



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 5, 2016

Michael Rekhelman
VP Technical Services
ABC Compounding Co., Inc.
P.O. Box 16247
Atlanta, GA 30321

Subject: Label Amendment – Adding Zika claim, in addition to other repellency claims to the label.
Product Name: Insect Repellent
EPA Registration Number: 3862-102
Application Date: March 1, 2016
Decision Number: 514770

Dear Mr. Rekhelman:

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.

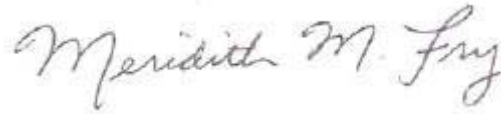
Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded 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, please contact Jennifer Gaines at 703-305-5967 or via email at gaines.jennifer@epa.gov.

Sincerely,

A handwritten signature in cursive script that reads "Meredith M. Fry".

Meridith M. Fry, Ph.D., Product Manager 4
Invertebrate & Vertebrate Branch 1 (IVB1)
Registration Division (7505P)
Office of Pesticide Programs

Enclosure

ACCEPTED

04/05/2016

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 3862-102



Insect Repellent

FOR PERSONAL APPLICATION AND CLOTHING

**Repels Mosquitoes, Chiggers, Ticks, Deer Flies, Stable Flies,
Black Flies, Gnats and Fleas on Exposed Skin Surfaces.**

**Repels mosquitoes that may carry diseases such as West Nile
Virus, the Zika virus, encephalitis and malaria.**

ACTIVE INGREDIENT:

DEET*15.00%
Other Ingredients:.....85.00%
*N, N-Diethyl-meta-toluamide and other isomers

FIRST AID

IF IN EYES:	<ul style="list-style-type: none">● Hold eye open and rinse slowly and gently with water for 15-20 minutes.● Remove contact lenses, if present, after the first five minutes, then continue rinsing.● Call a poison control center or doctor for treatment advice.
IF SWALLOWED:	<ul style="list-style-type: none">● Call a poison control center or doctor immediately for treatment advice.● Have person sip a glass of water if able to swallow.● Do not induce vomiting unless told to do so by a poison control center or a doctor.● Do not give anything by mouth to an unconscious person.

HOT LINE NUMBER

In case of emergency call toll free 1-800-535-5053. Have the product container or label with you when calling a poison control center or doctor or going for treatment.

KEEP OUT OF REACH OF CHILDREN

WARNING

CONTENTS UNDER PRESSURE

See back panel for additional precautionary statements

NET WT. 6 OZ. (170 GRAMS)

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
WARNING**

Causes substantial but temporary eye injury. Harmful if swallowed. Do not get in eyes. Use of this product may cause skin reactions in rare cases. Wash treated clothing before wearing it again. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

PHYSICAL OR CHEMICAL HAZARDS:

FLAMMABLE. Contents under pressure. Keep away from heat, sparks and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.

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 Outdoor Use Only. Do not spray in enclosed areas. Never use repellents over cuts, wounds, sunburned or irritated skin. Do not apply near eyes and mouth, and apply sparingly around ears. Do not allow children to handle this product, and do not apply to children's hands. When using on children, apply to your own hands and then put it on the child. Apply only to exposed skin and/or clothing (as directed on the product label). Do not use under clothing. Use just enough repellent to cover exposed skin. Heavy application and saturation is unnecessary for effectiveness; if biting insects do not respond to a thin film of repellent, apply a bit more. After returning indoors, wash treated skin with soap and water or bathe. This is particularly important when repellents are used repeatedly in a day or on consecutive days. Also, wash treated clothing before wearing it again. **Use of this product may cause skin reactions in rare cases. If you suspect a reaction to this product, discontinue use, wash treated skin, and call your local poison control center. If you go to a doctor, take this product with you.**

For application to exposed skin to repel mosquitoes, biting flies, gnats, and fleas: Hold unit 4-6 inches from the skin of arms or legs while applying with a slow sweeping motion, until surface is slightly moistened. Rub with hand to insure an even distribution. To apply to face and neck, spray in palm of hand in short bursts and spread on the skin sparingly avoiding eyes.

For application to outer surfaces of clothing to repel mosquitoes, biting flies, chiggers, fleas, and ticks: Spray outer surfaces of clothing, especially socks, shoe tops, pant legs, and waistband.

Do not apply to synthetic fabrics such as acetate, rayon or spandex. May damage furniture finishes, leather, plastics, painted and varnished surfaces including watch crystals, and automobiles.

**STORAGE AND DISPOSAL
Do Not Puncture Or Incinerate!**

PESTICIDE STORAGE: Store in a cool dry place away from heat or open flame in an area that is inaccessible to children. **PESTICIDE**

DISPOSAL: Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. **If Partly Filled:** Call your local solid waste agency or 1-800-CLEANUP for disposal instructions.



Manufactured by: ABC Compounding Co., Inc.
P.O. Box 16247, Atlanta, GA 30321-0247
Toll Free 800-795-9222

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