

HAWAIIAN TROPIC ISLAND SPORT SPF 30- 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.

Hawaiian Tropic Island Sport SPF 30

Drug Facts

Active Ingredients

Avobenzone 0.01mL / 1mL

Octocrylene 0.077mL / 1mL

Oxybenzone 0.03mL / 1mL

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

When 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 away.

Directions

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

SD Alcohol 40-B, Acrylates/Octylacrylamide Copolymer, Caprylyl Glycol, Retinyl Palmitate (Vitamin A), Ascorbic Acid (Vitamin C), Tocopheryl Acetate (Vitamin E), PEG-8 Dimethicone, Sodium Propoxyhydroxypropyl Thiosulfate Silica, Octyldodecanol, Silica, Carica Papaya (Papaya) Fruit Extract, Mangifera Indica (Mango) Fruit Extract, Plumeria Acutifolia Flower Extract, Colocasia Antiquorum Root Extract, Psidium Guajava Fruit Extract, Passiflora Incarnata Fruit Extract, Mineral Oil, Aloe Barbadensis Leaf Extract, Fragrance.

Questions or Comments?

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

Distributed by:

**TANNING RESEARCH
LABORATORIES, LLC**

Ormond Beach, FL 32174

Made in U.S.A.

PRINCIPAL DISPLAY PANEL

NEW

HAWAIIAN

Tropic®

ISLAND

sport™

Clear Spray Sunscreen

hydrates skin

very water resistant

skin-nourishing antioxidants

30

UVB/SPF

WITH UVA

SUNSURE

Protection™

Protect Pamper Nourish

6 FL. OZ. (177 ml)

NEW

HAWAIIAN Tropic

ISLAND sport

Clear Spray Sunscreen

hydrates skin
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30

UVA/SPF WITH UVA

SUNSURE PROTECTION™

Protect • Pamper • Nourish

6 FL. OZ. (177 ml)

Blue water, golden sun, and Island Sport spray sunscreen:
Quench your skin with this moisture-rich blend.
Formulated to revitalize and hydrate, to protect and replenish. SunSure™ formula combines patented broad-spectrum UVA & UVB sunscreens with skin-nourishing antioxidants.
It's very water and sweat resistant, and won't run in eyes.

Drug Facts

Active Ingredients	Purpose
Azobenzene 1%, Octocrylene 7%, Oxybenzone 3%	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.

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Inactive ingredients SD Alcohol 40-B, Acrylates/Octylacrylamide Copolymer, Caprylyl Glycol, Retinyl Palmitate, Vitamin A, Ascorbic Acid, Vitamin C, Tocopheryl Acetate, Vitamin E, PEG-8 Dimethicone, Sodium Propylhydroxypropyltrimellitate Silica, Octyldecyl, Silica, Carica Papaya (Papaya) Fruit Extract, Mangifera Indica (Mango) Fruit Extract, Passiflora Acidifolia Flower Extract, Cissampelos Andigarrum Root Extract, Psidium Guajava Fruit Extract, Passiflora incarnata Fruit Extract, Mineral Oil, Aloe Barbadosis Leaf Extract, Fragrance.

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Visit paradise at www.hawaiiantropic.com

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FPO 85%

HAWAIIAN TROPIC ISLAND SPORT SPF 30

avobenzone and octocrylene and oxybenzone spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17630-2035
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.01 mL in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	0.077 mL in 1 mL
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	0.03 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
PAPAYA (UNII: KU94FIY6JB)	
MANGO (UNII: I629I3NR86)	
PLUMERIA EXTRACT (UNII: LGC8P2PC4H)	
GUAVA (UNII: 74O70D6VG0)	
PASSIFLORA INCARNATA TOP (UNII: CLF5YFS11O)	
MINERAL OIL (UNII: T5L8T28FGP)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17630-2035-1	177 mL in 1 CAN		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	10/03/2009	

Labeler - Accra-Pac, Inc. (024213616)

Establishment

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

Revised: 3/2010

Accra-Pac, Inc.