

US EPA ARCHIVE DOCUMENT

toXcel

Toxicology & Regulatory Affairs

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Hand Delivered

August 8, 2007

Mr. Richard Gebken
Registration Division
Document Processing Desk (HSRB)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

ATTN: John Carley

RE: Submission of a Protocol for the Evaluation of Personal Insect Repellents Against Mosquitoes in the Laboratory for Consideration by the Human Studies Review Board

Dear Mr. Gebken and Mr. Carley:

On behalf of Avon Products, Inc. (Avon), we are submitting the enclosed protocol and its associated informed consent document for review and approval by the Human Studies Review Board (HSRB) at its upcoming meeting in October 2007. This protocol is intended to be used to substantiate the label claim of efficacy against West Nile Virus vector species on two EPA registered products – Avon Skin-So-Soft SSS Bug Guard Plus Picaridin Insect Repellent (EPA Reg. No. 806-29) and Avon Skin-So-Soft SSS Bug Guard Plus Picaridin Insect Repellent Spray (EPA Reg. No. 806-31).

The enclosed protocol and informed consent document have been reviewed and approved by the independent Essex Institutional Review Board. Supplemental documentation satisfying 40 CFR §26.1125 are also included with this package. Please note that the study protocol will be used for two test materials (806-29 and 806-31). If this protocol is approved, separate study reports will be submitted on each test material following completion of the studies.

Mr. Richard Gebken

August 8, 2007

Page 2 of 2

If you have any questions, please feel free to contact Micah Reynolds or me by phone at (703) 335-5670 or by e-mail at micah@toxcel.com or alan@toxcel.com, respectively.

Sincerely,

A handwritten signature in cursive script that reads "Alan Katz". The signature is written in black ink and is positioned above the printed name.

Alan C. Katz, D.A.B.T.

Principal

toXcel, LLC

Authorized Representative for Avon Products, Inc.

Enclosures

Cc: A. Pechko (Avon)
E. Gilberti (Avon)
R. Labib (Avon)
C. Bartlett (Avon)
P. Quinn (The Accord Group)

TRANSMITTAL DOCUMENT

1. Name and Address of Submitter (Registrant)

(EPA Company ID No. 806)

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

2. Regulatory Action for which this Package is Submitted:

Submission of a protocol for the evaluation of personal insect repellents against mosquitoes in the laboratory for review by the Human Studies Review Board (HSRB). The registrant intends to use this protocol to conduct laboratory efficacy studies for two currently registered products (EPA Reg. Nos. 806-29 and 806-31) in order to support a label claim of efficacy against West Nile Virus.

3. Transmittal Date

August 8, 2007

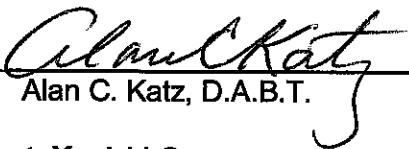
4. List of Submitted Documents

Volume 1 Protocol for the Evaluation of Personal Insect Repellents Against Mosquitoes in the Laboratory;
ICR Protocol ID: G0590607001A117

5. Company Contact

Company Name: Avon Products, Inc.

Authorized Representative:


Alan C. Katz, D.A.B.T.

8/8/07
DATE

toXcel, LLC
P.O. Box 363
7140 Heritage Village Plaza
Gainesville, VA 20155
email: alan@toxcel.com
Telephone: (703) 335-5670
FAX: (703) 310-6950

	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 & 806-31	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Protocol ID: G0590607001A117	PM# 10	
5. Name And Address Of Applicant (Include ZIP Code) Avon Products, Inc. 1251 Avenue of the Americas New York, NY 10020	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

<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 type="checkbox"/> Notification – Explain below.	<input checked="" type="checkbox"/> Other – Explain Below.


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

Submission of a protocol for the evaluation of personal insect repellents against mosquitoes in the laboratory for review by the Human Studies Review Board (HSRB). The registrant intends to use this protocol to conduct laboratory efficacy studies for two currently registered products (EPA Reg. Nos. 806-29 and 806-31) in order to support a label claim of efficacy against West Nile Virus.

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 If "Yes" Unit Packaging wgt. No. per Container	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per Container	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)
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"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____	

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Alan C. Katz, D.A.B.T. / 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 Alan C. Katz, D.A.B.T.	5. Date August 8, 2007	