

806-29

10-23-2008

17



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

J. Michael Kelly, Ph.D.
Authorized Representative for Avon Products, Inc.
toXcel, LLC
Toxicology & Regulatory Affairs
P.O. Box 363
7140 Heritage Village Plaza
Gainesville, VA 20156

OCT 23 2008

SUBJECT: Applications for Pesticide Notification – Removal of Label Claims Regarding
Product's Effectiveness on Clothing
Avon Skin-So-Soft SSS Bug Guard Plus Picaridin Insect Repellent
EPA Reg. No. 806-29
Avon Skin-So-Soft SSS Bug Guard Plus Picaridin Insect Repellent Spray
EPA Reg. No. 806-31
Applications Dated October 31, 2007

Dear Dr. Kelley:

The Agency is in receipt of your Applications for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above products. The Registration Division (RD) has conducted a preliminary screen of these requests for their applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10. The labels submitted with the applications have been stamped "Notification" and will be placed in our records.

If you have any questions, please me directly at 703-305-6249 or Terri Stowe of my staff at 703-305-6117.

Sincerely,

A handwritten signature in black ink, appearing to be "Linda Arrington".

Linda Arrington
Notifications & Minor Formulations Team Leader
Registration Division (7505P)
Office of Pesticide Programs

2/7

	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. / 806-29	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Avon Skin-So-Soft SSS Bug Guard Plus Picaridin Insect Repellent	PM# 10	
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: NOTIFICATION EPA Reg. No. <u> OCT 23 2008 </u> Product Name _____	

Section II

<input type="checkbox"/> Amendment – Explain below.	<input type="checkbox"/> Final Printed labels in response to Agency letter dated _____
<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.

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


Notification of the removal of label claims regarding the product's effectiveness on clothing.

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:				2. Type of Container	
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		<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 October 31, 2007	

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

October 31, 2007

Richard Gebken, PM-10
Document Processing Desk (NOTIF)
Registration Division
Office of Pesticide Programs - (7504P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

RE: Notification of the Removal of the Claim of Product Performance on
Clothing for *Avon Skin-So-Soft SSS Bug Guard Plus Picaridin
Insect Repellent*
EPA Reg. No. 806-29

Dear Mr. Gebken,

On behalf of Avon Products, Inc., we are submitting the enclosed notification for the above referenced product. The Agency is hereby notified that Avon intends to drop the label claim regarding the above referenced product's effectiveness when applied to clothing. In the original EPA conditional approval letter of November 8, 2005, Mr. Joseph Tavano stated:

"4) The claim for use on clothing is being accepted under the following conditions: Data must be submitted to support the efficacy of the product when applied to clothing. A protocol for running the study must be submitted. Once the protocol has been approved, the data must be submitted within one year or you must delete the claim by submitting a label amendment to that effect. You must agree to these conditions."

In a letter dated November 10, 2005, Mr. Andrew Pechko (Avon) agreed to the terms set forth in the Agency's November 8, 2005 correspondence. In conjunction with Insect Control & Research, Inc., the registrant developed a study protocol for evaluation of the efficacy of treated fabric on the repellency of mosquitoes. This protocol was submitted to the Agency on November 9, 2006. Mr. Kevin Sweeney (OPP/RD) subsequently responded in an e-mail noting that the protocol would have to be reviewed by the Human Studies Review Board (HSRB) because the protocol involves the participation of human volunteers as

4/7
Mr. Richard Gebken
October 31, 2007
Page 2 of 2

test subjects. After consideration of the time and effort associated with the HSRB review process, the registrant has elected to remove the claim of product effectiveness on clothing.

As required, three (3) copies of the revised product label are enclosed along with one "red-lined" version of the label showing the exact changes made.

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

Sincerely,



J. Michael Kelley, Ph.D.
Vice President
toXcel, LLC
Authorized Representative for Avon Products, Inc.

Cc: K. Sweeney (EPA/OPP/RD)
A. Pechko (Avon)
T. Gilman (Avon)
H. Estreicher (Keller & Heckman)

5/7

[Bracketed and parenthetical text is additional product information, which may or may not appear on final product label]

FRONT OF CONTAINER:

AVON
SKIN-SO-SOFT
S
S
S
BUG GUARD PLUS
PICARIDIN
INSECT REPELLENT

[ALTERNATE BRAND NAME #1:]

AVON
SKIN-SO-SOFT
S
S
S
PICARIDIN
INSECT REPELLENT

NOTIFICATION
OCT 23 2008

[ALTERNATE BRAND NAME#2:]

AVON
BUG GUARD PLUS
PICARIDIN
INSECT REPELLENT

[Strong repellency against mosquitoes, deer ticks, black flies, gnats, no-seeums, sand flies and biting midges]

[Strong and long-lasting repellency against mosquitoes up to 6 hours and deer ticks up to 7 hours]

[Strong repellency against mosquitoes and deer ticks]

[Repels mosquitoes up to 6 hours and deer ticks up to 7 hours]

[Repels mosquitoes up to 6 hours]

[Repels deer ticks up to 7 hours]

[Repels deer ticks that may (carry) (transmit) Lyme Disease up to 7 hours]

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

[OUTDOOR COOL™ SCENT]

[with vitamin E]

KEEP OUT OF REACH OF CHILDREN

CAUTION

See back panel for additional precautionary statements

ACTIVE INGREDIENT:

Picaridin[*] 10.0%

OTHER INGREDIENTS: 90.0%

TOTAL: 100.0%

[*Bayrepel™]

4 OZ. (113.4 g)

[6 OZ. (170.1g)]

[2 OZ. (56.7g)]

6/7

[Bracketed and parenthetical text is additional product information, which may or may not appear on final product label]

BACK OF CONTAINER:

REPELLENCY – [Avon’s exclusive formula (with Picaridin) (with Bayrepel™) repels mosquitoes up to 6 hours and deer ticks up to 7 hours.] [Patented technology that] Provides strong [and dependable] repellency against mosquitoes, deer ticks, black flies, gnats, no-seeums, sand flies and biting midges.

SUITABLE FOR THE ENTIRE FAMILY – [Pleasantly scented.] [Non-oily spray.] [Light feel.] [Non-greasy spray.] [Pleasantly scented, (non-oily) (non-greasy) (light feeling) spray.] Provides the whole family with an effective broad-spectrum outdoor (bug) (insect) repellent. [Contains Vitamin E.]

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read and follow all directions and precautions on this product label. Hold container 6 to 8 inches from skin and spray with a slow sweeping motion liberally and evenly. Do not spray in enclosed areas. Do not apply under clothing, on cuts, wounds, freshly shaved, excessively sunburned or irritated skin. **TO APPLY TO FACE:** Spray palm of hand and rub on, avoiding the eye and lip area. Use sparingly around ears. Use just enough repellent to cover exposed skin. Avoid over application of product. Do not allow children to handle this product. When applying to children, apply to your own hands and then put it on the child. Do not apply directly to children’s hands. **FOR CONTINUED PROTECTION** from deer ticks, gnats, no-seeums, sand flies and biting midges reapply after 7 hours; for mosquitoes reapply after 6 hours; for black flies reapply after 3 hours. Do not exceed 2 applications per day.

STORAGE: Store in cool, dry place away from heat or flame.
DISPOSAL: Do Not Puncture or Incinerate! **If empty:** Place in trash or offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions.

PRECAUTIONARY STATEMENTS: Hazards to Humans. Caution: Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes and do not spray on face. Wash thoroughly with soap and water after handling, returning indoors, and before eating, drinking, chewing gum, or using tobacco. Wash treated clothing before wearing again. Discontinue use and consult a doctor if irritation or rash occurs.

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.
If swallowed	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to by a poison control center or doctor.• Do not give anything to an unconscious person.
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: Contents under pressure. Keep away from heat, sparks and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting. Keep treated surface away from fire or flame until dry. [Intentional misuse by deliberately concentrating and inhaling contents may be harmful or fatal.]

7/7

[Bracketed and parenthetical text is additional product information, which may or may not appear on final product label]

BACK OF CONTAINER- continued:

[Will not harm most plastics or synthetic fabrics.]
[May damage painted or varnished surfaces(, including nail polish).]

To order, see an Avon Representative, or call 1-800-FOR-AVON. www.avon.com

[Not for sale or use after expiration date.]

[Bayrepel™ is a trademark of (Bayer Corporation) (Lanxess)]

EPA Reg. No. 806-29 EPA Est. No. [013891-IN-001] [054487-GA-001] [33590-MA-003]

AVON PRODUCTS, INC., DISTR.

1251 AVE. OF THE AMERICAS, NY, NY 10020

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[U.S. Patent Nos. 6,719,959, 6,969,521 and 7,150,878]

Bottom of Container:

Julian Day Lot Code Number

Exp. Month/ Year