

806-33

7/12/2012

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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

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

Sincerely,



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

3048

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™

ACCEPTED

JUL 12 2012

Under the Federal Insecticide Fungicide
and Rodenticide Act as amended for
the pesticide registered under
EPA Reg No 806-33

[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™
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™

4098

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-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 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.]

5028

FIRST AID	
If in eyes	<ul style="list-style-type: none"> • 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. 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-1[M], 806-IL-1, 82208-NJ 001[MC], 82208 NJ 001]
 [Boxed letters are first letters of lot number]
 AVON PRODUCTS, INC , DISTR , 777 THIRD AVENUE, 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
- 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

6008

[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

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]

[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] 10 hours

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

Made in the USA