

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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

April 15, 2016

Matthew R. Schneider, Esq. Authorized Representative EMD Performance Materials Corporation c/o Garvey Schubert Barer Law 1000 Potomac Street, N.W., 5th Floor Washington, DC 20007

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling Amendment – Adding optional marketing claims: "Repels mosquitoes that may carry [transmit] [Zika]
[Chikungunya] [Dengue Fever] [and] West Nile Virus [for up to 8 hours];"
"Protection [you can count on for up to 8 hours][from mosquitoes that may carry (transmit) (West Nile), (Zika), (Chikungunya) Virus, (and) (Dengue Fever)];" and "Effective, dependable protection."
Product Name: Bug Repell IR3535 10% Lotion
EPA Registration Number: 70759-2
Application Date: March 1, 2016
OPP Decision Number: 514571

Dear Mr. Schneider:

The amended labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

This approval does not affect any terms or conditions that were previously imposed on this registration. You continue to be subject to existing terms or 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 (1) copy of the final printed labeling before you release this 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 your company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the U.S.

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Environmental Protection Agency (EPA). If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the 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 EPA 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 Assurance.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6.

If you have any questions, please contact Menyon Adams of my team by phone at (703) 347-8496 or via email at adams.menyon@epa.gov.

Sincerely,

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Andrew Bryceland, Team Leader Biochemical Pesticides Branch Biopesticides and Pollution Prevention Division (7511P) Office of Pesticide Programs

Enclosure

(Front Panel)

Bug Repell IR3535® 10% Lotion

KEEP OUT OF REACH OF CHILDREN WARNING

ACTIVE INGREDIENT

3-[N-Butyl-N-acetyl]-amino	
propionic acid ethyl ester*	10.0%
	00.00/

OTHER INGREDIENTS.	90.0%
TOTAL	
*IR3535®	

FIRST AID - If In Eyes: [optional front and back panel]

- 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 eye.
- Call a Poison Control Center or doctor for treatment advice.
- Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
- For information on this pesticide product call the National Pesticide Information Center at 1-800-858-7378.

EPA Reg. No. 70759-2 EPA Est. No. 13891-IN EMD Millipore Corporation One International Plaza Suite 300 Philadelphia, PA 19113 © 2008 EMD Millipore Corp. - ALL RIGHTS RESERVED [optional front and back panel]

128 FL.OZ (3785 ml); 32 FL.OZ (946 ml); 8 FL.OZ (236 ml); 4 FL.OZ (118 ml); 2FL.OZ (59 ml); 1.7 FL.OZ (50 ml); .16 FL.OZ (5 ml) .13 FL.OZ (4 ml)

[Batch Code ______ or Lot Number____] [or similar phrase]

A C C E P T E D 04/15/2016

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 202700.0

70759-2

(Back Panel)

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS- Warning: For external use only. Causes substantial but temporary eye injury. Do not get in eyes. Discontinue use and consult a doctor if irritation or rash occurs. Ask a doctor before using on children under 1 year of age.

DIRECTIONS FOR USE

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

REPELLENCY- REPELS MOSQUITOES AND TICKS FOR UP TO 8 HOURS [optional front and back panel]

Apply liberally and evenly over dry, exposed skin. An adult must apply this product to children under 10. Do not apply to children's hands.

FOR CONTINUED PROTECTION: reapply about every 8 hours or sooner if effectiveness is diminished; not to exceed 3 applications per day.

STORAGE AND DISPOSAL

Storage: Store in cool dry place away from heat or flame.

Disposal:

If Empty: Nonrefillable Container. Do not reuse or refill this container. Place in trash or offer for recycling if available.

If Partly Filled: Call your local solid waste agency or call 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

Expiration (date).

Optional Label Claims:

Use only as directed. Avoid contact with plastics, costume jewelry, leather and synthetic fibers. May damage painted or varnished surfaces, including nail polish. **DEET** free Complete protection against mosquitoes and ticks for up to 8 hours Family friendly For the whole family Long protection for the whole family 8-hour protection for the entire family Lightweight Non-greasy Non-oily Pleasant feel Fragrance free Odorless No odor No need to wash off when returning from outdoors Mosquitoes may transmit West Nile Virus

Ticks may transmit Lyme disease

 <u>Touch/Feel descriptors [to be used as stand-alone statements or</u> inserted into additional statements as indicated below]

Dry	Fresh	Not Greasy
Not Oily	Light	Non-Oily
Good	Comfortable	Pleasant
Greaseless	Not Sticky	Touchable
Non-Greasy	Not Wet	

Feels [insert touch/feel descriptor] (on) (on your skin) [Insert touch/feel descriptor] feel (formula) [Insert touch/feel descriptor] touch (formula) [Insert touch/feel descriptor] formula [Insert touch/feel descriptor] protection [Insert touch/feel descriptor] skin feel (Insect repellent that) leaves (your) skin feeling [insert touch/feel descriptor]

- (Light feel) (Light weight) (Strong) (Effective) (Proven) protection
- Feel good protection for (the entire family) (your family)
- Dry (shield) (defense) (performance) (repellent) (spray)
- Smart (shield) (defense) (performance) (repellent) (spray)
- (Formulated) (with) feel dry technology
- (Formulated) (with) dry feel technology
- Quick dry (ing)
- Fast dry (ing)
- Dries fast

Optional Label Claims (CONTINUED):

Mosquitoes can transmit diseases like Malaria, Yellow Fever, and Encephalitis According to the Centers for Disease Control and Prevention, West Nile has been detected in 48 states Tough on insects, gentle on skin **DEET** alternative No odor, no grease, no worries Arc Flash Compliant Will Not Affect Flame Resistant (FR) Clothing Dermatologically tested Industrial Insect Repellent formulated as an odorless body lotion with the active ingredient IR 3535© to be used on exposed skin of outdoor workers. Helps to repel mosquitoes and ticks that can transmit vector-borne diseases such as dengue fever, yellow fever, chikungunya, Lyme disease, malaria, and West Nile virus. Non-flammable Made by Americans for the Outdoor American Worker Lineman's Glove Test Compliant ASTM F 2621 ASTM D 120

Repels mosquitoes that may carry [transmit] [Zika] [Chikungunya] [Dengue Fever] [and] West Nile Virus [for up to 8 hours]

Protection [you can count on for up to 8 hours][from mosquitoes that may carry (transmit) (West Nile), (Zika), (Chikungunya) Virus, (and) (Dengue Fever)]

Effective, dependable protection

Alternate Brand Name:

Industrial Insect Repellent