806-18

08/26/2008



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

August 26, 2008

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

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

> RE: Product Name: Avon Skin-So-Soft SSS Bug Guard Plus IR3535 Insect Repellent SPF 15 Sunscreen Spray Gentle Breeze EPA Reg. No: 806-18

Application for label Notification dated July 21, 2008 to Add Revise Storage and Disposal Section and to Add 1-800-Number in First Aid 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 <u>hudson.diana@epa.gov</u>.

Sincerely,

Linda Hollis

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

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Please read instructions on	reverse side before completin	g form.	Form Ap	proved. OMB No. 20	070-0060. Approval expires 05-31-98	
<b>€EPA</b>		United States ntal Protection / shington, DC 20460		☐ Registration ☐ Amendmen ☑ Other		
		Application for	Pesticide – Sectio		·	
1. Company/Product Nu		206-12	2. EPA Product Mana	•	3. Proposed Classification	
Avon Products, Inc. / 806-18 4. Company/Product (Name)			Linda Hollis		None Restricted	
	oft SSS Bug Guard SPF 15 Sunscree		90 e			
5. Name And Address C	of Applicant (Include ZIP C	ode)			ce with FIFRA Section 3(c)(3)	
Avon Products, Inc.			<ul><li>(b)(i), my product is similar or identical in composition and labeling to:</li></ul>			
1251 Avenue of the Americas			EPA Reg. No.			
<u> </u>	ork, NY 10020		Product Name			
			ection II	······		
	·····	- <u></u>				
Amendment – Explain below.			Final Printed labels in respon SOTIFICATION			
	esponse to Agency letter d	ated	- Me Too" Appli	catioDate Rev	iewed: 8-26-08	
Notification – Expla	ain below.		Other – Explair	n Below.	By: D. Hudson	
labeling or the confident statement to EPA. I furt	ial statement of formula of her understand that if this	this product. I unders notification is not consist	tand that it is a violation of	18 U.S.C. Sec. 100 <sup>4</sup> Notice 98-10 and 40	er changes have been made to the 1 to willfully make any false ) CFR 152.46, this product may be in	
		Ś	ection III			
1. Material This Product	Will Be Packaged In:					
Child Resistant Packag		Water Soluble Packaging 2. Type of C			Container	
∐ Yes*	Yes		Yes		Metal	
No No			No		Plastic Glass	
* Certification mus be submitted	st If "Yes" Unit Packaging wgt.	No. per If "Y Container Unit	'es" No. pe Packaging wgt. Contai	ner 🛛 🖵 F	Paper Dther (Specify)	
3. Location of Net Contents Information       4. Size(S) R         Label       Container		4. Size(S) Retail Cor	tetail Container		abel Directions ibel ibeling accompanying product	
6. Manner in Which Lab	el is Affixed to Product	Lithographed Paper glued Stenciled	Oth	er		
· · · · · · · · · · · · · · · · · · ·		S	ection IV	·		
	ete items directly below fo	r identification of individ Title	lual to be contacted, if nec			
Name J. Michael Kelley, Ph.D. / toXcel, LLC			Authorized Represe	lephone No. (Include Area Code) (703) 335-5670		
I certify that th	ne statements I have made e that any knowingly false	Certification on this form and all att	achments thereto are true, It may be punishable by fin		6. Date Application lete. Received	
2. Signature mathematic For			Authorized Represent	(c) (c)		

# toXcel

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

Phone: (703) 335-5670

Fax: (703) 310-6950

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#### Hand Delivery

July 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

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RE: Notification of Addition of 1-800 Number to the First Aid section and Revision of Storage and Disposal Labeling for Avon Skin-So-Soft SSS Bug Guard Plus IR3535<sup>®</sup> Insect Repellent SPF 15 Sunscreen Spray Gentle Breeze™; EPA Registration No**®806-18** 

## Dear Ms. Hollis:

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In accordance with Pesticide Registration (PR) Notice 1998-10, the registrant is formally submitting this notification of revisions to the First Aid section and the Storage and Disposal section of the product label, as indicated on the enclosed Notification (EPA Form 8570-1). Based on the guidance in PR Notice 2007-4, the registrant is amending the Storage and Disposal language to comply with the new container regulations located in 40 CFR Part 156 and is also taking the opportunity to update its label format to be consistent with its recently registered products. That is, many of the optional and/or marketing claims appear on the last page of the label.

Regarding the Storage and Disposal section, 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 recycling statement conforms to PR Notice 2007-4 as well as to PR Notice 2007-1. In addition, all of the registrant's pesticide products bear a batch code. As required by PR Notice 98-10, 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 July 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 <u>mike.kelley@toxcel.com</u> or <u>micah.reynolds@toxcel.com</u>, respectively.

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Sincerely,

J. Michael Kelley, Ph.D. Vice President Authorized Representative of Avon Products, Inc.

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Enclosures

Cc: A. Pechko (Avon) H. Estriecher (Keller & Heckman)

#### FRONT OF CONTAINER:

AVON S S S SKIN-SO-SOFT GENTLE BREEZE™ BUG GUARD *PLUS* IR3535® INSECT REPELLENT SPF 15 SUNSCREEN SPRAY

NOTIFICATION Date Reviewed: 8-26-08 Reviewed By:

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[Alternate Brand Name #1]

AVON SKIN-SO-SOFT S BUG S GUARD S *PLUS* IR3535® INSECT REPELLENT SPRAY GENTLE BREEZE™ SPF 15 SUNSCREEN VERY WATER RESISTANT

KEEP OUT OF REACH OF CHILDREN WARNING

ACTIVE INGREDIENTS: beta-alanine, n-acetyl-N-butyl-, ethyl ester\* / carboxylic acid OTHER INGREDIENTS: TOTAL: \*IR3535®

7.5% <u>92.5%</u> 100.0%

4 FL. OZ. (118 ml)

DRAFT MASTER LABEL FOR EPA REG. NO. 806-18 AVON SKIN-SO-SOFT SSS BUG GUARD PLUS IR3535 INSECT REPELLENT SPF 15 SUNSCREEN SPRAY Gentle Breeze™ Page 2 of 3

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

**DIRECTIONS FOR USE:** It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Apply liberally and evenly before sun and insect exposure. TO APPLY TO FACE: spray palm of hand and rub on. An adult must apply this product to children under 10. For continued insect protection, reapply about every 2 hours or sooner if effectiveness diminishes. For sunscreen protection, reapply as needed or after towel drying, swimming or sweating. Do not exceed 9 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 containers 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.** For external use only. Causes substantial but temporary eye injury. Do not get in eyes. Do not spray on face. Stop use and ask a doctor if rash or irritation develops and lasts. Ask a doctor before using on children under 6 months of age.

	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
	remergency-medical treatment information.

PHYSICAL HAZARDS: FLAMMABLE. Keep away from heat or open flame.

ACTIVE SUNSCREEN INGREDIENTS: Octocrylene 10.0%, Octinoxate 7.5%, Octisalate 5.0%

[OTHER INGREDIENTS: SD Alcohol 40-B, Isopropyl Myristate, C12-15 Alkyl Benzoate, Acrylates/Octylacrylamide Copolymer, Fragrance, BHT]

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. 806-18 EPA Est. No. 806-OH-001 AVON PRODUCTS, INC., DISTR. 1251 AVE. OF THE AMERICAS, NY, NY 10020 <sup>©</sup> AVON 200X – ALL RIGHTS RESERVED.

Day Lot Code Exp. Year / Month DRAFT MASTER LABEL FOR EPA REG. NO. 806-18 AVON SKIN-SO-SOFT SSS BUG GUARD PLUS IR3535 INSECT REPELLENT SPF 15 SUNSCREEN SPRAY Gentle Breeze™ Page 3 of 3

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

IR3535® is a registered trademark of Merck KGaA

Avoid contact with plastics, costume jewelry, leather and synthetic fibers

May damage painted or varnished surfaces, including nail polish

REPELLENCY - IR3535® provides effective and dependable repellency against mosquitoes, deer ticks, black flies, gnats, no-seeums, sand flies and biting midges

SPF 15 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

Suitable for the entire family

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

Dermatologist-tested

Hypoallergenic

Pleasantly scented

U.S. Patent No. 7,037,515

#### FRONT OF CONTAINER:

AVON S S

S SKIN-SO-SOFT GENTLE BREEZE™ BUG GUARD *PLUS* IR3535® INSECT REPELLENT SPF 15 SUNSCREEN SPRAY

NOTIFICATION Date Reviewed: 8-26-08 Reviewed By: D. Hudse

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## [Alternate Brand Name #1]

AVON SKIN-SO-SOFT S BUG S GUARD S *PLUS* IR3535® INSECT REPELLENT SPRAY GENTLE BREEZE™ SPF 15 SUNSCREEN VERY WATER RESISTANT

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4 FL. OZ. (118 ml)

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	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.				

**PHYSICAL HAZARDS:** FLAMMABLE. Keep away from heat or open flame.

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