



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

April 30, 2008

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

J. Michael Kelley, Ph.D.Authorized Representative of Avon Products, Inc.P.O. Box 3637140 Heritage Village Plaza Gainesville, VA 20156

RE:

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

Repellent SPF 30 Sunscreen Spray Very Water Resistant Gentle Breeze

EPA Reg. No: 806-33

Application for label Notification dated April 21, 2008 to Revise Storage and Disposal

Section

## Dear Dr. Kelley:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under 98-10 dated above. A preliminary screen of this request has been conducted for its applicability under PRN 98-10 and it has been determined that the action(s) requested falls within the scope of PRN 98-10. Our records have been duly noted, and the label submitted with this application has been stamped "Notification, received and reviewed" and will be placed accordingly in our records.

Questions concerning this action should be directed to Ms. Diana Hudson at (703) 308-8713 or email at <a href="mailto:hudson.diana@epa.gov">hudson.diana@epa.gov</a>.

Sincerely,

## Linda Hollis

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

	Registration
	<b>Amendment</b>
ᅒ	Other

<b>SEPA</b>		Environmer Was	ency	│	_	ration Iment	OPP Ide	intifier Number				
Application for Pesticide – Section 1												
	Company/Product Number					2. EPA Product Manager				Proposed Classification		
4. Company/Produc		oducts, Inc. / 8	306-33		Linda Hollis				None None	Restricted		
		e, SSS-Bug-Guard	l Plus IR3	535®	90							
		t Repellent SPF										
		Resistant Gentle										
5. Name And Addres	ss Of Ap	plicant (Include ZIP Co	ode)		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)							
Avon	Prod	ucts, Inc.			(b)(i), my product is similar or identical in composition and labeling							
1251	Aven	ue of the Ame	ricas		to:							
New `	York,	NY 10020			EPA Reg. No							
Check	k if this is	s a new address			Product Name							
Section II												
NOTIFICATION NOTIFICATION										ON		
Amendment – Explain below.  Resubmission in response to Agency letter dated					Agency letter dated  "Me Too" Application. Date Reviewed: 4-30-08							
	•		iteu		"Me Too" Application. Date Heviewed:							
Notification – E	Other - Explain Below. Reviewed By: D. Huson											
•		al page(s) if necessary			on II.)			····································				
		ns to the storage	-		•					_		
		elative to PR Notice 20 1 156.10, 156.140, 156										
statement of formula	of this p	product. I understand t	that it is a viola	ation of 18 U	J.S.C. Sec. 1001 to w	illfully ma	ake any	false stater	ment to EPA	. I further		
		led label is not consiste and I may be subject t							3, and 156.1	56, this product		
					tion III							
1. Material This Prod	Juct Will	Be Packaged In:										
Child Resistant Pack	kaging	Unit Packaging		Water S	Water Soluble Packaging 2. Type of Cont							
Yes*		Yes		Yes				Metal	Metal			
☐ No	ļ	No No		☐ No				Plastic				
* Certification m	nust	If "Yes"	No. per	If "Yes" No. per				Glass Paper				
be submitted	ļ	Unit Packaging wgt.	Container	Unit Pa	Onit Fackaging wgt. Container   ==				(Specify)			
3. Location of Net Contents Information 4. Size(S) R			4. Size(S) R					n of Label Di On Label	irections			
Label Container							_		accompany	ying product		
6. Manner in Which L	ahal is .	Affived to Product	phed		<u></u>							
Paper gl				plued								
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Section IV  1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application. (Section IV)												
1. Contact Point (Con	mpiete ii	ems airectly below for	Identification	of individual Title	to be contacted, it rie	)cessary,	to proc			ude Area Code)		
	lev. P	h D. <i>l toXcel</i> . Li	c		uthorized Representative				์ (7กจ์ร์ ัร	35-5670		
J. Michael Kelley, Ph.D. / toXcel, LLC Avon Au									6	opiication		
I certify tha	atements I have made	ments thereto are tru	ie, accura	ate and	compléte: c	Receiv						
l acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment ರಾಧ್ಯ ಎಂದಿ												
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2. Signature				3. Title Avon Authorized Representative (toXcel, LLC)				(	ι ( ( (			
					duronzed Representative (toxcer, LLC)					<b>.</b>		
4 Typed Name 5. Date					April 24 2008					!		
J. Michael Kelley, Ph.D.					April 21, 2008					•		

# toXcel

# Toxicology & Regulatory Affairs P.O. Box 363 7140 Heritage Village Plaza Gainesville, VA 20156 USA

Phone: (703) 335-5670 Fax: (703) 310-6950

### **Hand Delivery**

April 21, 2008

Ms. Linda Hollis, PM-90
Document Processing Desk (NOTIF)
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs - (7504P)
U.S. Environmental Protection Agency
Room S-4900, 4<sup>th</sup> Floor, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

RE: Notification of Revision of Storage and Disposal Labeling for Avon

Skin-So-Soft SSS Bug Guard Plus IR3535<sup>®</sup> Expedition™ Insect Repellent SPF 30 Sunscreen Spray Very Water Resistant Gentle

Breeze™;

EPA Registration No. 806-33

Dear Ms. Hollis:

In accordance with Pesticide Registration (PR) Notice 2007-4, the registrant is formally submitting this notification of revisions to the storage and disposal section of the product label, as indicated on the enclosed Notification (EPA Form 8570-1). It is understood that this PR Notice provides guidance for the revision of the storage and disposal section for all pesticide products to comply with the new container regulations located in 40 CFR Part 156.

The registrant has revised the disposal statement of the product label for the above referenced product to read, "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 any unused product down any indicate or outdoor drain." The registrant believes that all requirements of this PR Notice are fulfilled in this label revision. The recycling statement conforms to this PR Notice as well as to PR Notice 2007-1. In addition, all of the registrant's pesticide products bear a batch code. As required in the PR Notice, one "highlighted" copy of the product labeling is enclosed that denotes the changes made as well as one "clean" copy of the label.

Ms. Linda Hollis April 21, 2008 Page 2 of 2

We would appreciate being informed of the acceptance of this notification after it is reviewed. If you have any questions or require additional information or documentation, please do not hesitate to contact me or Micah Reynolds by phone at 703-335-5670 or by email at <a href="mailto:mike.kelley@toxcel.com">mike.kelley@toxcel.com</a> or <a href="mailto:mike.kelley@toxcel.com">micah.reynolds@toxcel.com</a>, respectively.

Sincerely,

J. Michael Kelley, Ph.D.

Vice President

Authorized Representative of Avon Products, Inc.

**Enclosures** 

Cc: A. Pechko (Avon)

H. Estriecher (Keller & Heckman)

DRAFT MASTER LABEL FOR EPA REG. NO. 806-33 04/11/08 AVON SKIN SO SOFT SSS BUG GUARD PLUS IR3535 EXPEDITION INSECT REPELLENT SPF 30 SUNSCREEN (PUMP SPRAY) Page 1 of 5

#### **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™** 

INSECT REPELLENT

SPF 30 SUNSCREEN SPRAY

**VERY WATER RESISTANT** 

**GENTLE BREEZE™** 

KEEP OUT OF REACH OF CHILDREN

WARNING

See back panel for First Aid

#### **ACTIVE INGREDIENT:**

3-[N-butyl-N-acetyl]-aminopropionic acid, ethyl ester\*

**OTHER INGREDIENTS:** 

TOTAL:

\*IR3535®

1 FL, OZ. (29.5 ml)

2 FL. OZ. (59 ml)

4 FL. OZ. (118 ml)

6 FL. OZ. (177 ml)

8 FL. OZ. (236 ml)

NOTIFICATION

Date Reviewed: 4-30-08

Reviewed By D. Hudson)

80.4% ((((( . . . . .

CC

.....

19.6%

100.0%

DRAFT MASTER LABEL FOR EPA REG. NO. 806-33

AVON SKIN SO SOFT SSS BUG GUARD PLUS IR3535 EXPEDITION INSECT REPELLENT SPF 30 SUNSCREEN (PUMP SPRAY)

Page 2 of 5

[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. Do not apply over wounds, freshly shaved or irritated skin. TO APPLY TO FACE: Spray palm of hand and rub on, avoiding the eye area. TO APPLY TO SKIN: Spray liberally and rub product on evenly before sun and insect exposure. FOR CONTINUED 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 after towel drying, swimming or sweating. 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 any unused product down any indoor or outdoor drain.

**PRECAUTIONARY STATEMENTS:** Hazards to Humans. **WARNING.** Causes substantial but temporary eye injury. Do not spray on face, clothing or in eyes. Do not rub eyes with fabric that has contacted product or treated skin. Discontinue use and consult a doctor if irritation or rash occurs. Ask a doctor before using on children under 6 months of age. For external use only.

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.]

#### **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.

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 10.0%
Octinoxate 7.5%
Oxybenzone 6.0%
Octisalate 5.0%

[OTHER INGREDIENTS: SD Alcohol 40-B, Water, Hexylene glycol, Polyurethahe-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-OH-001

AVON PRODUCTS, INC., DISTR. 1251 AVE. OF THE AMERICAS, NY, NY 10020

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DRAFT MASTER LABEL FOR EPA REG. NO. 806-33

O4/11/08

AVON SKIN SO SOFT SSS BUG GUARD PLUS IR3535 EXPEDITION INSECT REPELLENT SPF 30 SUNSCREEN

(PUMP SPRAY)

Page 3 of 5

#### **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 Very Water Resistant

Helps prevent sunburn

Higher SPF gives more sunburn protection

Retains SPF after 80 minutes of activity in the water or sweating

PABA-free

U.S. Patent Nos. 6,719,959 and 7,150,878 [and other patents pending]

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]

Gentle Breeze™ [scent]

Pleasantly scented

Easy to apply

Sprays at any angle

Light feeling spray

Non-oily

Not oily

Non-greasy

Not greasy



DRAFT MASTER LABEL FOR EPA REG. NO. 806-33

AVON SKIN SO SOFT SSS BUG GUARD PLUS IR3535 EXPEDITION INSECT REPELLENT SPF 30 SUNSCREEN (PUMP SPRAY)

Page 4 of 5

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

