

54287-20

02/17/2009

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

FEB 17 2009

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

Tomothy H. Dickens, Ph.D.  
Agent for Associated Registrations  
Scientific Coordination, Inc.  
4629 Cherry Valley Drive  
Rockville, MD 20853

RE: Product Name: Super Guard 3535 Insect Repellent  
EPA Reg. No: 54287-20  
Application for Label Notification Dated November 24, 2008 to Add Marketing  
Statements, Lot Number and Graphics

Dear Dr. Dickens:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under Pesticide Registration Notice (PRN) 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.

For any question you may have concerning this action, please contact Ms. Diana Hudson at (703) 308-8713 or email at [HUDSON.DIANA@EPA.GOV](mailto:HUDSON.DIANA@EPA.GOV).

Sincerely,

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

Please read instructions on reverse before completing form.

# NOTIFICATION

OMB No. 2070-0080. Approval expires 2-28-95



United States  
**Environmental Protection Agency**  
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number 54287-20	2. EPA Product Manager Dr. Sheryl K. Reilly	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) SUPER GUARD 3535 INSECT REPELLENT	PM# BPPD/Team 91	
5. Name and Address of Applicant (Include ZIP Code) Associated Registrations c/o Scientific Coordination, Inc. 4629 Cherry Valley Drive Rockville, MD 20853 <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: <b>NOTIFICATION</b> EPA Reg. No. _____ Date Reviewed: <u>2-17-09</u> Product Name _____ Reviewed By: <u>J. Hudson</u>	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ Reviewed By: _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application. _____ Date Reviewed: _____
<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 to add marketing statements and graphics per PR Notice 98-10." "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 checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
		If "Yes" Package wgt.	No. per container	<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 0.5 thru 32 oz.		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input checked="" type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product		<input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input checked="" 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 Timothy H. Dickens	Title Authorized Agent	Telephone No. (Include Area Code) 301-570-4390
2. Signature 		6. Date Application Received (Stamped)
3. Title Authorized Agent		
4. Typed Name Timothy H. Dickens, Ph.D.		
5. Date 24 November 2008		

# SCIENTIFIC COORDINATION, INC.

Helping Technology Transfer  
4629 Cherry Valley Drive  
Rockville, MD 20853

November 24, 2008

Document Processing Desk (NOTIF)  
Biopesticides and Pollution Prevention Division (BPPD) 7504P  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501  
ATTN: Dr. Sheryl Reilly, Chief

Subject: Super Guard 3535 Insect Repellent  
EPA Reg. No. 54287-20  
NOTIFICATION

Dear Dr. Reilly:

By notification, our Client, Associated Registrations, Inc. is adding the following to the subject product label:

1. Marketing statements: [Travel Size] Meets Airline [3 oz.] Carry-On Requirements, Insect Repellent [With Sun Block], [Contains] IR3535
2. Lot number
3. Addition of graphics:



Enclosed, please find the following:

1. Application for Pesticide (Other), EPA Form 8570-1;
2. One copy of a final label as a reference illustrating all label revisions; and
3. Two copies of the final label.

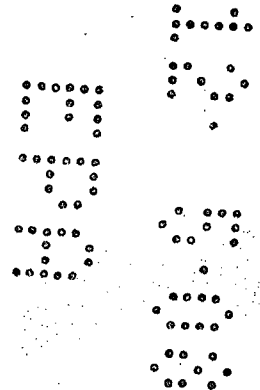
We would appreciate receiving a copy of the label stamped approved – notification.

If you have any questions or comments regarding this submission, please do not hesitate to contact me at (301) 570-4390 or by e-mail at dickensth@aol.com.

Sincerely,

Timothy H. Dickens, Ph.D.  
Registered Agent

encl./as listed



**SUPER GUARD 3535  
INSECT REPELLENT**

~ OPTIONAL MARKETING LANGUAGE, SYMBOLS & GRAPHICS: SEE LAST PAGE ~

**NOTIFICATION**

Date Reviewed: 2-17-09

Reviewed By: D. Hudson

**ACTIVE INGREDIENT:**

3-((N-butyl-N-acetyl)-amino  
propionic acid ethyl ester\*.....20%

**OTHER INGREDIENTS:**.....80%

**TOTAL:** .....100%

\*IR3535® Insect Repellent

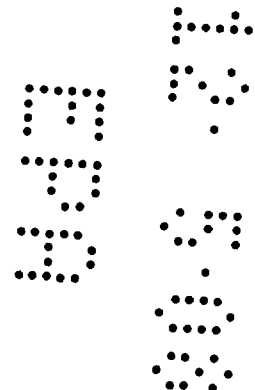
**Keep Out of Reach of Children  
CAUTION**  
See back panel for additional precautionary statements.  
[See (inside)(back) panel for precautions.]

Net [Contents][Weight] \_\_\_\_\_ fl. oz.

Lot Number: \_\_\_\_\_

[ ] – Brackets indicate optional text.

Underline represents new text.



(Company Name) Sun Block with Insect Repellent formula provides all day waterproof SPF 30 sun protection and repels mosquitoes for up to 8 hours. Gentle formula does not need to be washed off when returning from the outdoors. Pleasant fragrance.

**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 over dry, exposed skin. Do not spray directly on face. Spray on palm of hand and apply to face. An adult must apply this product to children under 10. For continued protection from mosquitoes, reapply after 8 hours. For sunscreen protection, reapply after toweling off or as needed. Do not exceed 7 applications per day for adults, 3 applications per day for children.

**STORAGE:** Store in a cool, dry place in tightly closed container.

**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 [or toll free number or website which meets the criteria in paragraph II.E., PR Notice 2007-1] for disposal instructions. Never place unused product down any indoor or outdoor drain.

**PRECAUTIONARY STATEMENTS:**

**Hazards to Humans: CAUTION:** For external use only. Causes moderate eye irritation. Do not get in eyes. Use on children under 6 months of age only with the advice of a physician.

**PHYSICAL OR CHEMICAL HAZARDS: Flammable.** Keep away from heat and open flame. Contains alcohol. Avoid contact with plastics.

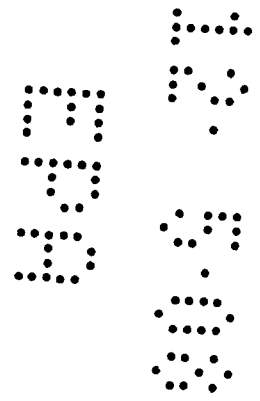
**FIRST AID**

If In Eyes:	<ul style="list-style-type: none"> <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 the eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<p>Have product container with you when calling for help or going for treatment. [Questions: 800-940-4464, Weekdays from 9-5 EST.]</p>	

NOTE: The First Aid statement's grid format will be used if market label space permits; otherwise a paragraph format will be used.

**ACTIVE SUNSCREEN INGREDIENTS:** Octinoxate (7.5%), Octisalate (5%), Octocrylene (10%), Oxybenzone (6%). **INACTIVE INGREDIENTS:** acrylates/octylacrylamide copolymer, SD alcohol 40 (48.67%), aloe barbadensis leaf extract, C12-15 alkyl benzoate, fragrance, isopropyl palmitate, tocopheryl acetate

**ASSOCIATED REGISTRATIONS,** P.O. Box 188; Safety Harbor, FL 34695  
EPA Reg. No. 54287-20 EPA Est. 58188-FL-1  
IR3535® is a registered trademark of Merck KgaA.



~ OPTIONAL MARKETING LANGUAGE, SYMBOLS & GRAPHICS ~

[Travel Size] Meets Airline [3 oz.] Carry-On Requirements

Insect Repellent [With Sun Block ]

[Contains] IR3535

Sun Block With Insect Repellent

Repels (mosquitoes)(for) Up to 8 Hours

Dries Instantly

Waterproof

Pleasant Fragrance

DEET Free

SPF 30

PABA Free

Contains 20% IR3535 Insect Repellent

Contains Aloe and Vitamin E to soothe and naturally moisturize skin

Hypoallergenic

Non-comedogenic - won't clog pores

Waterproof & Sweatproof

All Day Waterproof and Sweatproof protection

(8 hour) UVA / UVB Protection

Dries Instantly - no greasy residue

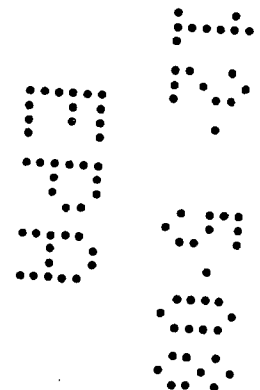
Easy to use spray formula for no hassle application

Light spray gel won't drip - or cause your grip to slip

Pleasant fragrance (scent may be defined)

Suitable for the entire family

Quick dry waterproof spray



DEET Free formula doesn't require washing off of skin upon return to indoors.

Repels mosquitoes that may (carry) (transmit) the West Nile virus (encephalitis) (diseases).

Provides effective, dependable, and long lasting repellency against mosquitoes.

Spray Pump (Spray) (Squirt)

Dense Bugs

Family

Daytime

Fishing

220+Sprays

SPF 30 Sun Screen & Insect Repellent

(Patent Pending) Combo-Clip™ with key ring hole

Water & Sweat Proof

Personal Pocket Size

SPF 30 UVA/UVB Protection

Compact, portable, convenient

Clips anywhere, hangs anywhere

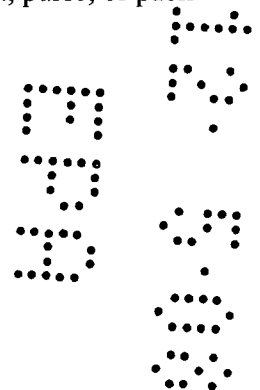
Ideal for the pocket, purse, pack, backpack, beach bag, travel bag, tackle box, fly jacket

If you're going to go... GoReady

Goes anywhere

Combo-Clip™ Hangs or Clips

Hang it! Snap in carabiner rings, lanyards, key rings, etc... or Clip it! in a pocket, purse, or pack



The following graphics and symbols have been added:

