

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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

March 25, 2016

Matthew R. Schneider, Esq. Authorized Representative EMD Performance Materials Corporation c/o Garvey Schubert Barer Law 1000 Potomac Street, N.W., Suite 200 Washington, DC 20007

Subject: Labeling Notification per Pesticide Registration Notice (PRN) 98-10 – Adding new net

content sizes: 128 FL.OZ (3785 ml); 32 FL.OZ (946 ml); 8 FL.OZ (236 ml); 1.7 FL.OZ (50 ml); and .13 FL.OZ (4 ml). Adding optional label claims: "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"; and

"Dermatologically tested"

Product Name: Bug Repell IR3535 10% Lotion

EPA Registration Number: 70759-2 Application Date: November 12, 2015

OPP Decision Number: 511200

Dear Mr. Schneider:

The U.S. Environmental Protection Agency (EPA) is in receipt of your application for notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Biopesticides and Pollution Prevention Division (BPPD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The labeling submitted with this application has been stamped "Notification" and will be placed in our records. You must submit one (1) copy of the final printed labeling with the modifications.

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 the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and is subject to review by the 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

Page 2 of 2 EPA Reg. No. 70759-2 OPP Decision No. 511200

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.

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,

Andrew C. 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%
OTHER INGREDIENT	90.0%
TOTAL	100.0%
*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

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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); .13 FL.OZ (4 ml)

[Batch Code	or Lot Number_]
[or similar phrase]		

NOTIFICATION

70759-2

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

03/25/2016

(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.

PHYSICAL OR CHEMICAL HAZARDS

Use only as directed. Avoid contact with plastics, costume jewelry, leather and synthetic fibers. May damage painted or varnished surfaces, including nail polish.

DIRECTIONS FOR USE

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

REPELLENCY- REPELS MOSQUITOS 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 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.

Exp. (date).

Optional Label Claims:

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 inserted into additional statements as indicated below]</u>

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

[New Optional Label Claims]:

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

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