

806-22

08/26/2008

1/10



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 Active Insect Repellent Gentle Breeze Towelettes SPF 15 Sunscreen
EPA Reg. No: 806-22
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 HUDSON.DIANA@EPA.GOV.

Sincerely,

Linda Hollis

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

	United States Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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Application for Pesticide - Section 1

1. Company/Product Number: Avon Products, Inc. / 806-22	2. EPA Product Manager Linda Hollis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Avon Skin-So-Soft SSS Bug Guard Plus IR3535® Active Insect Repellent Gentle Breeze Towelettes SPF 15 Sunscreen	PM# 90	
5. Name And Address Of Applicant (Include ZIP Code) Avon Products, Inc. 1251 Avenue of the Americas New York, NY 10020 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section II

NOTIFICATION

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final Printed labels in response to Agency letter dated Date Reviewed: 8-26-08
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain Below. Reviewed By: D. Hudson

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

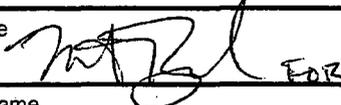
Notification of additional of sites of manufacture and revisions to the Storage and Disposal section.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and 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 this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, 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.

Section III

1. Material This Product Will Be Packaged In:			
Child Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted If "Yes" No. per Unit Packaging wgt. Container		If "Yes" No. per Unit Packaging wgt. Container	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(S) Retail Container	5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithographed <input type="checkbox"/> Other <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name J. Michael Kelley, Ph.D. / toXcel, LLC	Title Avon Authorized Representative	Telephone 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 	3. Title Avon Authorized Representative (toXcel, LLC)	
4. Typed Name J. Michael Kelley, Ph.D.	5. Date July 21, 2008	

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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

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, 4th Floor, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

RE: Notification of Addition of Sites of Manufacture and Revision of Storage and Disposal Labeling for *Avon Skin-So-Soft SSS Bug Guard Plus IR3535[®] Active Insect Repellent Gentle Breeze[™] Towelettes SPF 15 Sunscreen*;
EPA Registration No. **806-22**

Dear Ms. Hollis:

In accordance with Pesticide Registration (PR) Notice 1998-10, the registrant is formally submitting this notification of additional sites of manufacture and revisions to the Storage and Disposal section 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.

FRONT OF PACKAGE:

AVON
SKIN-SO-SOFT
S
S
S
BUG GUARD PLUS
IR3535®
ACTIVE
INSECT REPELLENT
GENTLE BREEZE™
TOWELETTE[S]
SPF 15 SUNSCREEN
VERY WATER RESISTANT

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

KEEP OUT OF REACH OF CHILDREN
WARNING

ACTIVE INGREDIENTS: beta-alanine, n-acetyl-N-butyl-, ethyl ester* / carboxylic acid 7.5%
OTHER INGREDIENTS: 92.5%
TOTAL: 100.0%
*IR3535®

1 TOWELETTE
Total: 0.3 FL. OZ. (10 ml)

[8 TOWELETTES
Total: 2.4 FL. OZ. (80ml)]

[10 TOWELETTES
Total: 3 FL. OZ. (100 ml)]

BACK OF PACKAGE: [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. Open package, remove and unfold towelette. Use as many towelettes as necessary to ensure liberal and even coverage before sun and insect exposure. Adults may need to use more than one towelette. 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 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.~~

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PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS. Warning. For external use only. Causes substantial but temporary eye injury. Do not get in eyes. 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 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.	

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

[ALERT: To avoid danger of suffocation, keep this and all other plastic bags away from babies and children. Do not use in cribs, beds, carriages or playpens. The thin film may cling to nose and mouth and prevent breathing.]

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

EPA Reg. No. 806-22

EPA Est. No. [052631-NJ-001 AP], 052631-NJ-001 (74058-CA-001 IO, 74058-CA-001),
(806-OH-001)

[Boxed letters are first letters of lot number] [Not for sale or use after expiration date]

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

© AVON 200X – ALL RIGHTS RESERVED

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

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-see-ums, sand flies and biting midges

SPF 15 Very Water Resistant

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Helps prevent sunburn

Higher SPF gives more sunburn protection

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

Suitable for the entire family

Pleasantly scented

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

Dermatologist-tested

Hypoallergenic

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

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FRONT OF PACKAGE:

AVON
SKIN-SO-SOFT
S
S
S
BUG GUARD PLUS
IR3535®
ACTIVE
INSECT REPELLENT
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10/10