

#### OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

June 16, 2025

Nicole Perkinson, Authorized Representative EMD Performance Materials Corporation c/o ToXcel Toxicology & Regulatory Affairs 7140 Heritage Village Plaza Gainesville, VA 20155-3061

Subject: PRIA (Pesticide Registration Improvement Act) Labeling and Formulation Amendment

Updating the Confidential Statement of Formula (CSF) Alternate #1

Product Name: Bug Repell IR3535 10% Lotion

EPA Registration Number: 70759-2 EPA Receipt Date: 09/21/2023 Action Case Number: 00489275

#### Dear Nicole Perkinson:

The amended labeling and Confidential Statement of Formula (CSF) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, are 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.

Please note that the record for this product currently contains the following acceptable CSFs:

- Basic CSF dated 06/29/2020
- Alternate CSF #1 dated 04/08/2025

Any CSFs other than those listed above are superseded/no longer valid.

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

Page 2 of 2 EPA Reg. No. 70759-2 Action Case No. 00489275

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. Environmental Protection Agency. 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 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 EPA find or if it is brought to our attention that a website contains statements or claims substantially differing from statements or claims made in connection with obtaining a FIFRA section 3 registration, the website will be referred to 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 by phone at (202) 566-1604 or via email at <a href="mailto:adams.menyon@epa.gov">adams.menyon@epa.gov</a>.

Sincerely,

Linda Hollis, Chief Biochemical Pesticides Branch Biopesticides and Pollution

Prevention Division (7511M)

Office of Pesticide Programs

NV

**Enclosure** 

{Text in braces { } is explanatory or informational and will not appear on the labeling}

{Text in brackets [] is optional and may or may not appear on the labeling}

{Note: Boxed format, bullet or paragraph format may be used if label space permits}

{For small containers where the label text will not fit, a folding label will be used on the container, or the container will be attached to a cardboard backing with back panel labeling.}

{Label text may also appear all or in part in [a foreign language] [insert one or more foreign language]in addition to

English.

{Front Panel}

### Bug Repell IR3535® 10% Lotion

# KEEP OUT OF REACH OF CHILDREN WARNING

ACCEPTED

06/16/2025

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

70759-2

See back [panel] [booklet] for [precautions] [and] [first aid.] [optional front and back panel]

#### **ACTIVE INGREDIENT**

**FIRST AID** [optional front and back panel]

If in Eyes: Hold eye open and rinse slowly and gently with water for 15-20minutes. 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] [1-XXX-XXX-XXXX].

EPA Reg. No. 70759-2 EPA Est. No.

EMD Performance Materials Corporation 1200 Intrepid Avenue, Suite 300 Philadelphia, PA 19112

© 2015 EMD Performance Materials Corp. – All rights reserved. [optional front and back panel]

X FL. OZ (X ml) {Alternate Containers}

{Batch Code or Lot Number or similar phrase} {May be on label or container} {Bar Code} {Optional back or front panel}

{Back Panel}

#### **PRECAUTIONARYSTATEMENTS**

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.

#### **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 text on front or back panel}

Apply liberally and evenly over dry, exposed skin. Do not apply over cuts, wounds, freshly shaven or irritated skin. 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. After returning indoors, wash your child's treated skin and clothes with soap and water or bathe.

[To apply to face: Apply product to the palm of your hand and [rub] [wipe] on face.]

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. [Always store Insect repellents safely out of the reach of children]

**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] [Call 1-XXX-XXX-XXXX] for disposal instructions. Never place unused product down any indoor or outdoor drain.

#### {Optional Label Claims:}

## {Touch/Feel descriptors to be used as stand-alone statements, inserted or added into additional statements or joined with + - or and}

[Clean]	[Fast]	[Lightweight]	[Not Sticky]
[Clear]	[Feel(s)]	[No Odor]	[Not wet]
[Colorless]	[Fresh]	[Non-Greasy]	[Odorless]
[Comfortable]	[Good]	[Non-Oily]	[Pleasant]
[Dries]	[Greaseless]	[Non-Tacky Feel]	[Quick]
[Dry]	[Invisible]	[Not Greasy]	[Smells]
[Drying]	[Light]	[Not Oily]	[Touchable]

[Feels] {insert touch/feel descriptor} [on] [on your skin]

[ {insert touch/feel descriptor}] [feel] [touch] [formula]

[ {insert touch/feel descriptor}] [ protection]

[ {insert touch/feel descriptor}] [skin feel]

[Insect repellent that leaves your skin feeling [insert touch/feel descriptor]

[A Friend to People.] [An enemy to [Bugs†][Bugs (mosquitos and ticks][mosquitos and ticks].]

[†Mosquitos and ticks]

[A Solution Consumers Can Rely On]

[Accurate] [Convenient] [Easy] [Effortless] [Simple] [Smooth] [Quick] [Application] [Coverage] [to apply] [to carry] [to pack] [to use]

[Active] [Adventure] [Explorer] [Forest] [Trail] [Sport] [Sportsman] [Woods] [edition] [version]

[Active][Armor][Block[s]] [Blocks the bite] [Bugs] [Guard] [Security] [from] [against] [mosquitoes] [and]

[+] [&] [ticks] [for the [entire] [whole] [your] [family] [for] [Up to 8-hours]

[Adults no need to] [wash off when returning from outdoors] [shower after use]

[Airplane] [Bargain] [Bonus] [Carry-on] [Club] [Economy] [Large] [Larger] [Mega] [On the go] [Pocket]

[Travel] [TSA- Approved] [Value] [Size]

[Airplane][Bargain] [Bonus] [Carry-On] [Club] [Combo] [Convenient] [Double] [Economy] [Multi] [On the go] [Pocket] [Two] [Twin] [2] [Three] [3] [Travel] [Triple] [TSA approved] [Value] [-] [Pack]

Versatile [mosquito and tick)] protection anytime, anywhere

Effective wherever you go

[Apply [and] ['N] go]

[Apply Repellent and get your adventure started]

[Apply sunscreen first, wait 10 to 15 minutes and then apply IR3535® Insect repellent]

[Arc Flash] [ASTM F2621] [Compliant]

[Avoid contact with [plastics,] [costume jewelry,] [leather] [and] [synthetic fibers.]

[Bad For Bugs.]

[Beat bug bites before they happen]

[Bio-Degradable in Water]

[Bug] [Insect] [blocker] [Screen] [repellent] [without the ick] [protection that feels good]

[Bugs the bugs†.] [Not people]

[Buh-Bye] [Bye] [Bye] [Bugs.] [Happy People.] [Hello fun]

[Campsite] [coverage]

[Can be] [used daily,] [used every day,] [while camping,] [hiking,] [and] [traveling]

[Classified as a Biopesticide by the EPA]

[Contains moisturizing & skin conditioning ingredients]

[DEET] [Alternative\*\*] [Free\*\*]

{Deet Free or Deet Alternative are optional statements which may or may not be used on the label. If either statement is used, then it is to be noted with an \*\* and the statement "\*\*Not a safety claim" will be included adjacent to the claim using the same font type and color. The size of the qualifier will be at least one half the type size of the claim. The following additional more detailed Deet qualifying statements must may also be included elsewhere on the label with the \*\*.}

[\*\* [For] [Customer] [Marketing] [Consumer] [Purchaser] [User] [Information.] [Does not imply a [safety] [toxicity] [health] [claim] [issue] [ of this product vs DEET.]

[\*\*Claim] [does not concern] [is not related to] safety [of this product vs. DEET.] [Statement is provided for [Customer] [Marketing] [Consumer] [Purchaser] [User [informational purposes only.]

[\*\*Claim] [Phrase]Does not imply any [safety] [health] [concern] [issue] of this product vs. DEET]

[\*\*The phrase [DEET-free] [Deet Alternative] should not be viewed as a statement on the safety of this product relative to any product containing DEET.]

[Tested on sensitive skin][Evaluated for use on sensitive skin

[Designed for active moments]

[Developed for [backpackers,] [bikers,] [campers,] [fishermen,] [golfers,] [hikers,] [hunters,] [joggers]

[and] [active outdoor enthusiasts]

[Do not use on pets.]

[Does not kill, only repels [insects†][insects (mosquitos and ticks][mosquitos and ticks]]

[Dry] [Safety] [shield] [Smart] [defense] [performance] [repellent] [for] [the] [entire] [whole]

[your][family] [for] [Up to 8-hours]

[Enjoy the [backyard] [forest] [great outdoors] [outdoors] [outside] [park] [woods] [with protection

[from] [against] [mosquitoes] [&] [+] [and] [ticks]] [for the] [entire] [whole] [your] [family]

[Feel the difference.] [Fend off [bugs+][bugs (mosquitos and ticks)[mosquitos and ticks]].

[Fight the bite.]

[Fits anywhere.] [Carry everywhere]

[For use at [home] [country clubs] [and] [farms] [or on the go!]

[For] [Up to 8-hour] [All Day] [Backyard] [Bug][Camping][Complete] [Dependable] [Effective] [Feel-

Good] [Forest] [Family] [Formula] [Hiking] [Insect] [Instant] [Immediate] [Light][feel] [Lightweight] [Hard-

working] [Long] [Long-lasting] [Mosquito] [On the Go] [Outdoor] [Picnic] [Powerful] [Proven] [Quick] [Repellent]

[Strong] [Tick] [Tick] [Weightless] [Woods] [protection] [against] [from] mosquitoes] [and] [+] [&] [ticks] [for the

[entire] [whole] [your] [family]

[Up to 8HR Protection]

[Mosquito + tick repellent]

[Formulated] [with] [feel dry] [dry feel] technology]

[Fragrance free]

[Friendly to Humans]

Gentle to the [environment] [skin]

[Goodbye bugs.] [Hello outdoors.]

[Great] [Ideal] [for camping]

[Harmless for Insects]

[Helps to] [Repel mosquitoes] [and] [+} [&] [ticks] that can [carry] [transmit] vector-borne diseases such

as [chikungunya [fever]] [dengue fever], [encephalitis], [Lyme disease], [malaria], [West Nile [virus]] and

[yellow fever] and [Zika] [virus]]

[Here's an idea. How about we annoy the bugs instead?]

[Hypoallergenic]

[Ideal for those who dislike strong repellent odor]

[Increased need due to climate warming]

[Insect Repellent formulated] [as an odorless body [Lotion][application] with [IR3535® Active] [IR3535® Active Ingredient] IR3535® Active Substance] [IR3535® Biopesticide] [IR3535® Molecule] [IR3535® Ingredient] [IR3535® Repellent] [IR3535® Insect Repellent] [IR3535® Bug Repellent] to be used on exposed skin of [outdoor] [industrial] workers.]

{Insert Brand} is what separates the bugs from the people.]

[Instructions do not require washing skin after returning indoors for adults]

[Invisible on skin] [after it dries]

[IR3535® Active] [IR3535® Active Ingredient] IR3535® Active Substance] [IR3535® Biopesticide] [IR3535® Molecule] [IR3535® Ingredient] [IR3535® Repellent] [IR3535® Insect Repellent] [IR3535® Bug Repellent] is [structurally] [equivalent] [like that] [related] [a derivative of] [inspired by nature based on a] [to] [naturally occurring] [natural substance] [ $\beta$ -alanine] [the] [amino acid]] [--a human amino acid] [which occurs naturally]

[IR3535® Active] [IR3535® Active Ingredient] IR3535® Active Substance] [IR3535® Biopesticide] [IR3535® Molecule] [IR3535® Ingredient] [IR3535® Repellent] [IR3535® Insect Repellent] [IR3535® Bug Repellent] [Tough on] [Mosquitoes] [Ticks] [Insects.] [Easy on you.] [Gentile on skin.] [Is gentle on human's skin.]

[IR3535® Active] [IR3535® Active Ingredient] IR3535® Active Substance] [IR3535® Biopesticide] [IR3535® Molecule] [IR3535® Ingredient] [IR3535® Repellent] [IR3535® Insect Repellent] [IR3535® Bug Repellent] [Protection On.] [Guard on] [Mosquitoes] [Ticks] [Off.] [Repelled]

[Keep [bugs†][bugs (mosquitos and ticks)][mosquitos and ticks]] [away] [so you can play] [where they belong] [Lineman's Glove [Test] [ASTM D 120] [Compliant]

[Made by Americans for the Outdoor American Worker]

[Made to [Guard] [Protect][Against] [Ticks] [and] [+] [&] [Mosquitoes] [Made to bother[ bugs+][bugs (mosquitos and ticks)][mosquitos and ticks].] [Not your family.]

[Make your life a no-fly zone.]

[Makes you invisible to [bugs<sup>†</sup>][bugs (mosquitos and ticks)][mosquitos and ticks]]

[Mask odors that attract [insects<sup>†</sup>][mosquitos and ticks]]

[May be [rubbed] [wiped] on face]

[May [be left on overnight for adults] [repeat application] [when used as directed]

[May damage painted or varnished surfaces, including nail polish.]

[Mosquito] [+] [and] [&] [tick] [defense]

[Mosquitoes can transmit diseases like [chikungunya [fever],] [dengue fever,] [encephalitis] [malaria,] [yellow

fever,] [West Nile [virus],]] and [Zika [virus].]

[Suitable for all ages][Can be applied on all age groups]

[No [bugs.†] [bugs (mosquitos and ticks)]] [More hugs.]

[No compromise on efficacy]

[No Insecticide Effect.]

[No odor that mammals can smell]

[No odor,] [no grease,] [no worries] [yes, please]

[No one will know you are wearing it]

[Suitable for use on children]

[No squitoes.] [No problems]

[Non-Flammable]

[People love [us] [it] [Bugs hate] [us.] [it]

[Protect and go]

[Protect yourself] [and your loved ones]

[Protection] [you can count on [for] [up to] [8 hours] [from mosquitoes that may [carry] [transmit] [chikungunya [fever]] [dengue fever], [encephalitis] [malaria], [West Nile [virus]]. [yellow fever] [and] (Zika [virus]].

[Protects your health by [repelling [[mosquitos][that] [which] [may] [carry] [transmit] [chikungunya [fever]] [dengue fever], [encephalitis] [malaria], [West Nile [virus]], [yellow fever] [and] (Zika [virus]]] [for] [up to 8-hours] [and] [[ticks] which may carry Lyme disease]]

[Helps reduce exposure to mosquitos and ticks [that] [which] [may] [carry] [transmit] [chikungunya [fever]] [dengue fever], [encephalitis] [malaria], [West Nile [virus]], [yellow fever] [and] (Zika [virus][and] [Lyme disease]]

[Recommended for use when travelling [in tropical countries] to safeguard from vector borne diseases which may be carried by mosquitoes and ticks.]

[Relax and rely on {insert brand name} [IR3535® Active] [IR3535® Active Ingredient] IR3535® Active.

Substance] [IR3535® Biopesticide] [IR3535® Molecule] [IR3535® Ingredient] [IR3535® Repellent]

[IR3535® Insect Repellent] [IR3535® Bug Repellent] protection from [mosquito bites] [tick bites]

[mosquitoes] [and] [+] [&] [ticks] [For] [Up To] [8-hour(s)] [protection]

[Reliable Consumer Solution]

[Repel] [+] [&] [and] [Moisturize] [Refresh]

[Repels mosquitoes] [that] [which] [may] [carry] [transmit] [chikungunya [fever]] [dengue fever],

[encephalitis] [malaria], [West Nile [virus]]. [yellow fever] [and] (Zika [virus]] [for] [up to] 8-hours]

[Repels ticks] which may carry Lyme disease]

[Repels] [bugs][Not people] [without bugging people] [from] [ticks] [and] [+] [&] [mosquitos] [for the]

[entire] [whole] [your] family] [For] [Up To] [8-hour(s)

[Repels] [mosquitoes] [and] [+] [&] [ticks] [For] [Up To] [8-hour(s)] [protection]

[Say hello to {Insert Brand}. [Say goodbye to bugs.]

[Scare Bugs. Not people.]

[IR3535® is gentle on human skin]

[Smitten not bitten.]

[Soft] [Gentle] [on][Sensitive] [Stressed] [Skin]

[Spray it on] [Wipe it on] Rub it on] [Apply it] [when] [attending concerts and sporting events,] [enjoying your yard,] [mowing the lawn,] [having parties] [and] [during] [social events] [and] [for] [all your outdoor activities]

[STOP. Read and follow all directions and precautions on this product label.]

[The] [sharable] [solution]

[Ticks can [transmit] [carry] Lyme disease]

[Toss in your [Bag] [Beach Bag] [Back-Pack] [Briefcase] [Car] [Desk] [Gym Bag] [Purse]

[Tried and Trusted Worldwide]

[Undetectable to your senses]

[Use [only as directed] [with confidence] [for ALL Age groups] [for consumers of all ages] [including

those with] [sensitive skin] [stressed skin] [on the] [entire] [whole] [your] family]

[Water based formula]

[We learned to speak bug.] [We told them to leave.]

[We love people.] [We hate bugs.]

[We're the people friendly, bug enemy people.]

[WHO lists IR3535® repellent [as] Class U]]

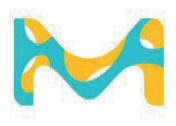
[Will not affect flame resistant [FR] clothing]

[X]% More] {Insert value for X}

[You [will forget you are wearing it] [won't smell it]

[Your] [best friend for protection] [personal bodyguard] [skin will thank you]

{OPTIONAL GRAPHICS—Note: The format and color of these graphics may vary as long as the general content is consistent.}







[IR3535 is a registered trademark of Merck KGaA, Darmstadt, Germany]

{alternative family configurations may be used}

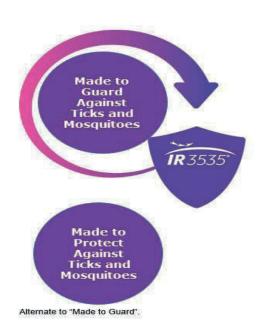














Page 11 of 11 LABEL Bug Repell IR3535® 10% Lotion

