

JUN 4 2003

Katherine A. Buteau  
Regulatory Consultant for Iguana, LLC  
Technology Sciences Group Inc.  
712 Fifth Street, Suite A  
Davis, California 95616

Subject: Revised Label For:  
Sunsect Insect Repellent Sunscreen SPF 30  
EPA Registration No. 66306-5  
Application dated January 24, 2003

Dear Ms. Buteau:

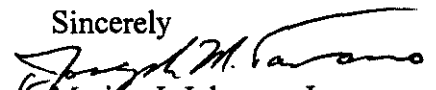
The proposed amendment to the registration for the product cited above under The Federal Insecticide, Fungicide And Rodenticide Act, as amended revising the label in accordance with PR Notices 2001-1 and 2001-6, the DEET RED and the Final Monograph for Sunscreen Drug Products for Over-The -Counter Human Use is acceptable subject to the following comments.

- 1) The alternate brand name, SPF 30 Sunsect Sunscreen Insect repellent for Kids, is not acceptable. Refer to the DEET RED.
- 2) Your suppliers of DEET are no longer claiming that their products are 100 percent active. Therefore to maintain the 10 percent claim on your label you must adjust the amount of your suppliers product that goes into your product. The various suppliers of DEET are claiming a different active percentage, therefore the amount will vary depending on which supplier you use. Submit a revised Confidential Statement Of Formula.

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

If you have any questions please contact Joseph Tavano at (703) 305-6411.

Sincerely

  
Joseph M. Tavano  
Product Manager 10  
Insecticide Branch  
Registration Division(7505C)



[Front Panel]

Sunsect Insect Repellent Sunscreen SPF 30

*INSECT REPELLENT*

Alternate Brand Names:

- SPF 30 Sunsect® Sunscreen Insect Repellent for Kids
- SPF 30 SUNSECT® SUNSCREEN INSECT REPELLENT
- Sunsect® Sunscreen Insect Repellent
- Iguana® Safari Sunscreen SPF 30
- Sunsect*

**ACCEPTED  
with COMMENTS  
In EPA Letter Dated:  
JUN 4 2003**

*Under the Federal Insecticide,  
Fungicide, and Rodenticide Act,  
as amended, for the pesticide  
registered under EPA Reg. No.  
66306-5*

SPF 30

Hypo-allergenic

Waterproof [up to 8 hours]

[Non-Greasy Lotion]

[Moisturizes with Aloe Vera]

**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, waterproof, sweatproof, [ 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 because of over-exposure to the sun.

ACTIVE SUNSCREEN INGREDIENTS: Octocrylene; *Octinoxate*; Benzophenon-3

***alternate text***

SUNSECT® is a pleasant smelling, waterproof, sweatproof sunscreen lotion specially formulated to repel mosquitos, ticks, chiggers, deer flies, stable flies, black flies, fleas and gnats on exposed skin surfaces. SUNSECT'S® formula (patent pending) provides 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 overexposure to the sun. SUNSECT® also moisturizes your skin leaving it feeling smooth and natural without ever feeling sticky or greasy.

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 WATERPROOF 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, waterproof, sweatproof 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***

[ACTIVE SUNSCREEN INGREDIENTS: Octocrylene; Ethyl hexyl p- methoxycinnamate; 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 your 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. wash treated skin and call your local poison control center. 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. Not recommended for use on infants or toddlers.*

(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 do 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.*

**STORAGE AND DISPOSAL [heading added 10-16-02]**

**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.*

EPA Reg No. 66306-5

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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

1-800-344-8262  
Patent No. 5,518,712  
Est. 066804-FL-001  
EPA Reg. No. 66306-5