

66306-5

11/10/2005

1/6

Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0080, Approval expires 2-28-95



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 66306-5	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Sunsect Insect Repellant Sunscreen SPF 30	PM# Team 10	
5. Name and Address of Applicant (Include ZIP Code) Iguana, LLC 2474 Magnolia Road Thomasville, GA 31792-8701 <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

<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.

NOTIFICATION

NOV 10 2005

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

This notification is to revise the waterproof and sweatproof claims and is not subject to PRIA. These claims have been revised to read "water resistant" and "sweat resistant" to be consistent with the FDA monograph for sunscreen products. 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.A. Sec. 1001 to willfully make any false statements 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
* Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	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"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <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 Heather R. Bjornson, Technology Sciences Group, Inc.	Title Regulatory Assistant to Iguana, LLC	Telephone No. (Include Area Code) (202) 828-8945
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 (Stamped)
2. Signature <i>Heather R. Bjornson</i>	3. Title Regulatory Assistant to Iguana, LLC	
4. Typed Name Heather R. Bjornson	5. Date October 13, 2005	

2/6

NOTIFICATION

NOV 10 2005

[Front Panel]

Sunsect® Insect Repellent Sunscreen SPF 30

INSECT REPELLENT

Alternate Brand Names:

- SPF 30 SUNSECT® SUNSCREEN INSECT REPELLENT
- Sunsect® Sunscreen Insect Repellent
- Iguana® Safari Sunscreen SPF 30
- Sunsect®
- Formula 7511/1 Insect Repellent Sunscreen (old name)

SPF 30

- Hypo-allergenic
- Water resistant [up to 8 hours]
- [Non-Greasy Lotion]
- [Moisturizes with Aloe Vera]

- Sweat-resistant
- Sweat-resistance
- With resistance to sweat
- Designed for people on the go
- Take-along
- (Perfect to) take-along with you

- Repels mosquitoes that may carry West Nile Virus
- Repels mosquitoes that may carry diseases
- Contains DEET
- Mosquito Protection

KEEP OUT OF REACH OF CHILDREN

CAUTION: See additional precautionary statements on back panel.

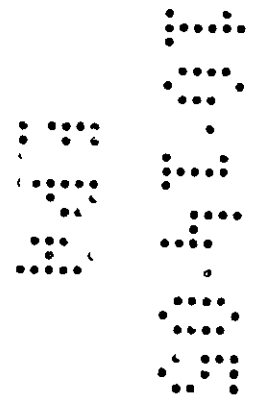
ACTIVE INGREDIENTS:

DEET 10.0%

INERT INGREDIENTS:

90.0%

2 FL. OZ. (59 ML)



SUNSECT® provides up to 8 hours of UVA and UVB protection that's PABA free. Its pleasant smelling, non-greasy, water resistant, sweat resistant, [and] formula prevents tanning and sunburn. [and moisturizes with Aloe Vera.] SUNSECT® repels mosquitos, ticks chiggers, deer flies, stable flies, black flies, fleas and gnats on exposed skin surfaces. The regular use of SUNSECT® may also help reduce the chance of premature aging and wrinkling [due to] [because of] over-exposure to the sun.

ACTIVE SUNSCREEN INGREDIENTS: Octocrylene, Octinoxate, Benzophenone-3

alternate text

SUNSECT® is a pleasant smelling, water resistant, sweat resistant sunscreen lotion specially formulated to repel mosquitos, ticks, chiggers, deer flies, stable flies, black flies, fleas and gnats on exposed skin surfaces. SUNSECT'S® patented formula provides [protection from the listed insects while][a continuous long lasting shield repelling the listed insects while] providing a UVA and UVB sun block that is Paba-free. The regular use of SUNSECT® may also help reduce the chance of premature aging and wrinkling [due to] [because of] overexposure to the sun. SUNSECT® also moisturizes [your skin leaving it feeling smooth and natural without ever feeling sticky or greasy][the skin providing a non-greasy, smooth and natural feeling.

ACTIVE SUNSCREEN INGREDIENTS: Octocrylene; Octinoxate; Benzophenone-3

alternate text

[(*Insert trade name*) offers convenient dual protection in one bottle, for total outdoor skin protection. This WATER RESISTANT SPF 30 sunscreen protects kids from harmful UVA and UVB rays, while it also repels mosquitos, gnats, ticks, chiggers, deer flies, stable flies, black flies and fleas on exposed skin surfaces. This pleasant fragranced, PABA-free, NON-GREASY lotion also MOISTURIZES children's sensitive skin with soothing Aloe Vera. (*Insert trade name*) is hypoallergenic. Regular use of a sunscreen may help reduce the chance of long term sun damage such as premature aging, wrinkling, and skin cancer.]

alternate text

[(*Insert trade name*) is a pleasant smelling, water resistant, sweat resistant sunscreen lotion specially formulated to repel mosquitos, ticks, chiggers, deer flies, stable flies, black flies, fleas and gnats on exposed skin surfaces. (*Insert trade name*) 's formula provides protection from the listed insects while providing a UVA and UVB sun block that is PABA-free. The regular use of (*Insert trade name*) may also help reduce the chance of premature aging and wrinkling because of over exposure to the sun. (*Insert trade name*) also moisturizes the skin providing a non-greasy, smooth and natural feeling. ACTIVE SUNSCREEN INGREDIENTS: Octocrylene; Octinoxate; Benzophenon-3

4/6

alternate text

Sweat-resistant, Sweat-resistance, With resistance to sweat, Designed for people on the go, Take-along, (Perfect to) take-along with you

alternate text

[ACTIVE SUNSCREEN INGREDIENTS: Octocrylene; Ethyl hexyl p- methoxycinnamate; Oxybenzone.]

ACTIVE SUNSCREEN INGREDIENTS: Octocrylene; Octinoxate; Oxybenzone.

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.

For best results, spread evenly and completely over all exposed skin. Apply to hand for application to face and neck. Do not apply near eyes and mouth. Apply sparingly around ears. Repeat application as necessary [such as after prolonged swimming, or excessive perspiration, vigorous activity or toweling]. Do not apply over cuts, wounds or irritated skin. Do not apply to children's hands. Do not allow children to handle this product. When using on children, apply to you own hands and then put it on the child. Use just enough repellent to cover exposed skin and/or clothing. Do not use under clothing. Avoid contact with plastics, such as eyeglass frames and plastic watch crystals, leather and synthetic fabrics such as acetate, rayon, Spandex and Dynel. May damage painted or varnished surfaces. After returning indoors, wash treated skin with soap and water. Wash treated clothing before wearing it again. Avoid over-application of this product - frequent reapplication and saturation are unnecessary for the effectiveness of SUNSECT®. Use of this product may cause skin reactions in rare cases. If you suspect a reaction to this product, discontinue use, wash treated skin and call your local poison control center. If you go to a doctor, take this product with you. Consult a physician before use on children under 6 months of age.

PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION - Causes eye irritation. Harmful if swallowed. Do not get in eyes or on lips.

(Note to reviewer: Boxed format or bullets may be used in First Aid section if label space permits)

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 do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information call 1-800-344-8262 or the National Pesticide Information Center at 1-800-858-7378. ["For additional information" statement may be substituted by alternative company preferred comments questions 800 number located elsewhere on label]

STORAGE AND DISPOSAL

STORAGE: Store in a cool, dry area inaccessible to children.

DISPOSAL: Before disposing, empty container by using the product according to the label. Do not reuse this container. Place in trash or offer for recycling if available. If partially filled: Call your local solid waste agency or 1-800-558-5252 for disposal instructions. Never place unused product down any indoor or outdoor drain.

Buyer assumes all risks of use, storage or handling of this product not in strict accordance with this label.

Manufactured by
Iguana, LLC
2474 Magnolia Road, P.O. Box 2597
Thomasville, GA 31792-8701
[Comments, questions? 1-800-XXX-XXXX][alternative statement company preference for providing 800 number]
1-800-344-8262
Patent No. 5,518,712
Est. 066804-FL-001
EPA Reg. No. 66306-5

6/6



WASHINGTON

1101 17th Street, N.W.
Suite 500
Washington, D.C. 20036
Telephone 202 223-4392
Fax 202 872-0745

Richard Gebken
Office of Pesticide Products, EPA
Registration Division
Insecticide Branch
1801 South Bell Street (7505C)
Arlington, VA 22202

October 13, 2005

**RE: Iguana, LLC: Notification to revise claims on Sunsect®
Insect Repellant Sunscreen SPF 30 (EPA Reg. No. 66306-5)**

SACRAMENTO

712 Fifth Street
Suite A
Davis, CA 95616
Telephone 530 757-1298
Fax 530 757-1299

Dear Mr. Gebken:

Technology Sciences Group, on behalf of Iguana, LLC is submitting enclosed label notification revising the waterproof and sweatproof claims to read, "water resistant" and "sweat resistant". The purpose of this notification is to be consistent with the FDA OTC Monograph for Sunscreen products (FR Vol. 64, No. 98/Friday, May 21, 1999). You will find the following in support of this notification:

- 1) EPA Notification Application Form;
- 2) One redline copy of the product label; and
- 3) Three copies of the clean revised label.

Please do not hesitate to contact me directly with any questions and/or concerns at (202) 828-8945 or via e-mail: hbjornson@tsgusa.com.

CANADA

275 Slater Street
Suite 900
Ottawa, Ontario
K1P 5H9
Telephone 613 247-6285
Fax 613 236-3754

Sincerely,

Heather R. Bjornson
Regulatory Assistant for Iguana LLC (formerly Amon-Re, Inc.)

cc: Ernie Stewart, Iguana, LLC

