# SUNSECT INSECT REPELLENT SUNSCREEN- octinoxate, oxybenzone, octisalate lotion Iguana LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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## **Drug Facts**

## **Active Ingredients**

Octinoxate: 7.5% Oxybenzone: 6% Octisalate: 5%

### **Purpose**

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 sunbrun, **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 the reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions**

- apply liberally 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

#### Other Information

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

### **Inactive Ingredients**

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

## Comments/Questions?

## **Principal Display Panel**



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, or using
tobacco.

#### STORAGE AND DISPOSAL

STORAGE: Store in a cool, dry area inacce-

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

#### Comments, questions? 1-229-228-0980

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

Manufactured for: Iguana, LLC. PO Boy 6159





Front Cover



Inside

Directions For Use

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Rase



# Repels Mosquitoes That May Carry WEST NILE VIRUS











Buyer assumes all risks of use, storag or handling of this product not in stric accordance with this label.
Directions For Use
It is a violation of Federal Law to use this product in a manner inconsistent with its sibeling. Read and follow all directions and precautions on this product label.
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## Repels Mosquitoes That May Carry WEST NILE VIRUS

MATER RESISTANT (BD MIN) | NON-GREASY
ACTIVE INGREDIENT
DEET 20.00%
OTHER INGREDIENTS 50.00%
TOTAL 100.00%
KEEP OUT OF REACH OF CHILDREN
CAUTION | See back panel for additional
NSN #6840-01-288-2188
NET CONTENTS: 2 FL OZ. (59ml)

#### FIRST AID

IT Says: If AID

If Says: 16-06 ye goes and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue mining eye. Call a potion control center or douter for 15-20 minutes. The properties of the second of the se

#### STORAGE AND DISPOSAL

STORAGE: Store in a cool, dry area inaccessible to children.
DISPOSAL: Nonretiliable container. Do not reuse or millithic container. If empty: Place in trash or offer for
recycling if a valiable. If I party filled: Call your local solid waste agency for disposal instructions. Never place
unused product down any indoor or outdoor drain.

Comments, questions? 1-229-228-0980

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





KEEP OUT OF REACH OF CHILDREN

CAUTION See tide purels for additional

WATER RESISTANT (80 MIN)

NON-GREASY

DEET 20.00% OTHER INGREDIENTS 80.00% TOTAL 100.00%



NET CONTENTS: 1gal. (3.78L)

Drug Facts

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

For External Use Only
Do not use III on damaged or broken skin
When using this product III keep out of eyes. Rinse with water

When using mis product a very second so the common to remove to remove Stop use and ask a doctor milifrash occurs alkeep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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■ Protect the product in this container from excessive heat and direct sum.

Buyer assumes all risks of use, storage or handling of this product not in strict accordance with this label.

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.

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Comments, questions? EPA Reg. No. 66306-1 1-229-228-0980 EPA Est. No. 89989-IL-001

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#### SUNSECT INSECT REPELLENT SUNSCREEN

octinoxate, oxybenzone, octisalate lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57595-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	5 g in 100 g	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g	
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	6 g in 100 g	
<b>DIETHYLTOLUAMIDE</b> (UNII: FB0C1XZV4Y) (DIETHYLTOLUAMIDE - UNII:FB0C1XZV4Y)	DIETHYLTOLUAMIDE	20 g in 100 g	

Inactive Ingredients		
Ingredient Name	Strength	
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809 Y72KV36)		
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
Carrageenan (UNII: 5C69 YCD2 YJ)		
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)		
DIETHANOLAMINE CETYL PHO SPHATE (UNII: 4UG0316 V9S)		
TRICONTANYL POVIDONE (UNII: N0SS3Q238D)		
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8 X80 D2L0)		
WATER (UNII: 059QF0KO0R)		
DIAZO LIDINYL UREA (UNII: H5RIZ3MPW4)		
METHYLPARABEN (UNII: A2I8C7HI9T)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		
CITRONELLA OIL (UNII: QYO8Q067D0)		

Packaging				
# Ite	em Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:	:57595-001-	59 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2015	
2 NDC:	:57595-001-	118 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2015	
3 NDC:	:57595-001-	3672 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/01/2015	
4 NDC:	:57595-001-	50 in 1 BOX	06/01/2015	
4		9 g in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/01/2015	

## Labeler - Iguana LLC (109358551)

## Establishment

Name	Address	ID/FEI	Business Operations
Solo Laboratories, Inc.		005126784	manufacture(57595-001), pack(57595-001), label(57595-001)

Revised: 6/2015 Iguana LLC