



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

May 22, 2008

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

J. Michael Kelley, Ph.D.
Toxcel
Authorized Representative of Avon Products, Inc.
P.O. Box 363
7140 Heritage Village Plaza Gainesville, VA 20156

Subject:

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

Your Revised Application Dated May 8, 2008 to Correct the Storage and Disposal

Instructions per PR Notice 2007-4

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 hudson.diana@epa.gov.

Sincerely,

Linda Hollis

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

Please read instructions	s on reve	rse side before còtin-	g form.		F	orm Ap	ed. □	OMB N	o. 2070-00	060. Approv	al expires 05-31-98	
SEPA United States Environmental Protect Washington, DC 20				ection Agency 20460			T 23 - 0 11 10 1			OPP Ide	ntifier Number	
			Application	n for P	esticide –							
1. Company/Product Number  Avon Products, Inc. / 806-33					2. EPA Product Manager  Linda Hollis					3. Proposed Classification		
4. Company/Product (Name) Avon Skin-So-Soft SSS Bug Guard Plus IR3535 <sup>®</sup> Expedition™ Insect Repellent SPF 30 Sunscreen Spray Very Water Resistant Gentle Breeze™					PM# 90				None	Restricted		
5. Name And Addres	s Of Ap	oplicant (Include ZIP Co	ode)		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)							
Avon Products, Inc. 1251 Avenue of the Americas New York, NY 10020  Check if this is a new address					(b)(i), my product is similar or identical in composition and labeling to:  NOTIFICATION  EPA Reg. No.  Product Name  D. Hudson							
				Sec	tion II Reviewed By.							
Amendment – Explain below.  Resubmission in response to Agency letter dated  Notification – Explain below.					Final Printed labels in response to Agency letter dated  "Me Too" Application.  Other – Explain Below.							
Explanation: Use additional page(s) if necessary. (For section I and Section II.)  Notification of revisions to the storage and disposal section per PR Notice 2007-4. This Notification replaces the notification filed on April 22, 2008.  Notification of label change relative to PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.												
				Sec	tion III							
1. Material This Prod	uct Will	Be Packaged In:							······································	1		
Child Resistant Packaging  Yes* No No  * Certification must  Unit Packaging  No No Yes No No No			No. per Container	Water Soluble Packaging  Yes  No  If "Yes"  Unit Packaging wgt.  Container						c c c c c c c c c c c c c c c c c c c	C C C C C C	
be submitted		Office acreaging rig.	Ooman.c.	Onit rackaging wgt. Container					Othe: (	Othe: (Specify) <u>, c c c</u>		
3. Location of Net Contents Information 4. Size(S) R  Label Container				Retail Container  5. Location of Label Diractions On Labeling accompanying product							C C	
6. Manner in Which Label is Affixed to Product  Lithogra Paper g Stencile				glued Unter								
Section IV												
1. Contact Point (Cor	mplete il	tems directly below for	identification of	f individual	to be contacted	d, if neces	sary, to	o proce	ss this app	lication.)		
				Title Avon Au	Telephon Avidential Telephon Avon Authorized Representative					ne No. (Include Area Code) (703) 335-5670		
Certification  I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.  6. Date Application Received												
2. Signature Melle				3. Title Avon Authorized Representative (toXcel, LLC)								
4. Typed Name 5.				5. Date	May 8 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**

May 8, 2008

Ms. Linda Hollis, PM-90 c/o Ms. Diana Hudson
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® 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 Formes 8570-1). It is understood that this PR Notice provides guidance for the registrant is formally submitted and disposal section for all pesticide products to comply with the new container regulations located in 40 CFR Part 156.

Please Note: It is extremely important to identify that this Notification replaces the Notification filed on April 22, 2008 for the same product. The previous Notification submitted included product labeling that contained an erroneous word in the Storage and Disposal section. On the previous label, the Storage and Disposal section concluded with the following phrase: "Never place any unused product down any indoor or outdoor drain." The label enclosed has been corrected to remove the extra "any" that occurred early in the sentence in order to align with current Agency guidance.

Ms. Linda Hollis May 8, 2008 Page 2 of 2

The remainder of the enclosed label is identical to the version previously reviewed and approved by Ms. Hudson in her April 30, 2008 correspondence. Per the guidance in PR Notice 2007-4, 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 unused product down any indoor 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.

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 05/08/08 AVON SKIN SO SOFT SSS BUG GUARD PLUS IR3535 EXPEDITION INSECT REPELLENT SPF 30 SUNSCREEN Page 1 of 5 (PUMP SPRAY)

# **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\*

19.6%

**OTHER INGREDIENTS:** 

80.4% 100.0%

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: 5/22/08
Reviewed By: D. Hudsen

[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 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	00000							
If in	•	Hold eye open and rinse slowly and gently with water for	15 – 20ີຫi	nutes. c						
eyes:	•	Remove contact lenses, if present, after the first 5 minutes, then continue								
		rinsing eye.		<b>L</b> E C						
	•	Call a poison control center or doctor for treatment advice	• 00000	ເັ້ເັເ						
Havet	ho r	product container or label with you when calling a noison con	atrof contar	or doctor						

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 medicales treatment information.

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

Octocrylene 10.0% Octinoxate 7.5% Oxybenzone 6.0% Octisalate 5.0%

© AVON 200X - ALL RIGHTS RESERVED

[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-OH-001

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

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c ccc

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 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 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

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

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 5 of 5

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