

66306-1

02/25/2013

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

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION PREVENTION

FEB 25 2013

Mr. Micah T. Reynolds
Lguana LLC
1716 Smith Avenue
Thomasville, GA 31792

Subject: Amended Labeling
Iguana® Insect Repellent Sunscreen
EPA Registration Number: 66306-1
Application Dated: January 23, 2013
Decision: 462560

Dear Mr. Reynolds:

The label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the following comments.

1. Remove the following marketing claims from your product label:
 - And other biting insects
 - Repels mosquitoes that may carry diseases
2. Add the following statement to the Directions for Use":
 - "Do not apply to excessively sunburned skin."
3. "The "Precautionary Statements" should be revised to read as follows:
Causes moderate eye irritation,. Avoid contact with eyes. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco".

If you have any questions, please contact Melody Banks on 703 305-5413 or via E-mail @ banks.melody@epa.gov.

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

Sincerely,



Richard Gebken
Insecticide Branch
Product Manager
Registration Division (7504P)

Enclosure: Stamped Copy of Product Label with Comments

(Note to Reviewer: [bracketed text] is optional or alternate wording; (parenthetical text) is informational.)

(MASTER LABEL)

Iguana[®] Insect Repellent Sunscreen

(Alternate Brand Names: SPF 15 Sunsect[®] Sunscreen Insect Repellent,
Sunsect[®] Sunscreen & Insect Repellent)

Non-Greasy
SPF 15
Patented Formula
Water Resistant (80 minutes)
Made With 20% DEET

Repels mosquitoes that may carry West Nile Virus
And other biting insects
Repels mosquitoes that may carry diseases
Contains DEET

ACCEPTED
with **COMMENTS**
in EPA Letter Dated
FEB 25 2013
Under the Federal Insecticide
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No
66306-1

KEEP OUT OF REACH OF CHILDREN

CAUTION

See [back] [other] [side] [panel] for [first aid] [and additional precautionary statements].

Active Ingredients

DEET.....	20.00%
Other Ingredients.....	80.00%
TOTAL	100.00%

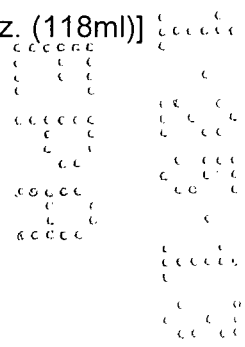
Manufactured for:
Iguana, LLC
1716 Smith Avenue
Thomasville, GA 31792

EPA Reg. No. 66306-1
EPA Est. No. [66804-FL-001]

Net Contents: [2 fl. oz. (59ml)] [4 fl. oz. (118ml)]

[Comments, questions? 1-229-228-0980]

[Patent # 5,518,712]
[NDC _____]



(Note to Reviewer: [bracketed text] is optional or alternate wording; (parenthetical text) is informational.)

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

(Note to Reviewer: Since this product is also regulated as an over-the-counter sunscreen by the FDA, the following information required by 21 CFR §201.327 will appear in accordance with the formatting requirements of 21 CFR §201.66.)

Drug Facts [(continued)]

Active ingredients	Purpose
Octinoxate 7.5%, Octisalate 5.0%, Oxybenzone 6.0%.....	Sunscreen

Uses

- helps prevent sunburn

Warnings

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging.

For external use only

Do not use • on damaged or broken skin

When using this product • keep out of eyes. Rinse with water to remove

Stop use and ask a doctor • if rash occurs

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply [liberally] [generously] [and evenly] 15 minutes before sun exposure
- children under 6 months of age: Ask a doctor
- reapply:
 - after 80 minutes of swimming or sweating
 - immediately after towel drying
 - at least every 2 hours

Inactive ingredients

acrylates/C10-30 alkyl acrylate copolymer, carrageenan, carboxy vinyl polymer, cetostearyl alcohol, diazolidinyl urea, diethanolamine cetyl phosphate, [fragrance], methylparaben, propylparaben, propylene glycol, tocopheryl acetate (Vitamin E), tricontanyl povidone, water

Other information

(Note to Reviewer: [bracketed text] is optional or alternate wording; (parenthetical text) is informational.)

- Protect the product in this container from excessive heat and direct sun

Questions or comments?

1-229-228-0980

[Arrow graphic (if Drug Facts section is to be continued on another label panel)]

[INSECT REPELLENT] 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. Use just enough repellent to cover exposed skin and/or clothing. Repeat application as necessary. 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 your own hands and then put it on the child. 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 Iguana® 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.

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 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. For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-344-8262 [or] [the National Pesticide Information Center at 1-800-858-7378, 6:30 AM to 4:30 PM Pacific Time (PT), seven days a week].

(Note to Reviewer: [bracketed text] is optional or alternate wording; (parenthetical text) is informational.)

(Note to reviewer; "For additional information" statement may be substituted by alternative company preferred comments, questions 800 number located on front panel)

STORAGE AND DISPOSAL

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

DISPOSAL: Nonrefillable container. Do not reuse or refill this container. **If empty:** Place in trash or offer for recycling if available. **If partly filled:** Call your local solid waste agency 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.

