7/7/2011 74843-2



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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Insect Shield, LLC c/o Ms. Juli Mann Steptoe & Johnson, LLP 1330 Connecticut Avenue, NW Washington, DC 20036-1795

JUL - 7,2011

Dear Ms. Mann:

Subject: Amendment: Change Primary Brand Name, and Add Optional Marketing Statements Insect Shield Insect Repellent Apparel [Old Name] Insect Shield Repellent Apparel [New Name]

EPA Reg. No. 74843-2

Your submission dated April 8, 2011

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) section 3(c)(7)(a), is acceptable provided the following revisions are made prior to release for shipment under the amended labeling:

- 1) Delete the proposed claims "The active ingredient [in Insect Shield] is a man-made version of a/n [natural][insect repellent][repellency] found in certain types of chrysanthemum[s] [plants]." and "The active ingredient [in Insect Shield] is a [[synthetic][man-made]] [[replica][version]] of pyrethrum which [is an insect repellent found in][which is a/an [repellent] extract from] certain types of chrysanthemum[s][plants]". The US EPA has regulatory authority over this pesticide product and does not allow comparisons between pesticides with different profiles, as is the case with permethrin and pyrethrum. Citations to comment/descriptions by other government agencies or departments do not constitute EPA regulatory decisions.
- 2) Delete the overly promising "Insect Shield has the potential to be an important tool in the battle against insect-borne disease [and improve the health of people worldwide.]".

A stamped copy of the label is enclosed for your records. Please submit two copies of the revised amended labeling prior to release for shipment.

The Agency's records will be revised to reflect the change in the Primary Brand Name as follows:

Insect Shield Insect Repellent Apparel [Old Name]
Insect Shield Repellent Apparel [New Name]

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on <u>nonrefillable</u> containers. The code may appear either on the label (and can be added by non-notification/PR Notice 98-10) or durably marked on the container itself.

If you have any questions regarding this letter, please contact Dana Pilitt, PhD of my staff at (703) 305-7071 or via e-mail at pilitt.dana@epa.gov.

Sincerely,

Dana R. Pilett

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

Note: [Bracketed information is optional text.] Text separated by "/" denotes and/or options.

Amendment to change primary brand name and add optional marketing statements 4/7/2011

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

INSECT SHIELD REPELLENT APPAREL from [clothing brand]

- THIS GARMENT HAS BEEN TREATED WITH INSECT SHIELD PERMETHRIN INSECT REPELLENT
- REPELS MOSQUITOES, TICKS, ANTS, FLIES, CHIGGERS, AND MIDGES
- DRYCLEANING REMOVES ACTIVE INGREDIENT- DO NOT DRY CLEAN
- REPELLENCY REMAINS EFFECTIVE FOR 70 WASHINGS
- DO NOT RE-TREAT GARMENT WITH OTHER PERMETHRIN INSECT REPELLENT 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-xx-XXX

Active Ingredient
Permethrin

0.52%

Other Ingredients (Garment)

99.48%

100.00%

Manufactured by/for Insect Shield, LLC. P.O. Box 10129 Greensboro, NC 27404

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.

ACCEPTED with COMMENTS
In EPA Letter Dated:
JUL - 7, 2011

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the posticide registered under EPA Reg. No. 74843 Note: [Bracketed information is optional text.] Text separated by "/" denotes and/or options.

Amendment to change primary brand name and add optional marketing statements 4/7/2011

Optional Marketing Statements for hang-tag/outer label

- o Repels mosquitoes (including those which may carry West Nile Virus) [including those which may transmit malaria]
- o Repels ticks (including those which may carry Lyme disease)
- o In heavily infested areas, you may prefer to wear long-sleeved shirts and pants to increase protection
- Neither 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
- o No bugs, no bite
- Whether in the backwoods or the backyard, Insect Shield helps keep you protected
- o Insect Shield is a patent-pending technology for treating apparel that repels mosquitoes, ticks, ants, flies, chiggers and midges
- By taking advantage of the latest fibers and technology, we've created a comfortable microclimate for your feet that also repels insects
- o All Buzz, No Bite
- o Enjoy the Outdoors
- o Insect Shield has you covered
- o You can't tell it's there but the bugs can
- o Built-In Insect Protection
- o Invisible
- o Invisible Protection
- o Invisible protection just by putting on your clothes
- o Durable
- Lasts through 70 washes, the expected lifetime of a garment
- o Lasts through 70 washes
- o Convenient
- o Comfortable
- o Effective
- Easy care
- o Normal home laundering is recommended. [Do not dry clean.]
- o [Used as a heading:] Insect Shield Advantages
- o Repels insects including those that can carry [Lyme disease], [West Nile virus], [malaria] and [other insect borne diseases]
- o [Insect Shield] protects against insects including those that can carry [Lyme disease], [West Nile Virus], [malaria] and [other insect borne diseases]
- o Tested/proven
- o Proven protection
- o Dependable protection
- o Long-lasting protection
- o Built-in [Insect Shield]
- Odorless
- Built-in invisible, odorless insect protection
- o Unscented
- o Unscented protection
- o No unpleasant scent
- o Repel without the smell
- o [Insect Shield] feels and smells just like your other clothes
- o Repels Mosquitoes, ticks, ants, flies, chiggers and midges (no-see-ums).

Note: [Bracketed information is optional text.] Text separated by "?" denotes and/or options.

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- The active ingredient [in Insect Shield] is a man-made version of a/n [natural] [insect repellent] [repellency] found in certain types of chrysanthemum[s] [plants]
- o Technology is the result of years of research and field study
- o No special care or storage required
- [Insect Shield] technology converts clothing into long-lasting effective and convenient insect protection.
- The active ingredient in [Insect Shield] is so tightly bonded to fabric fibers that it retains effective repellency through the life of the product
- o [Insect Shield] protection is built right in and lasts the expected lifetime of the product
- o [Insect Shield] lasts beyond the life of most performance fabric finishes
- o Who can wear it? [Everyone] [Your whole/entire family]
- o [Insect Shield] offers protection for the entire family
- o Helps you protect your entire family from insects
- o Family protection
- Insect protection for your entire family
- o Protecting you and your family
- o [Insect Shield] can be used by the entire family
- o No restrictions for use
- o Bug barrier
- O What makes it work?
- o Powerful weapon in the war with insects
- Winning the battle against bugs
- o Put on clothes, put off bugs
- Don't be bugged
- o Changing the way you think about insect protection
- o Ditch the itch
- o If you love being outdoors, you'll love [Insect Shield]
- o Insect repellent you'll love to wear
- O Stays in your clothes, not on your skin
- o It's time to annoy them for a change
- o It's time to annoy the bugs for a change
- O Wouldn't it be great to annoy them for a change?
- A better way to keep bugs at bay
- o [Insect Shield] keeps bugs at bay
- o [Insect Shield] keeps bugs at bay so you can enjoy the greater outdoors in peace
- o The following agencies recommend permethrin treated apparel:

The U.S. Centers for Disease Control and Prevention (CDC), www.cdc.gov/travel

The World Health Organization (WHO), www.who.int

National Institute for Occupational Health and Safety, www.cdc.gov/niosh/topics/lyme/

The American Academy of Family Physicians, http://www.familydoctor.org

The Public Health Agency of Canada, www.phac-aspc.gc.ca

o Who recommends permethrin treated apparel?

The U.S. Centers for Disease Control and Prevention (CDC), www.cdc.gov/travel

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The American Academy of Family Physicians, http://www.familydoctor.org

The Public Health Agency of Canada, www.phac-aspc.gc.ca

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Note: [Bracketed information is optional text.] Text separated by "f" denotes and/or options.

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- o The active ingredient [in Insect Shield] is a [[synthetic] [man made]] [[replica] [version]] of pyrethrum which [is an insect repellent found in][which is a/an [repellent] extract from] certain types of chrysanthemum[s] [plants]]
- o Invisible, odorless protection just by putting on your clothes.
- o Insect Shield is a revolutionary defense in the battle against bugs.
- o Insect Shield apparel protection is built right into your clothes and lasts the expected lifetime of the garment. This is well beyond the life of most performance fabric finishes.
- o Insect Shield apparel offers excellent durability.
- o Insect Shield has the potential to be an important tool in the battle against insect-borne disease [and improve the health of people worldwide.]

Insect Shield
Repellent
Apparel
Do Not Dry Clean
Repels mosquitoes,
ticks, ants,
flies, chiggers
and midges.
Repellency
remains effective
for 70 washings
-[fold line]Active Ingredient:
Permethrin
0.52% w/w
EPA Reg No.
74843-2
EPA Est No.
74843-xx-xxx
Dispose of garment
in trash. Wash
separately from other
clothing. Refer to
hang tag for more
information

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[NOTE: This is the actual size of the label.]

[Primary brand name label (apparel inner label); amendment to change primary brand name and add optional marketing statements; 4/8/2011]