

74843-2

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

December 1, 2006

Elizabeth Brown, Ph.D.
Authorized Representative for Buzz-Off Insect Shield, LLC
Technical and Regulatory Analyst
Steptoe & Johnson LLP
Attorneys at Law
1330 Connecticut Avenue, NW
Washington, DC 20036-1795

Dear Dr. Brown,

Subject: Product Label Amendment with Data
Buzz-Off Insect Shield Insect Repellent Apparel
EPA Reg. No. 74843-2
Submissions dated July 14 and November 20, 2006

The amendment referred to above, submitted in connection with registration under Section (3) (c) (7) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended is acceptable subject to the comments and terms for conditional registration listed below.

1. You will submit and/or cite all data required for registration/reregistration of your product under FIFRA sec 3 (c) (5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

2. Remove the following claims from the hang-tag/label

- a. Bug repellent for feet
- b. Buzz Off is to bugs what Gore-Tex is to rain.
- c. No matter where you go, your feet are going into bug country. These socks keep your feet comfortable and bugs in their place.
- d. The insect repellent alternative.
- e. A revolution in personal insect protection.
- f. "New" (This product was registered on July 7, 2003)

g. Remove the word "new" from the claim "Buzz-off Insect Shield is a new patent-pending technology for treating apparel that repels mosquitoes, ticks, ants, flies, chiggers, and midges".

3. Change 80 washings to 70 washings. The data support 70 washings provided you submit conditional confirmatory *in-vitro* bioassay data with *Culex* sp., *Anopheles* sp. and *Ochlerotatus* sp. mosquitoes by August 1, 2007 for 25, 50, and 70 washings. A minimum of 10 replicates per sample per species should be submitted. Use 50% nylon/50% cotton samples as in the tests already submitted and reviewed.

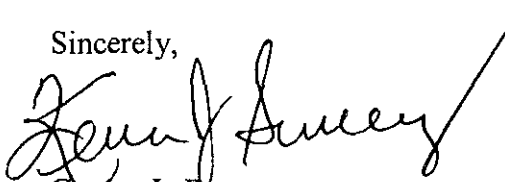
4. Change "Repels mosquitoes (including those that transmit West Nile virus)" to "Repels mosquitoes".

You should note that if you fail to satisfy any of the conditions imposed on this registration, e.g., you fail to submit the required data by the specified deadlines or the data submitted were not generated in accordance with the applicable test guidelines, or agreed upon protocols, EPA may issue notice to cancel this use under FIFRA 6(e).

Please note that the availability of EPA's reregistration eligibility document (RED) for products containing permethrin was published in the FR on June 28, 2006 (Vol. 71 No. 124 pg. 36788). Additional data or labeling changes may be required for products containing permethrin.

Please submit two (2) copies of the final printed label before releasing the product for shipment. A stamped copy of the label and a copy of the product performance DER are enclosed for your records. If you have any questions, please contact Kevin Sweeney at (703) 305-5063.

Sincerely,


George LaRocca
67 - Product Manager 13
Registration Division (7505P)
Insecticides Branch

Enclosure

Hang-tag on outside of garment (removable by consumer)

BUZZ OFF INSECT SHIELD INSECT REPELLENT APPAREL from [clothing brand]

- THIS GARMENT HAS BEEN TREATED WITH **BUZZ OFF INSECT SHIELD** PERMETHRIN INSECT REPELLENT
- REPELS MOSQUITOES, TICKS, ANTS, FLIES, CHIGGERS, AND MIDGES
- DRYCLEANING REMOVES ACTIVE INGREDIENT- DO NOT DRYCLEAN
- REPELLENCY REMAINS EFFECTIVE FOR 80 WASHINGS
- DO NOT RE-TREAT GARMENT WITH OTHER PERMETHRIN INSECT REPELLANT PRODUCTS
- FOR PROTECTION OF EXPOSED SKIN, USE IN CONJUNCTION WITH AN INSECT REPELLENT REGISTERED FOR DIRECT APPLICATION TO SKIN.
- WASH TREATED GARMENTS SEPARATELY FROM OTHER CLOTHING.

EPA Reg No. 74843-2

EPA Establishment No. 74843-NC-001

Active Ingredient

Permethrin

0.52%

Other Ingredients (Garment)

99.48%

100.00%

Manufactured by Buzz Off Insect Shield, LLC.

Greensboro, NC 27408

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Storage and Disposal

Do not contaminate water, food or feed by storage or disposal.

Disposal: Discard in trash when clothing is worn out. Do not reuse clothing for other purposes than as a garment.

RETAIN THIS TAG FOR FUTURE REFERENCE ON PROPER HANDLING OF THIS GARMENT. THIS TAG NOT TO BE REMOVED EXCEPT BY CONSUMER.

EPA-APPROVED. 7-7-2003

Revisions: 7-25-03, 9-5-03 (notification), 10-2-03 (EPA letter), 8-19-2004 (notification)

Amendment – DRAFT – 7-13-06

ACCEPTED
with COMMENTS
In EPA Letter Dated
DEC 01 2008
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
74843-2

Optional Marketing Statements for hang-tag/outer label

- Repels mosquitoes (including those which may carry West Nile Virus)
- Repels ticks (including those which may carry Lyme disease)
- In heavily infested areas, you may prefer to wear long-sleeved shirts and pants to increase protection
- Neither Buzz Off Insect Shield Apparel nor any other insect protection product can guarantee complete protection from insects or insect bites
- Does not protect against diseases or reactions from insect bites
- Bug repellent
- Bug repellent for feet
- No bugs, no bite
- Whether in the backwoods or the backyard, Buzz Off Insect Shield helps keep you protected
- Buzz Off is to bugs what Gore-Tex is to rain
- Buzz Off Insect Shield is a new patent-pending technology for treating apparel that repels mosquitoes, ticks, ants, flies, chiggers and midges
- No matter where you go, your feet are going to be in bug country. These socks keep your feet comfortable and bugs in their place
- By taking advantage of the latest fibers and technology, we've created a comfortable microclimate for your feet that also repels insects
- The insect repellent alternative
- A revolution in personal insect protection
- New *(for the first 6 months only)*
- All Buzz, No Bite
- Buzz Off and Get Out [Outside]
- Enjoy the Outdoors
- Buzz Off has you covered
- You can't tell it's there but the bugs can

Buzz Off

Insect Shield
insect repellent
apparel

Do Not Dry Clean
Repels mosquitoes,

ticks, ants,
flies, chiggers
and midges.

Repellency
remains effective
for 80 washings

- { fold line } -

Active Ingredient:

Permethrin

0.52% w/w

EPA Reg No.

74843-2

EPA Est No.

74843-NC-001

Dispose of garment
in trash. Wash
separately from other
clothing. Refer to
hang tag for more
information

EPA Approved

7-7-03

Revisions: 7-25-03

9-5-2003 (notification)

8-19-2004 (notification)

Amendment ~ DRAFT ~ 7-13-06

NOTE: This is the actual size of the label.