. Geyer
S.C. Johnson & Son, Inc.
1525 Howe Street
Racine, WI 53403-2236

Subject: OFF! Lotion Formula HU
EPA Registration No. 4822-468
Application dated February 20, 2004

Dear Ms. Geyer:

The proposed amendment to the registration for the product cited above under The Federal Insecticide, Fungicide And Rodenticide Act, as amended revising the label in response to PR Notices 2001-1 and 2001-6 and making additional labeling changes is acceptable subject to the comments listed below:

- 1) Place the following statement in the First Aid section:

✻For additional information in case of emergency call toll free (Insert phone number).✻

- 2) The following statements must be added to the directions for use:

✻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.✻

- 3) Add the statement, ✻Wash treated clothing before wearing it again.✻, to the Precautionary Statements.

Once the efficacy guidelines are in place, efficacy data will be required. You will be notified of the efficacy requirements

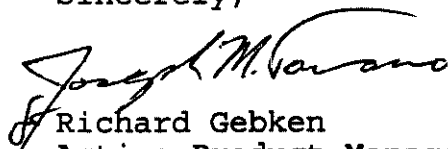
Re-registration for repellent/sunscreen combination products is deferred.

A stamped copy of the amended label is enclosed for your records. Submit two copies of the final label before the product is released for shipment under this revised label.

The Confidential Statements Of Formula dated February 19,2004 for the basic formula and seven alternate formulas are acceptable and have been placed into the file for this product.

If you have any questions or comments please contact Joseph Tavano at (703) 305-6411.

Sincerely,



Richard Gebken
Acting Product Manager 10
Insecticide Branch
Registration Division (7505C)



OFF! Lotion Formula HU

- **SC Johnson A Family Company**
- Insect repellent (with) (plus) Sunscreen
- Provides protection from mosquitoes, biting flies, gnats, no-see-ums and chiggers
- Repels insects
- Light, pleasant scent
- Pleasant scent
- Clean fresh scent
- Lotion
- Spray lotion
- Spritz lotion
- Non-greasy
- Not sticky or greasy
- Leaves your skin feeling smooth and natural
- With aloe vera
- Moisturizes (with aloe vera)
- Feels great on. Keeps bugs (and the sun) off!
- Low DEET formula
- (With) Sunscreen
- (Plus) Sunscreen
- Waterproof Sunscreen
- SPF 15
- Complete Outdoor Protection
- Complete Summer Protection
- Protection from both the sun and annoying mosquitoes (biting insects)
- PABA free
- (Full spectrum) protection from both UVA and UVB rays
- Waterproof
- (Very) Water Resistant
- Sweat Proof
- Sweat resistant
- Sun-Alert: The sun causes skin damage. Regular use of sunscreens over the years may reduce the chance of skin damage, some types of skin cancer, and other harmful effects due to the sun.
- (Liquid) (Spritz) Lotion
- Fine (spray) mist
- Fine (mist) spray
- Sprays evenly (for total coverage)
- Mosquito repellent
- Spritz
- Mist
- Spray
- OFF! Lotion Formula HU provides complete outdoor protection from biting insects and the damaging effects of the sun.
- It's a waterproof sunscreen that provides SPF 15 protection from both UVA and UVB rays.
- It feels great on – not sticky, or greasy, and has a light, clean scent.

ACCEPTED
with COMMENTS
In EPA Letter Dated:
 APR 14 2004

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 4822-468

- And because it's from the makers of OFF!, it's specially formulated to effectively repel mosquitoes, ticks (including ticks that cause Lyme disease), biting flies, gnats, no-see-ums and chiggers for up to 2 hours.
- **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**

ACTIVE INGREDIENT:

DEET..... 7.5%
INERT INGREDIENTS:.....92.5%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See additional precautions on back label

NET WT. 0.4 - 12 fl. oz.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS - CAUTION: Causes moderate eye irritation. Avoid contact with 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.

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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.

For best results, spread evenly and completely over all exposed 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

(Depending on the formula used, the corresponding content listing as stated below will be used.)

ACTIVE SUNSCREEN INGREDIENTS: Octyl Methoxycinnamate, Octyl Salicylate, Benzophenone-3 **OTHER INGREDIENTS:** Deionized Water, DEET, Octyldodecyl Neopentanoate, Glycerin, DEA-Cetyl Phosphate, PVPIEicoseneCopolymer, Stearic Acid, Propylene Glycol (and) Diazolidinyl Urea (and) Methylparaben (and) Propylparaben, Cetyl Alcohol, Silicone Fluid, Magnesium Aluminum Silicate, Fragrance, Xanthan Gum

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(If this product is sold in individual pouches, the following additional labeling may be added to the container: Single use pouches)

Directions for use:

- 1) Cut (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.

(Exp. Month/Year) Lot Code

EPA Reg. No. 4822-468

EPA Est. No. 4822-XX