

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

May 15, 2017

Juli Mann
Senior Regulatory Analyst
Authorized Agent for Insect Shield, LLC
Steptoe and Johnson LLP
1330 Connecticut Avenue NW
Washington, DC 20036-1795

Subject: Label Amendment – Add marketing claim for Zika virus

Product Name: INSECT SHIELD REPELLENT APPAREL

EPA Registration Number: 74843-2

Application Date: fill-in Decision Number: 527018

Dear Ms. Mann:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

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 or if 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.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

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with FIFRA section 6. If you have any questions, you may contact Elizabeth Fertich at 703-347-8560 or via email at <a href="mailto:fertich.elizabeth@epa.gov">fertich.elizabeth@epa.gov</a>.

Sincerely,

Gene Benbow, Acting Product Manager 4

Invertebrate & Vertebrate Branch 1

Su to

Registration Division (7505P)

Office of Pesticide Programs

(Hang-tag on outside of garment, removable by consumer. The hang tag, if removed, must be reattached prior to sale.)

**INSECT SHIELD REPELLENT APPAREL** [optional wording identifying brand or style]

- 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][50][25] 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
Other Ingredients (Garment)

0.52% 99.48% 100.00% ACCEPTED

05/15/2017

Label Amendment

Edit date: 02/24/2017

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 74843-2

Manufactured by/for Insect Shield, LLC. 814 West Market St. Greensboro, NC 27401

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.

## 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] [including those which may transmit Zika virus]
- 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
- o Neither Insect Shield Apparel nor any other insect protection product can guarantee complete protection from insects or insect bites
- o Does not protect against diseases or reactions from insect bites
- o Bug repellent
- o No bugs, no bite
- o 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
- o 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
- o Lasts through [70] [50][25] washes, the expected lifetime of a garment
- o Lasts through [70] [50][25] washes
- Convenient
- o Comfortable
- o Effective
- o Easy care
- o Normal home laundering is recommended. [Do not dry clean.]
- o [Used as a heading:] Insect Shield Advantages
- Repels insects including those that can carry [Lyme disease], [West Nile virus], [malaria],
   [Zika virus] and [other insect borne diseases]
- o [Insect Shield] protects against insects including those that can carry [Lyme disease], [West Nile Virus], [malaria], [Zika virus] and [other insect borne diseases]
- o Tested/proven
- o Proven protection
- o Dependable protection
- o Long-lasting protection
- o Built-in [Insect Shield]
- Odorless
- o Built-in invisible, odorless insect protection
- Unscented

Label Amendment

Note: [Bracketed text] is optional or alternate text.; text separated by "/" denotes and/or options; (parenthetical text) is informational.

- Unscented protection
- 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).
- o Technology is the result of years of research and field study
- o No special care or storage required
- o [Insect Shield] technology converts clothing into long-lasting effective and convenient insect protection.
- o 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
- 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
- o Insect protection for your entire family
- o Protecting you and your family
- o [Insect Shield] can be used by the entire family
- No restrictions for use
- 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
- o 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
- Wouldn't it be great to annoy them for a change?
- o 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
- 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, <a href="www.cdc.gov/niosh/topics/lyme/">www.cdc.gov/niosh/topics/lyme/</a>

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

Label Amendment

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The World Health Organization (WHO), <a href="www.who.int">www.who.int</a>
National Institute for Occupational Health and Safety, <a href="www.cdc.gov/niosh/topics/lyme/">www.cdc.gov/niosh/topics/lyme/</a>
The American Academy of Family Physicians, <a href="http://www.familydoctor.org">http://www.familydoctor.org</a>
The Public Health Agency of Canada, <a href="www.phac-aspc.gc.ca">www.phac-aspc.gc.ca</a>

- 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 Picture of grass
- o Picture of listed crawling bugs/mosquitoes
- o Pictures of Insect Shield Apparel being worn

Label Amendment

## (Sewn-in label, permanently affixed)

**Insect Shield Repellent Apparel** Do Not Dry Clean Repels mosquitoes, ticks, ants, flies, chiggers and midges. Repellency remains effective for [70][50][25] 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

(NOTE: Not shown as actual size. Actual size of sewn-in label is 1"x 3".)

Label Amendment