

66306-15

01/15/2007

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U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Registration Division (7505C)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

66306-15

Date of Issuance:

JAN 15 2007

NOTICE OF PESTICIDE:

Registration
 Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Insect Repellent Sunscreen II®

Name and Address of Registrant (include ZIP Code):

Iguana, LLC
2474 Magnolia Road
Thomasville, GA 31792-8701

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

(continued on page 2)

Signature of Approving Official:

See Page 3

Richard J. Gebken, Product Manager (10)
Insecticide Branch, Registration Division (7505P)

Date:

JAN 15 2007

2. Make the following change to the label:

- a. Change the product registration number to "EPA Reg. No. 66303-15"
- b. Make the following label revisions:
 - 1. Labeling Claims section comment(s):
 - Delete the labeling claim, "Repels mosquitoes that may carry diseases."
 - 2. Revise the Ingredient Statement section to appear as follows:

ACTIVE INGREDIENTS:

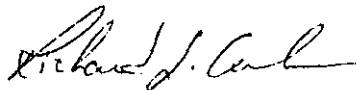
DEET	10.0%
OTHER INGREDIENTS:	90.0%
Total	100.0%

- 3. Labeling Claims section, label page 2 of 4, comment(s):
 - In general, please delete all (FDA) statements regarding premature aging and wrinkling from this label as these are implied safety claims.
 - Revise page 2 of 4 of your recently submitted (January 5, 2007) revised label as follows:
 - Paragraph 2, 2nd sentence, delete the words "patented formula" and "a continuous long lasting shield."
 - Paragraph 2, last sentence, delete the words "and natural" and "and natural."
 - Paragraph 2, last sentence, insert the word "and" immediately following the words "non-greasy."
 - Paragraph 3, 3rd sentence, delete the word "children's."
 - Paragraph 4, last sentence, delete the words "and natural."
 - Paragraph 4, last sentence, insert the word "and" immediately following the words "non-greasy."
- 4. Directions for Use section comment(s):
 - Insert a new subtitle directly following the statement starting with "Read and follow....." to read as follows: "USE PRECAUTIONS."
- 5. Precautionary Statements, Hazards to Humans and Domestic Animals section comment(s):
 - Delete the existing precautionary statement and add the following general statement to appear as paragraph #1 in the Hazards to Humans and Domestic Animals section: "Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Wear long-sleeved shirt and long pants, socks, shoes and chemical-resistant gloves. Remove contaminated clothing and wash clothing before reuse. Avoid contact with eyes or clothing."

- 6. Relocate the existing "If Swallowed" subsection to appear as the 1st line in the First Aid section.
 - 7. Revise the last statement in the First Aid section of this label as follows:
 - In the 2nd sentence, delete the words "For additional information" and replace with "You may also."
 - Insert the words "for emergency medical treatment information" at the end of the 2nd sentence.
 - An additional 800 number is acceptable at the end of the First Aid section, provided that number is available 24 hours per day, 7 days a week. ¹
 - 8. In the STORAGE AND DISPOSAL section, the subsection currently listed as "STORAGE" should be changed to "PESTICIDE STORAGE."
 - 9. Add the following new subsection immediately following the existing "STORAGE" subsection as follows: "PESTICIDE DISPOSAL: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility."
 - 10. The existing subsection currently listed as "DISPOSAL" should be changed to "CONTAINER DISPOSAL."
 - 11. Data deficiencies were identified for storage stability and corrosion characteristics in the product chemistry review for this product. Therefore, Iguana is obligated to submit a One Year Storage Stability (830.6317) study and a Corrosion Characteristics (830.6320) study on this product in support of this registration within one (1) year from the date of this registration.
3. Submit two (2) copies of the revised final printed label for the record before the product is released for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.



Richard J. Gebken
 Product Manager (10)
 Insecticide Branch
 Registration Division (7505P)

Attachment: Copy of label stamped "Accepted with Comments"
 066306-00015 S796384

¹ See PR Notice 2000-1 for more information.

[Front Panel]

Insect Repellent Sunscreen II

INSECT REPELLENT

SPF 25

[Non-Greasy Lotion]

[Moisturizes with Aloe Vera]

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)

**ACCEPTED
with COMMENTS
in EPA Letter Dated
January 15, 2007**
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
66306-15

INSECT REPELLENT SUNSCREEN II provides up to 8 hours of UVA and UVB protection that's PABA free. Its pleasant smelling, non-greasy [and] formula prevents tanning and sunburn. [and moisturizes with Aloe Vera.] INSECT REPELLENT SUNSCREEN II repels mosquitos, ticks chiggers, deer flies, stable flies, black flies, fleas and gnats on exposed skin surfaces. ~~The regular use of INSECT REPELLENT SUNSCREEN II 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

INSECT REPELLENT SUNSCREEN II is a pleasant smelling sunscreen lotion specially formulated to repel mosquitos, ticks, chiggers, deer flies, stable flies, black flies, fleas and gnats on exposed skin surfaces. INSECT REPELLENT SUNSCREEN II'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 INSECT REPELLENT SUNSCREEN II may also help reduce the chance of premature aging and wrinkling [due to] [because of] overexposure to the sun.~~ INSECT REPELLENT SUNSCREEN II 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 SPF 25 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. [~~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 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

alternate text

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 INSECT REPELLENT SUNSCREEN II®. 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.

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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-