

4822-515

10/30/2009

1/2



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

October 30, 2009

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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

RE: Product Name: OFF! Botanicals 2
EPA Reg. No: 4822-515
Application for Label Notification Dated October 1, 2009 to make OFF!
Botanicals Insect Repellent the Alternate Brand Name and to update the
storage and disposal statement

Dear Ms. Fugate:


The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under Pesticide Registration (PR) Notice 98-10 dated above. A preliminary screen of this request has been conducted for its applicability under PR Notice 98-10 and it has been determined that the action(s) requested falls within the scope of PR Notice 98-10. Our records have been duly noted, and the label submitted with this application has been stamped "Notification, received and reviewed" and will be placed accordingly in our records.

If you have any questions concerning this action, please feel free to contact Ms. Menyon Adams at (703) 347-8496 or email at adams.menyon@epa.gov.

Sincerely,

Linda Hollis

Linda Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention
Division (7511P)

 <p>United States Environmental Protection Agency Washington, DC 20460</p>	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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Application for Pesticide - Section I

1. Company/Product Number S.C. Johnson & Son, Inc./4822-515	2. EPA Product Manager Dr. Sheryl Reilly	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) S.C. Johnson & Son, Inc./OFF! Botanicals 2	PM# <u>91</u> BPPD	
5. Name and Address of Application (Include ZIP Code) S. C. Johnson & Son, Inc. 1525 Howe St. Racine, WI 53403-2236 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. Product Name	

Section II

<input type="checkbox"/> Amendment – Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated <input checked="" type="checkbox"/> Notification – Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other - Explain below.	<p>NOTIFICATION</p> Date Reviewed: <u>10/30/09</u> Reviewed By: <u>MKA</u>
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Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

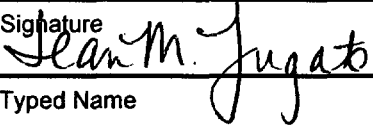
Notification to consolidate already-approved label elements.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms or PR Notice 98-10 and 40CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section III

1. Material This Product Will Be Packaged In:					
Child-Resistant Packaging <input type="checkbox"/> Yes * <input checked="" type="checkbox"/> No <i>*Certification must be submitted</i>	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wgt.	No. Per container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt.	No. Per container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) Foil Pouch
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 0.4 – 16 fluid ounces		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled					

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)		
Name Jean M. Fugate	Title Registration Specialist II	Telephone No. (Include Area Code) (262) 260-2871
Certification		6. Date Application Received (Stamped)
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.		
2. Signature 	3. Title Registration Specialist II	
4. Typed Name Jean M. Fugate	5. Date October 1, 2009	

October 1, 2009

Mr. Alan Reynolds
Microbial Pesticides Branch
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Via Courier**Re: OFF! Botanicals 2****EPA Reg. No. 4822-515****Notification to Consolidate Approved Label Elements per PR Notice 98-10**

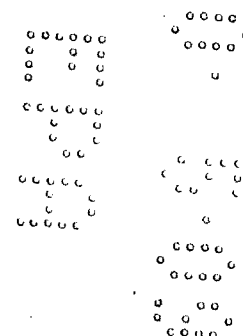
Dear Mr. Reynolds:

On January 30, 2009 S.C. Johnson & Son, Inc. (SCJ) submitted a notification to the Agency to add label language to comply with the Container Rule. The Agency replied on March 31, 2009 that the notification was received, reviewed and would be placed in Agency records.

It has recently come to our attention that some past instruction from the Agency to update the Storage and Disposal section (initial Agency request made 3/9/04 and confirmed as acceptable 4/4/05) was not incorporated into the label submitted March 31, 2009. The specific changes needed are to add a "Storage and Disposal" heading and to place a box around the entire section to clearly distinguish it from other Directions for Use.

SCJ would like to consolidate all approved label elements into one document. Since this consolidation involves no real changes or additions, we feel this certainly would qualify as a notification under PR Notice 98-10, II, N - *Labeling Notifications, Other Revisions*. We would also like to take the opportunity to incorporate the alternate brand name, **OFF! Botanicals Insect Repellent**, submitted to the Agency on May 15, 2000. We have added "[EPA base file name]" following the master name of record, OFF! Botanicals 2.

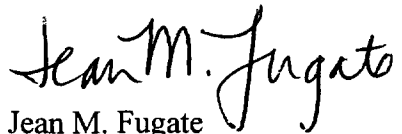
Although none of what is described above is a true addition, I have marked the areas in **bold italics** for ease of reference. In accordance with PR Notice 98-10 we have included a completed Application for Registration and one (1) copy of the subject label.



5/17

Should you have any questions or require anything additional please do not hesitate to contact me directly. Thank you for your assistance with this matter.

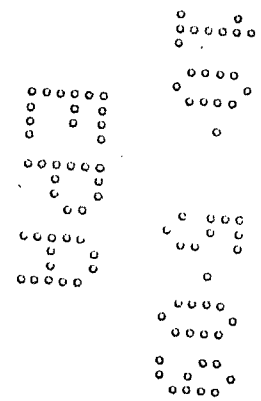
Best regards,



Jean M. Fugate
Registration Specialist II
Phone: (262) 260-2871
Fax: (262) 260-4716
Email: jmfugate@scj.com

Enclosures

cc: Lily Negash (via email)



OFF Botanicals 2 [EPA base file name]
OFF! Botanicals Insect Repellent

(SC Johnson)
(NEW!)
(Contains a) botanically-derived insect repellent
(Pick up a trial size today)
((With)(contains) a plant-based repellent)
(Botanical)
(Put it on to keep bugs OFF!)
(Feels great on. Keeps bugs OFF!)
(Non-greasy)
(Unscented lotion)
(Not sticky or greasy)
(Duplicates the repellency of eucalyptus)
(Contains no (added) fragrances (or dyes))
(Botanically inspired (insect) repellent)
(Protection form annoying (mosquitoes)(black flies)(gnats) (no-see-ums)(chiggers)(ticks)(for up to 2 hours))
((Contains)(with) Aloe (Vera))
(Outdoor protection)
(Moisturizes with Aloe (Vera))
(Provides protection from (mosquitoes)(black flies)(gnats) (no-see-ums)(chiggers)(ticks)(for up to 2 hours))
(Contains no dyes (or fragrances))

(Insect Repellent)
(A Family Company)
(Plant-based repellent)
(Plant-based protection from annoying (mosquitoes)(black flies)(gnats) (no-see-ums)(chiggers)(ticks)(for up to 2 hours))
(Repels (mosquitoes)(black flies)(gnats) (no-see-ums)(chiggers)(ticks)(for up to 2 hours))
(Clean, fresh scent)
(Light, pleasant scent)
(Contains plant extracts (oils, derivatives))
(With (a delicate blend of)(botanical) plant extracts (oils, derivatives))
(A luxurious insect repellent)
(Contains the insect repellent found in eucalyptus)
(Repels the mosquitoes that may carry diseases)
(Repels mosquitoes that may carry West Nile Virus)
(Leaves your skin feeling smooth and natural)
(Eucalyptus scent)
(Plant-based repellent repels (mosquitoes)(black flies)(gnats) (no-see-ums)(chiggers)(ticks)(for up to 2 hours))
(Anti-insect formula with moisturizer)
(Dermatologist Tested)
(Moisturizing(formula)(for beauty without bites))
(New eucalyptus ingredient repels (mosquitoes)(black flies)(gnats) (no-see-ums)(chiggers)(ticks)(for up to 2 hours))

ACTIVE INGREDIENT:

p-Menthane-3,8-diol* 10.0%

OTHER INGREDIENTS 90.0%

*cis/trans isomer ratio: min. 60% (+/-) cis and max. 40% +/- trans

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

See back panel for additional precautionary statements and complete directions for use.

Net Contents: 0.4 through 16-fl. oz.

(OFF! Botanicals 2's unique formula uses a plant-based ingredient (to repel (mosquitoes)(black flies)(gnats) (no-see-ums)(chiggers)(ticks)(for up to 2 hours)) (It contains the insect repellent found in eucalyptus plants.) (This new (eucalyptus) ingredient repels (mosquitoes)(black flies)(gnats) (no-see-ums)(chiggers)(ticks)(for up to 2 hours)(.)(!)) (OFF! Botanicals 2 is effective dependable protection that feels great on – not sticky or greasy (-- and it has a light, clean, fresh fragrance).) (OFF! Protection has never felt better!) (A luxurious moisturizing repellent that repels insects not humans.) ((...) And because it's from the makers of OFF! repellents, it's specially formulated to effectively repel (mosquitoes)(black flies)(gnats) (no-see-ums)(chiggers)(ticks)(for up to 2 hours))

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

CAUTION: Causes moderate eye irritation. Avoid contact with eyes. Do not use on children under the age of three. Apply with caution to small children. Do not allow children to apply this product to themselves. Do not apply to excessively sunburned or damaged skin. For external use only. Wash hands thoroughly with soap and water after applying.

(Note to reviewer: Boxed format or bullets may be used in the First Aid section if label space permits.)

FIRST AID

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. Call a poison control center or doctor for treatment advice. Have the product label with you when calling a poison control center or doctor, or going for treatment.

2/7

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read all directions before using this product.

General Instructions: 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 to eyes and mouth and do not apply to the hands of young children. For continued protection from listed insects, reapply every 2 hours or after swimming, perspiration, vigorous activity or toweling. (After returning indoors, wash treated skin with soap and water.)

STORAGE AND DISPOSAL

STORAGE: Store in a cool, dry area inaccessible to children.

DISPOSAL: Nonrefillable container. Before disposing, empty 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.

(Ingredients: Water, p-Menthane-3,8-diol, Octyldodecyl, Neopentanoate, Stearic Acid, Glycerine, DEA-Cetyl Phosphate, Cetyl Alcohol, PVP/Elcosene Copolymer, Propylene Glycol, Diazolidinyl Urea, Methylparaben, Propylparaben, Aloe, Magnesium Aluminum Silicate, Xanthan Gum, Dimethicone, (Fragrance).)

Questions? Comments? Call 1-800 558-5252 or write Helen Johnson. © (2003) S.C. Johnson & Son, Inc. Racine, WI 53404-2236 U. S. A. All rights reserved.

EPA Reg. No. 4822-515

EPA Est. No. 4822-WI-1

[Note to reviewer: a batch or lot code will be added to product at time of production]