806-31 10-23-2008 1/9

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,

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

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Please read instructions on reverse side before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

EPA	United States Environmental Protection Agency Washington, DC 20460	☐ Registration ☐ Amendment ☒ Other	OPP Identifier Number

Application for Pesticide – Section 1

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
Avon Products, Inc. / 806-31	**Richard Gebken**	☒ None ☐ Restricted
4. Company/Product (Name) **Avon Skin-So-Soft SSS Bug Guard Plus Picaridin Insect Repellent Spray**	PM# **10**	

5. Name And Address Of Applicant *(Include ZIP Code)*

Avon Products, Inc.
1251 Avenue of the Americas
New York, NY 10020

☐ *Check if this is a new address*

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar chemically in composition and labeling to:

NOTIFICATION

EPA Reg. No. _____

OCT 23 2008

Product Name _____

Section II

☐ 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 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:

Child Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per Container	If "Yes" Unit Packaging wgt. / No. per Container	

3. Location of Net Contents Information	4. Size(S) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithographed ☐ Paper glued ☐ Stenciled ☐ Other _____

Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
J. Michael Kelley, Ph.D. / *toXcel*, LLC	**Avon Authorized Representative**	**(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
JMKelley	**Avon Authorized Representative (*toXcel*, LLC)**
4. Typed Name **J. Michael Kelley, Ph.D.**	**5. Date** **October 31, 2007**

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete

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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

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 Spray*
EPA Reg. No. 806-31

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 September 28, 2006, Mr. Kevin Sweeney stated:

> *"4) In order to retain the directions for use of this product on clothing you must submit a product performance protocol by March 31, 2007 that describes a test to determine whether or not the listed pests are repelled when this product is applied to clothing in accordance with the label directions."*

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 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. In addition to the removal of the claim for product effectiveness on clothing, two additional claims have been removed as per the Agency's correspondence (from Mr. Sweeney) dated June 28, 2007: 1) claims regarding the product forming an unseen or hidden barrier of protection;

and 2) claims of product effectiveness against vectors of the West Nile Virus. The registrant and ICR are currently obtaining approval from the Agency and the HSRB in order to conduct a confirmatory laboratory study to support the West Nile Virus claim.

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)

FRONT OF CONTAINER:

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

[ALTERNATE BRAND NAME #1:]
AVON
SKIN-SO-SOFT
S
S
S
PICARIDIN
INSECT REPELLENT SPRAY

NOTIFICATION
OCT 23 2008

[ALTERNATE BRAND NAME#2:]
AVON
BUG GUARD PLUS
PICARIDIN
INSECT REPELLENT SPRAY

[ALTERNATE BRAND NAME#3:]
AVON
SKIN-SO-SOFT
S
S
S
BUG GUARD PLUS
PICARIDIN
DEER TICK REPELLENT SPRAY

KEEP OUT OF REACH OF CHILDREN
WARNING
See back panel for additional precautionary statements

ACTIVE INGREDIENT:	
Picaridin	10.0%
OTHER INGREDIENTS:	90.0%
TOTAL:	100.0%

0.85 FL. OZ. (25 ml) through 16 FL OZ. (473.1 ml)

[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. 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 reapply after 12 hours, and for mosquitoes reapply after 8 hours, and for gnats, no-seeums, sand flies and biting midges reapply after 6 hours.] [FOR CONTINUED PROTECTION from deer ticks reapply after 12 hours.] Do not exceed 2 applications per day.

STORAGE: Store in cool, dry place away from heat or flame.
DISPOSAL: **If empty:** Do not reuse 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. Harmful if swallowed. Do not get in eyes. 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:	• 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	• 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. Keep away from heat and open flame.

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. 806-31 EPA Est. No. 806-OH-001
AVON PRODUCTS, INC., DISTR.
1251 AVE. OF THE AMERICAS, NY, NY 10020
© AVON 200X [– ALL RIGHTS RESERVED]

Bottom of Container:

Julian Day Lot Code Number
Exp. Month/ Year

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[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]

Contains Vitamin E

With Vitamin E

Vitamin E

Contains Aloe

With Aloe

Aloe

Contains Vitamin E & Aloe

[Contains] Bayrepel®

Bayrepel® is a registered trademark of Lanxess

U.S. Patent Nos. 6,719,959 and 7,150,878

Gentle Breeze™ Scent

Gentle Breeze™

Pleasantly scented

Easy to apply

Sprays at any angle

Light feeling spray

Non-oily

Not oily

Non-greasy

Not greasy

Light feel

Quick drying

Fast drying

Will not harm most plastics or synthetic fabrics

May damage painted or varnished surfaces, including nail polish

For active [family] lifestyles

All day protection against mosquitoes

All day protection against deer ticks

All day protection against mosquitoes and deer ticks

Suitable for the [entire] [whole] family

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]

[Repellency –] Avon's exclusive formula [with Picaridin] 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 –] Avon's exclusive formula [with Picaridin] provides strong and dependable [repellency] [protection] against [mosquitoes] [deer ticks]

[Repellency -] Patented technology that provides strong and dependable [repellency] [protection] against [mosquitoes] [deer ticks]

Exclusive patented technology

Exclusive patented enhanced duration technology

Exclusive patented time-release technology

Patented time-release technology

Time-release formula

Time-release

Patented controlled-release technology

Controlled-release formula

Controlled-release

Creates an effective barrier of protection to repel [insects] [mosquitoes] [deer ticks] [mosquitoes and deer ticks] [gnats, no-seeums, sand flies and biting midges]

Strong and long-lasting [repellency] [protection] against mosquitoes [for] [up to] 8 hours

Strong and long-lasting [repellency] [protection] against deer ticks [for] [up to] 12 hours

Strong and long-lasting [repellency] [protection] against mosquitoes [for] [up to] 8 hours and deer ticks [for] [up to] 12 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

Strong and long-lasting [repellency] [protection] against 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 [for 8 hours]

Strong [repellency] [protection] against deer ticks

Long-lasting [repellency] [protection] against deer ticks

Strong [repellency] [protection] against mosquitoes and deer ticks

Repels mosquitoes

Repels mosquitoes up to 8 hours

Repels mosquitoes for 8 hours

Repels deer ticks

Repels deer ticks up to 12 hours

Repels deer ticks for 12 hours

Repels deer ticks that may [carry] [transmit] Lyme Disease up to 12 hours

Repels deer ticks that may [carry] [transmit] Lyme Disease for 12 hours

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

Made in the USA