

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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

January 23, 2018

Dr. Connie B. Welch Authorized Representative Toxcel Toxicology & Regulatory Affairs c/o New Avon LLC 7140 Heritage Village Plaza Gainesville, VA 20155-3061

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

diseases: Powassan Encephalitis and Lyme Disease

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

Repellent SPF 30 Sunscreen Spray Very Water Resistant Gentle Breeze

EPA Registration Number: 806-33 Application Date: 09/26/2017 OPP Decision Number: 533727

Dear Dr. Welch:

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

Sincerely,

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

NU

Office of Pesticide Programs

Enclosure

DRAFT MASTER LABEL FOR EPA REG. NO. 806-33 WITH NEW FDA INFORMATION 09/26/17 AVON SKIN SO SOFT SSS BUG GUARD PLUS IR3535 EXPEDITION INSECT REPELLENT SPF 30 SUNSCREEN (PUMP SPRAY) Page 1 of 6

### FRONT OF CONTAINER:

AVON

SKIN-SO-SOFT

S

S

S

BUG GUARD PLUS

IR3535®

**EXPEDITION™** 

INSECT REPELLENT

SPF 30 SUNSCREEN SPRAY

VERY WATER RESISTANT

GENTLE BREEZE™

### [ALTERNATE BRAND NAME #1:]

AVON

SKIN-SO-SOFT

S

S

S

IR3535®

**EXPEDITION™** 

INSECT REPELLENT

SPF 30 SUNSCREEN SPRAY

VERY WATER RESISTANT

GENTLE BREEZE™

### [ALTERNATE BRAND NAME#2:]

AVON

BUG GUARD PLUS

IR3535®

 $EXPEDITION^{TM}$ 

INSECT REPELLENT

SPF 30 SUNSCREEN SPRAY

VERY WATER RESISTANT

GENTLE BREEZE™

### [ALTERNATE BRAND NAME #3:]

AVON

SKIN-SO-SOFT

S

S

S

BUG GUARD PLUS

IR3535®

EXPEDITION™

INSECT REPELLENT

SPF 30 SUNSCREEN SPRAY

WATER RESISTANT (80 MINUTES)

GENTLE BREEZE™

## ACCEPTED

### 01/23/2018

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

806-33

DRAFT MASTER LABEL FOR EPA REG. NO. 806-33 WITH NEW FDA INFORMATION 09/26/17 AVON SKIN SO SOFT SSS BUG GUARD PLUS IR3535 EXPEDITION INSECT REPELLENT SPF 30 SUNSCREEN (PUMP SPRAY) Page 2 of 6

KEEP OUT OF REACH OF CHILDREN WARNING See back panel for First Aid

**ACTIVE INGREDIENT:** 

3-[N-butyl-N-acetyl]-aminopropionic acid, ethyl ester\* 19.6% OTHER INGREDIENTS: 80.4% TOTAL: 100.0%

\*IR3535®

1 FL. OZ. (30 ml)

2 FL. OZ. (59 ml)

4 FL. OZ. (118 ml)

6 FL. OZ. (177 ml)

8 FL. OZ. (236 ml)

[Text within brackets is optional and may appear on the back of container label]

### BACK OF CONTAINER:

**DIRECTIONS FOR USE:** It is a violation of Federal law to use this product in a manner inconsistent with its labeling. An adult must apply this product to children under age 10. Children under 6 months: Ask a doctor. Do not apply over wounds, freshly shaved or irritated skin. TO APPLY TO SKIN: Spray liberally and rub product on evenly 15 minutes before sun and insect exposure. TO APPLY TO FACE: Spray palm of hand and rub on, avoiding the eye area. FOR PROTECTION from deer ticks reapply after 10 hours, and for mosquitoes reapply after 8 hours, and for gnats, no-seeums, sand flies and biting midges reapply after 6 hours. For sunscreen protection, reapply immediately after towel drying, after 80 minutes of swimming or sweating, at least every 2 hours. REAPPLY AS NEEDED, 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 for disposal instructions. Never place unused product down any indoor or outdoor drain.

Protect product from direct sun.

**PRECAUTIONARY STATEMENTS:** Hazards to Humans. **WARNING.** For external use only. Causes substantial but temporary eye injury. **When using this product** keep out of eyes. Do not spray on face, clothing or in eyes. Do not rub eyes with fabric that has contacted product or treated skin. **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.

PHYSICAL OR CHEMICAL HAZARDS: Flammable. Keep away from heat and open flame.

[Avoid contact with plastics, costume jewelry, leather and synthetic fibers. May damage painted or varnished surfaces, including nail polish.]

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FIRST AID	
If in eyes:	<ul> <li>Hold eye open and rinse slowly and gently with water for 15 – 20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> </ul>
	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. You may also contact 1-800-FOR-AVON for emergency medical treatment information.	

#### **ACTIVE SUNSCREEN INGREDIENTS:**

Octocrylene 10% Octinoxate 7.5% Oxybenzone 6% Octisalate 5%

[OTHER INGREDIENTS: SD Alcohol 40-B, Water, Hexylene glycol, Polyurethane-1, Fragrance, Aloe barbadensis extract, Tocopheryl acetate (Vitamin E)]

To order, see an Avon Representative, or call 1-800-FOR-AVON. www.avon.com Not for sale or use after expiration date.

EPA Reg. No. 806-33

EPA Est. No. [806-IL-1M, 806-IL-1, 82208-NJ-001MC, 82208-NJ-001]

[Boxed letters are first letters of lot number]

[Distributed by] NEW AVON LLC, 777 THIRD AVENUE, NY, NY 10017

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### Bottom of Container:

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]

Dual protection from sun and certain insects

Combined sun and insect protection in one product

Light feel, strong protection

SPF 30 Water Resistant (80 minutes)

Helps prevent sunburn

PABA-free

U.S. Patent Nos. 6,719,959, 7,150,878 [,] [and] [&] 7,744,911

Contains Vitamin E

[With] Vitamin E

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[Contains] IR3535®

IR3535® is a registered trademark of Merck KGaA

IR3535® is chemically similar to β-alanine [, which occurs naturally]

Gentle Breeze™ [scent]

Pleasantly scented

Easy to apply

Sprays at any angle

Light feeling spray

Non-oily

Not oily

Non-greasy

Not greasy

Light feel

Quick drying

Fast drying

For active [family] lifestyles

Suitable for the [entire] [whole] family

[Gentle] [Mild] formula

Gentle and mild formula

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

Dermatologist tested

Hypoallergenic

Provides the whole family with an effective [broad-spectrum] outdoor insect repellent

Protection for the [entire] [whole] family

Strong protection for the [entire] [whole] family

[Strong] [Dependable] Protection

Effective, dependable protection

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Provides strong and dependable [protection] [repellency]

When used as directed, works anytime to prevent mosquitoes from biting

[Repellency –] Avon's exclusive formula [with IR3535®] provides strong and dependable [repellency] [protection] against deer ticks, mosquitoes, gnats, no-seeums, sand flies and biting midges

[Repellency -] Patented technology that provides strong and dependable [repellency] [protection] against deer ticks, mosquitoes, gnats, no-seeums, sand flies and biting midges

[Repellency –] Provides effective and long-lasting [repellency] [protection] from deer ticks, mosquitoes, gnats, no-seeums, sand flies and biting midges

Exclusive patented enhanced duration technology

Patented time-release technology

Time-release formula

Patented controlled-release technology

Controlled-release formula

Strong and long-lasting [repellency] [protection] against mosquitoes [up to] [for] 8 hours

Strong and long-lasting [repellency] [protection] against deer ticks [up to] [for] 10 hours

Strong [repellency] [protection] against deer ticks, mosquitoes, gnats, no-seeums, sand flies and biting midges

Long-lasting [repellency] [protection] against deer ticks, mosquitoes, gnats, no-seeums, sand flies and biting midges

Provides hours of [repellency] [protection] from deer ticks, mosquitoes, gnats, no-seeums, sand flies and biting midges

Strong [repellency] [protection] against mosquitoes

Long-lasting [repellency] [protection] against mosquitoes

Prevents mosquitoes from biting [up to 8 hours] [for 8 hours]

Repels mosquitoes [up to] [for] [8 hours]

Strong [repellency] [protection] against deer ticks

Long-lasting [repellency] [protection] against deer ticks

Repels deer ticks [up to] [for] [10 hours]

Repels gnats, no-seeums, sand flies and biting midges [up to] [for] [6 hours]

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[Creates an] [invisible] [unseen] [hidden] [layer] [barrier] of protection to repel [certain insects] [mosquitoes]

Repels mosquitoes that may [carry] [transmit] West Nile Virus [up to] [for] 8 hours

Repels mosquitoes that may [carry] [transmit] West Nile Virus

Repels deer ticks that may [carry] [transmit] [Lyme Disease] [and] [Powassan Encephalitis] [up to] [for] 10 hours

Repels deer ticks that may [carry] [transmit] [Lyme Disease] [and] [Powassan Encephalitis]

Made in the USA

Low odor formula

Effective, dependable insect repellency

Non-sticky

Quick and even coverage

Sprays evenly and consistently

Long lasting protection for the entire family

Smart (dependable) protection for the entire family

Effective protection you can count on from certain insects (including mosquitos and ticks)

Proven shield against mosquitos and deer ticks

Fights off mosquitos and unwanted (certain) insects

Easy on skin, tough on bugs

The right protection for your family

Stay protected for 8 hours from mosquitos and ticks

For hiking, fishing, hunting, camping and backpacking