

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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

January 13, 2017

Nicole Perkinson Authorized Representative for New Avon LLC c/o Toxcel Toxicology & Regulatory Affairs 7140 Heritage Village Plaza Gainesville, VA 20155

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling Amendment – Adding

additional marketing claims, including claims against mosquitoes carrying the Zika

virus, and updating the company name.

Product Name: Avon SSS Skin-So-Soft Gentle Breeze Bug Guard Plus IR3535 Insect

Repellent SPF 30 Moisturizing Sunblock Lotion

EPA Registration Number: 806-13 Application Date: 09/28/2016 OPP Decision Number: 522179

Dear Mrs. Perkinson:

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. 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

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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 by phone at (703) 347-8496 or via email at adams.menyon@epa.gov.

Sincerely,

Andrew C. Bryceland, Team Leader

NE

Biochemical Pesticides Branch

Biopesticides and Pollution Prevention Division (7511P)

Office of Pesticide Programs

Enclosure

DRAFT MASTER LABEL FOR EPA REG. NO. 806-13 WITH NEW FDA INFORMATION 01/04/17
AVON SKIN-SO-SOFT SSS BUG GUARD PLUS IR3535 INSECT REPELLENT GENTLE BREEZE SPF 30 SUNSCREEN LOTION Page 1 of 4

FRONT OF CONTAINER:

[Original Brand Name] AVON

S S

> SKIN-SO-SOFT GENTLE BREEZE™ BUG GUARD

PLUS IR3535®

INSECT REPELLENT

SPF 30

MOISTURIZING SUNBLOCK LOTION

ACCEPTED

01/13/2017

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under

806-13

EPA Reg. No.

[the words "E-Z SPONGE APPLICATOR" encircled around a

[Alternate Brand Name #1 (Notification submitted 2/4/03) - Bracketed information confined to sponge applicator container]

diagram of tube with sponge applicator.]

AVON

SKIN-SO-SOFT

S BUG

S GUARD S PLUS

IR3535®

[ACTIVE]

INSECT REPELLENT

GENTLE BREEZE™

SPF 30

MOISTURIZING SUNBLOCK LOTION

[Alternate Brand Name #2 - Bracketed information confined to sponge applicator container]

AVON [Words "E-Z SPONGE APPLICATOR" encircled around a

SKIN-SO-SOFT diagram of container with sponge applicator

S BUG

S GUARD

S PLUS

IR3535®

[ACTIVE]

INSECT REPELLENT

GENTLE BREEZE™

SPF 30 SUNSCREEN

VERY WATER RESISTANT

MOISTURIZING LOTION

[Alternate Brand Name #3 – Bracketed information confined to sponge applicator container]

AVON [Words "E-Z SPONGE APPLICATOR" encircled around a

SKIN-SO-SOFT diagram of container with sponge applicator]

S BUG

S GUARD

S PLUS

IR3535® [ACTIVE]

INSECT REPELLENT

GENTLE BREEZE™

SPF 30 SUNSCREEN

WATER RESISTANT (80 MINUTES)

MOISTURIZING LOTION

DRAFT MASTER LABEL FOR EPA REG. NO. 806-13 WITH NEW FDA INFORMATION 01/04/17
AVON SKIN-SO-SOFT SSS BUG GUARD PLUS IR3535 INSECT REPELLENT GENTLE BREEZE SPF 30 SUNSCREEN LOTION Page 2 of 4

FOLLOWING IS APPLICABLE ALL FRONT LABELS [Bracketed information is optional package size]:

KEEP OUT OF REACH OF CHILDREN CAUTION

ACTIVE INGREDIENTS:

beta-alanine, n-acetyl-N-butyl-, ethyl ester* / carboxylic acid 7.5% OTHER INGREDIENTS: 92.5% TOTAL: 100.0%

*IR3535®

4 FL. OZ. (118 ml) [2.5 FL. OZ. (75 ml)]

BACK OF CONTAINER:

[Bracketed information confined to use on sponge applicator container]

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Apply liberally 15 minutes before sun and insect exposure [using the E-Z Sponge Applicator]. An adult must apply this product to children under 10. Children under 6 months: Ask a doctor. For insect protection, reapply about every 2 hours or sooner if effectiveness diminishes. For sunscreen protection, reapply immediately after towel drying, after 80 minutes of swimming or sweating, at least every 2 hours. Do not exceed 9 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 for disposal instructions. Never place unused product down any indoor or outdoor drain.

Protect this product from sun.

PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS. **Caution.** For external use only. Causes moderate eye irritation. **When using this product** keep out of eyes. **Do not use** on damaged or broken skin. **Stop use and ask a doctor** if rash occurs. **Keep out of reach of children. Skin Cancer/Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer and early aging. This product has been shown only to prevent sunburn, **not** skin cancer or early aging.

FIRST AID	
If in eyes:	 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.
	ct container or label with you when calling a Poison Control Center or doctor, or nent. You may also contact 1-800-FOR-AVON for emergency medical treatment

ACTIVE SUNSCREEN INGREDIENTS: Octinoxate 7.5%, Oxybenzone 6%, Octisalate 5%

OTHER INGREDIENTS: Water, Butylene Glycol, Glycerin, PVP/Eicosene Copolymer, Aloe Barbadensis Gel, Isostearic Acid, Propylene Glycol Myristyl Ether Acetate, Stearic Acid, Benzyl Alcohol, Cetyl Alcohol, DEA-Oleth-3 Phosphate, Diglycol/CHDM/Isophthalates/SIP Copolymer, Dimethicone, Glyceryl Stearate, Magnesium Aluminum Silicate, Tocopheryl Acetate, Barium Sulfate, Fragrance, Imidazolidinyl Urea, Xanthan Gum, Disodium EDTA

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AVON SKIN-SO-SOFT SSS BUG GUARD PLUS IR3535 INSECT REPELLENT GENTLE BREEZE SPF 30 SUNSCREEN LOTION Page 3 of 4

> Day Lot Code Exp. Year / Month

Note to reviewer: The following statements, including those within brackets, are optional AND may appear on the product label AND / OR in marketing collateral materials AND the use of punctuation marks for each statement is optional

IR3535® is a registered trademark of Merck KGaA

Avoid contact with plastics, costume jewelry, leather and synthetic fibers

May damage painted or varnished surfaces, including nail polish

With vitamin E and aloe

REPELLENCY – IR3535® provides effective and dependable repellency against mosquitoes, deer ticks, black flies, sand flies, gnats, no-seeums and biting midges

Suitable for the entire family

Gentle formula does not need to be washed off when returning from the outdoors

Dermatologist-tested

Non-Comedogenic

Non-Acnegenic

Hypoallergenic

SPF 30 water resistant (80 minutes)

Helps prevent sunburn

PABA-Free

Moisturization

Non greasy formula helps replenish moisture and leaves skin soft and smooth

Pleasantly scented

Protects against mosquitos that may carry the Zika virus

Repels mosquitos that may carry the Zika virus

Protects against mosquitos that may carry the Dengue virus

Repels mosquitos that may carry the Dengue virus

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Protects against mosquitos that may carry the Chikungunya virus

Repels mosquitos that may carry the Chikungunya virus

Designed for active people

Low odor formula

Won't harm your clothing or bathing suit

Effective, dependable insect repellency

Non-sticky

No unpleasant odor

Long lasting protection for the entire family

Smart (dependable) protection for the entire family

Fights off mosquitos and unwanted (certain) insects

Easy on skin, tough on bugs

The right protection for your family