

**NEW HAWAIIAN TROPIC SENSITIVE SKIN LOTION SUNSCREEN- avobenzone and octocrylene and oxybenzone spray**  
**Accra-Pac, Inc.**

*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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**New Hawaiian Tropic Sensitive Skin Lotion Spray Sunscreen**

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***Drug Facts***

***Active ingredients***

Avobenzone 3%

Octocrylene 8%

Oxybenzone 6%

***Purpose***

Sunscreen

***Use***

helps prevent sunburn

***Warnings***

- For external use only
- Do not spray directly into face
- Flammable do not use near heat, flame or while smoking

***While using this product***

- Avoid spraying in eyes. If contact occurs rinse thoroughly with water.
- Do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120°F.

***Stop use and ask a doctor***

if irritation or rash develops

***Keep out of reach of children.***

If swallowed, get medical help or contact a Poison control center right way.

***Directions***

- Shake well before use
- Apply generously and evenly to all areas 15 minutes before sun exposure
- Spray on hands to apply to face
- Use in well-ventilated area

- Reapply at frequent intervals and after swimming or towel drying
- Ask a doctor before use on children under six months of age

### ***Other Information***

Sun Alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer and other harmful effects of the sun.

- May stain some fabrics.

### ***Inactive Ingredients***

Water, Dimethyl Ether, Butyloctyl Salicylate, Ethylhexyl Benzoate, Hydrogenated Dimer Dilinoleyl/Dimethylcarbonate Copolymer, Glycerin, Polymethylsilsesquioxane, Caprylyl Glycol, Cetareth-25, Disodium Ethylene Dicocamide PEG-15 Disulfate, Dimethyl Capramide, Aloe Barbadensis Leaf Juice, Trocopherol, Retinyl Palmitate (vitamin A), Tocopheryl Acetate (vitamin E), Gossypium Herbaceum (cotton) seed extract, Stevia Rebaudiana leaf/stem extract, Tamannus Indica Seed extract, Butylene Glycol, Pentylene glycol, BHT, Xanthan Gum, triethanolamine, Disodium EDTA, Phenoxyethanol, Hexylene Glycol,

### ***Questions or comments?***

Call 1-800-NO UV Ray, Mon-Fri

Distributed by:

Tanning Research Laboratories, LLC

Ormond Beach, FL 32174

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

### **Principal Display Panel**

New Hawaiian Tropic

Sensitive Skin

Lotion Spray Sunscreen

Oil free

Hypoallergenic

Skin-nourishing antioxidants

50 UVB/SPF with UVA

SunSure Protection™

Protect Pamper Nourish

Net Wt. 6 oz (170g)

**NEW**

# HAWAIIAN Tropic

**SENSITIVE SKIN**  
Lotion Spray Sunscreen

oil free  
hypoallergenic  
skin-nourishing antioxidants



**50**  
UVB/SPF  
WITH UVA

**SUNSURE**  
PROTECTION™

Protect • Pamper • Nourish

NET WT. 6 OZ. (170 g)

Sensitive skin needn't keep you out of the sun, or unprotected. Hawaiian Tropic® Sensitive Skin SPF 50 lotion spray – it's hypoallergenic, oil-free and won't clog pores. This clinically proven formula has been dermatologist tested for gentleness and protection without irritation. SunSure® formula combines broad-spectrum UVA & UVB sunscreens with skin-nourishing antioxidants so your skin is cared for and protected. It's fragrance-free and worry-free so you can be relaxed.

**Drug Facts**

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Avobenzone 3%, Octocrylene 8%, Oxybenzone 6%	Sunscreen

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**Directions** ■ shake well before use ■ apply generously and evenly to all areas 15 minutes before sun exposure ■ spray on hands to apply to face ■ use in well-ventilated area ■ reapply at frequent intervals and after swimming or towel drying ■ ask a doctor before use on children under six months of age

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**Inactive Ingredients** Water, Dimethyl Ether, Butylacetyl Salicylate, Ethylhexyl Benzoate, Hydrogenated Dimer Dinitrile Dimethylcarbonate Copolymer, Glycerin, Polymethylsiloxane, Caprylyl Glycol, Ceteareth-25, Dodecyl Ethylene Dicosamide PEG-15 Distearyl, Dimethyl Capramide, Aloe Barbadensis Leaf Juice, Tocopherol, Tetraol Palmitate (Vitamin A), Tocopheryl Acetate (Vitamin E), Gossypium Herbaceum (Cotton) Seed Extract, Stevia Rebaudiana Leaf/Flower Extract, Tamarindus Indica Seed Extract, Butylene Glycol, Pentylene Glycol, BHT, Xanthan Gum, Inulin, Sodium EDTA, Phenoxyethanol, Hexylene Glycol.

Questions or Comments? Call 1-800-NO UV RAY, Mon-Fri

Visit paradise at [www.hawaiiantropic.com](http://www.hawaiiantropic.com)  
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## NEW HAWAIIAN TROPIC SENSITIVE SKIN LOTION SUNSCREEN

avobenzone and octocrylene and oxybenzone spray

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17630-2000
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.03 g in 1 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	0.08 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.06 g in 1 g

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	

CAPRYLYL GLYCOL (UNII: 00YIU5438U)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)
LEVANT COTTON OIL (UNII: N5CFT140R8)
STEVIA LEAF (UNII: 6TC6NN0876)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
PENTYLENE GLYCOL (UNII: 50C1307PZG)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
XANTHAN GUM (UNII: TTV12P4NEE)
TROLAMINE (UNII: 9O3K93S3TK)
EDETATE DISODIUM (UNII: 7FLD91C86K)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
HEXYLENE GLYCOL (UNII: KEH0A3F75J)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17630-2000-1	170 g in 1 BOTTLE, SPRAY		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	11/04/2009	

**Labeler** - Accra-Pac, Inc. (024213616)

### Establishment

Name	Address	ID/FEI	Business Operations
Accra-Pac, Inc.		024213616	MANUFACTURE