

806-32

7/12/2012

1/8



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON D C 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

Avon Products, Inc  
c/o J Michael Kelley, Ph D  
toXcel  
7140 Heritage Village Plaza  
Gainesville, VA 20155-3061

**JUL 12 2012**

**Subject** Label Amendments to add label language pursuant to the U S Food and Drug Administration (FDA) Final Monograph Rule for Labeling Sunscreen Products (21 CFR § 201.327) and revise alternate brand names  
Avon Skin-So-Soft SSS Bug Guard Plus IR3535 Insect Repellent Gentle Breeze SPF 30 Sunscreen Lotion (EPA Reg No 806-13)  
Avon Skin-So-Soft SSS Bug Guard Plus IR3535 Insect Repellent Cool N Fabulous SPF 30 Sunscreen Lotion (EPA Reg No 806-14)  
Avon Skin-So-Soft SSS Bug Guard Plus IR3535 Expedition Insect Repellent SPF 30 Sunscreen Spray Very Water Resistant Unscented (EPA Reg No 806-32)  
Avon Skin-So-Soft SSS Bug Guard Plus IR3535 Expedition Insect Repellent SPF 30 Sunscreen Spray (EPA Reg No 806-33)  
Your submissions dated April 10, 2012  
Decision Numbers 463803, 463804, 463805, and 463806

Dear Dr Kelley

The amendments referred to above submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)(5), are acceptable provided that you

- 1) Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data
- 2) Submit two (2) copies of your final printed labeling before you release the products for shipment  
Final printed labeling means the label or labeling of the products when distributed or sold  
Clearly legible reproductions or photo reductions will be accepted for unusual labels, such as those silk-screened directly onto glass or metal containers or large bags or drum labels

If these conditions are not complied with, the registrations will be subject to cancellation in accordance with FIFRA section 6(e) Your release for shipment of the products bearing the amended labeling constitutes acceptance of these conditions A stamped copy of the labels are enclosed for your records

Should you have any questions, you may contact Mr Colin Walsh directly at (703) 308-0298 or via email at [walsh.colin@epa.gov](mailto:walsh.colin@epa.gov)

Sincerely,



Linda A Hollis, Chief  
Biochemical Pesticides Branch  
Biopesticides and Pollution  
Prevention Division (7511P)

3/8

FRONT OF CONTAINER

AVON  
 SKIN-SO-SOFT  
 S  
 S  
 S  
 BUG GUARD *PLUS*  
 IR3535®  
 EXPEDITION™  
 INSECT REPELLENT  
 SPF 30 SUNSCREEN SPRAY  
 VERY WATER RESISTANT  
 UNSCENTED

**ACCEPTED**

JUL 12 2012

Under the Federal Insecticide Fungicide  
 and Rodenticide Act as amended, for  
 the pesticide registered under  
 EPA Reg No 806-32

**[ALTERNATE BRAND NAME #1 ]**

AVON  
 SKIN-SO-SOFT  
 S  
 S  
 S  
 IR3535®  
 EXPEDITION™  
 INSECT REPELLENT  
 SPF 30 SUNSCREEN SPRAY  
 VERY WATER RESISTANT  
 UNSCENTED

**[ALTERNATE BRAND NAME #2 ]**

AVON  
 BUG GUARD *PLUS*  
 IR3535®  
 EXPEDITION™  
 INSECT REPELLENT  
 SPF 30 SUNSCREEN SPRAY  
 VERY WATER RESISTANT  
 UNSCENTED

**[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)  
 UNSCENTED

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

4/8

ACTIVE INGREDIENT	
3-[N-butyl-N acetyl]-aminopropionic acid, ethyl ester*	19.7%
OTHER INGREDIENTS	80.3%
TOTAL	100.0%
*IR3535®	

- 1.0 OZ (28.35 g)
- 2.0 OZ (56.7 g)
- 4.0 OZ (113.4 g)
- 6.0 OZ (170.1 g)
- 8.0 OZ (226.8 g)

[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. **Shake well** TO APPLY TO SKIN Spray liberally with a sweeping motion, 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 12 hours, and for mosquitoes reapply after 8 hours, and for gnats, no-see-ums, 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** Do Not Puncture or Incinerate! **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.

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 Contents under pressure. Keep away from heat, sparks and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.

[Intentional misuse by deliberately concentrating and inhaling contents may be harmful or fatal.]

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

5/8

BACK OF CONTAINER- continued

<b>FIRST AID</b>	
If in eyes	<ul style="list-style-type: none"><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><li>• Call a Poison Control Center or doctor for treatment advice</li></ul>
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 9%
- Octinoxate 6.8%
- Oxybenzone 5.4%
- Octisalate 4.5%

[OTHER INGREDIENTS SD Alcohol 40-B, Water, Isobutane, Hexylene glycol, Polyurethane 1, Propane, Tocopheryl acetate (Vitamin E)]

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

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 806-32  
EPA Est No [013891-IN-001] **PI**, 013891-IN 001, 054487-GA-001 **XP**, 054487-GA 001  
[Boxed letters are first letters of lot number]  
AVON PRODUCTS, INC , DISTR 777 THIRD AVE ,NY, NY 10017  
© AVON 200X – ALL RIGHTS RESERVED

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
- SHAKE WELL
- SPF 30 Water Resistant (80 minutes)
- Helps prevent sunburn
- PABA-free

6/8

U S Patent Nos 6,719,959, 6,969,521 7,150,878 [,] [and] [&] 7,744,911

Contains Vitamin E

[With] Vitamin E

[Contains] IR3535®

IR3535® is a registered trademark of Merck KGaA

IR3535® is chemically similar to  $\beta$ -alanine [, which occurs naturally]

Unscented

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

7/8

[Strong] [Dependable] Protection

Effective, dependable protection

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] 12 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] [12 hours]

8/8

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

[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 [up to] [for] 12 hours

Repels deer ticks that may [carry] [transmit] Lyme Disease

No CFCs

Contains no CFCs [or other ozone depleting substances]

Federal Regulations prohibit CFC propellants in aerosols

Made in the USA