



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

March 22, 2016

Micah T. Reynolds  
Regulatory Consultant to Iguana LLC  
Technology Sciences Group Inc.  
1150 18<sup>th</sup> Street, Suite 1000  
Washington, DC 20036

Subject: Label Amendment – addition of Zika claim  
Product Name: Iguana Insect Repellent Sunscreen  
EPA Registration Number: 66306-1  
Application Date: 4-Mar-2016  
Decision Number: 514825

Dear Mr. Reynolds:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

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

Page 2 of 2  
EPA Reg. No. 66306-1  
Decision No. 514825

with FIFRA section 6. If you have any questions, you may contact Julie Breeden at 703-347-0511 or via email at [Breeden.Julie@epa.gov](mailto:Breeden.Julie@epa.gov).

Sincerely,

A handwritten signature in black ink, appearing to read 'J S', with a long horizontal stroke extending to the right.

Jennifer Urbanski Saunders, Product Manager 4  
Invertebrate & Vertebrate Branch 1 (IVB1)  
Registration Division (7505P)  
Office of Pesticide Programs

Enclosure

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

**(MASTER LABEL)**

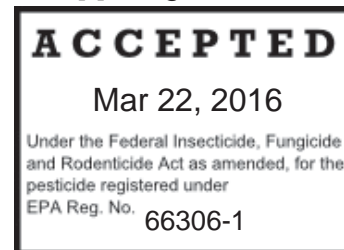
# Iguana<sup>®</sup> Insect Repellent Sunscreen

(Alternate Brand Names: SPF 15 Sunsect<sup>®</sup> Sunscreen Insect Repellent, Sunsect<sup>®</sup> Sunscreen & Insect Repellent, Sunsect<sup>®</sup> Insect Repellent + Sunscreen)

[Non-Greasy]  
SPF 15  
[Patented Formula]  
Water Resistant (80 minutes/mins)  
[Made With 20% DEET]  
[Repels mosquitoes that may [carry] [transmit] [West Nile Virus] [Zika Virus] [Dengue  
Fever] [and] [Chikungunya]]  
[Contains DEET]

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**



See [back] [other] [side] [panel] [package insert] [outer carton] [outer box] for [first aid] [Drug Facts] [Directions for Use] [and additional precautionary statements].

(Note to reviewer: the following reference statement for small container sizes):

[Peel [back] [here] for [Directions for Use] [First Aid] [Drug Facts] [and] [Precautionary Statements]]  
[Peel back for more info]  
[Open to read]  
[Resealable label]

**Active Ingredients**

DEET.....20.00%

**Other Ingredients**.....80.00%

**TOTAL**.....100.00%

Manufactured for:  
Iguana, LLC  
PO Box 6159  
Thomasville, GA 31758

EPA Reg. No. 66306-1  
EPA Est. No. [89989-IL-001]

Net Contents: [0.3 fl. oz. (9ml)] [2 fl. oz. (59ml)]  
[4 fl. oz. (118ml)] [1 gallon (128 fl. oz.)]  
[Contains X Packets] [X Packets] [each X oz.]

[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. 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**

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

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

### **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 excessively sunburned 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 moderate eye irritation. Avoid contact with eyes. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

(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.

**CONTAINER HANDLING:** 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.

### **Optional Marketing Statements**

Made in USA

[www.sunsect.com](http://www.sunsect.com)

[Repels mosquitoes that may carry [transmit] [Zika Virus] [Chikungunya] [West Nile Virus] [and] [Dengue Fever]

[Effective] [Protection [you can count on] [against] [mosquitoes that may [carry]

[transmit] [Zika Virus] [Chikungunya] [West Nile Virus] [and] [Dengue Fever]

[Sun and mosquito Protection]

[Images of target pests]

[[Prop 65] WARNING: This product contains a chemical known to the State of California to cause cancer.] (Only for product sold into California)