



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

March 29, 2017

Micah T. Reynolds  
Sunsect, Inc.  
2910 Kerry Forest Parkway, D-4-382  
Tallahassee, FL 32309

Subject: Notification per PRN 98-10 – PBN and other minor changes  
Product Name: SUNSET INSECT REPELLENT SUNSCREEN  
EPA Registration Number: 66306-1  
Application Date: 3/7/2017  
Decision Number: 527486

Dear Mr. Reynolds:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped “Notification” and will be placed in our records.

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.

If you have any questions, you may contact Angela Hollis at 703 347-0216 or by email at [hollis.angela@epa.gov](mailto:hollis.angela@epa.gov).

Sincerely,

A handwritten signature in black ink, appearing to read "Gene Benbow".

Gene Benbow, Acting Product Manager 4  
Invertebrate and Vertebrate Branch 1  
Registration Division (7505P)  
Office of Pesticide Programs

# NOTIFICATION

66306-1

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

03/29/2017

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

## (MASTER LABEL)

# Sunsect<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:

EPA Reg. No. 66306-1

Sunsect, Inc.

EPA Est. No. [89989-IL-001]

2910 Kerry Forest Parkway, D-4-382,

Tallahassee, FL 32309,

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? 1-850-396-0474]

[Patent # 5,518,712]

[NDC \_\_\_\_\_]

Sunsect<sup>®</sup> Insect Repellent Sunscreen; EPA Reg. No. 66306-1

MASTER LABEL – version dated March 5, 2017.

Primary Brand Name Change, Company Address Update and Formulation Update

Page 1 of 4

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

[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. Sunsect's® patented formula provides a continuous long lasting shield repelling the listed insects while providing a UVA and UVB protection that is Paba free. Sunsect® also moisturizes your skin leaving it feeling smooth and natural without ever feeling sticky or greasy.]

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(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 crosspolymer, aminomethyl propanol, carrageenan, carbomer, cetearyl alcohol, cetyl phosphate, diazolidinyl urea, methylparaben, propylparaben, propylene glycol, tocopheryl acetate (Vitamin E), triacetyl PVP, water

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**Other information**

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

**Sunsect® Insect Repellent Sunscreen;** EPA Reg. No. 66306-1  
MASTER LABEL – version dated March 5, 2017.  
**Primary Brand Name Change, Company Address Update and Formulation Update.**

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**Questions or comments?**

1-850-396-0474

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[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 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.

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**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].

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(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 ~~{and logo}~~

[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]

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

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