

HAWAIIAN TROPIC- avobenzone,homosalate,octisalate,octocrylene lotion
Edgewell Personal Care Brands, LLC

Active Ingredients

Avobenzone 2.0%, Homosalate 5.5%, Octisalate 4.5%, Octocrylene 4.0%

Purpose

Sunscreen

Uses

• helps prevent sunburn • if used as directed with other sun protection measures (see ***Directions***), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings

For external use only.

May stain some fabrics and surfaces

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 product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

• apply liberally 15 minutes before sun exposure • reapply: • after 80 minutes of swimming or sweating • immediately after towel drying • at least every 2 hours • **Sun Protection Measures:** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including: • limit time in the sun, especially from 10 a.m. - 2 p.m. • wear long-sleeved shirts, pants, hats, and sunglasses • children under 6 months: Ask a doctor

Other information

- protect this product from excessive heat or direct sun

Inactive Ingredients

Water, C12-15 Alkyl Benzoate, Diisopropyl Adipate, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Butylene Glycol, Cetearyl Alcohol, Acrylates/C12-22 Alkyl Methacrylate Copolymer, Phenoxyethanol, Isohexadecane, Caprylyl Glycol, Benzyl Alcohol, Chlorphenesin, Ceteth-10 Phosphate, Dicetyl Phosphate, Fragrance, Polysorbate 60, Xanthan Gum, Coco-Glucoside, Disodium EDTA, Aminomethyl Propanol, Mica, Tocopheryl Acetate, Titanium Dioxide, Panthenol, Aloe Barbadensis Leaf Juice, Silk Amino Acids, Sodium Ascorbyl Phosphate, Psidium Guajava Fruit Extract, Plumeria Acutifolia Flower Extract, Passiflora Incarnata Fruit Extract, Mangifera Indica (Mango) Fruit Extract, Carica Papaya (Papaya) Fruit Extract, Iron Oxides

Questions or Comments?

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

Principal Display Panel

HAWAIIAN TROPIC
SUNSCREEN LOTION
WEIGHTLESS
HYDRATION
12HR MOISTURIZATION

FACE
30

WON'T CLOG PORES
BROAD SPECTRUM SPF 30 UVA/UVB
1.7 FL. OZ (50 mL)

HAWAIIAN TROPIC[®]

SUNSCREEN LOTION

WEIGHTLESS
HYDRATION

12HR MOISTURIZATION

FACE

30



93047663

WON'T CLOG PORES

BROAD SPECTRUM SPF 30 UVA/UVB

1.7 FL. OZ (50 mL)



Drug Facts (cont.)	
Warnings	• 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 product is swallowed, get medical help or contact a Poison Control Center right away. • May stain some fabrics and surfaces.
Directions	• apply liberally 15 minutes before sun exposure • reapply: • after 80 minutes of swimming or sweating • immediately after towel drying • at least every 2 hours • Sun Protection Measures: Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including: • limit time in the sun, especially from 10 a.m. - 2 p.m. • wear long-sleeved shirts, pants, hats, and sunglasses • children under 6 months: Ask a doctor

Drug Facts (cont.)	
Other Information	• protect this product from excessive heat and direct sun
Inactive Ingredients:	Water, C12-15 Alkyl Benzoate, Diisopropyl Adipate, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Butylene Glycol, Cetearyl Alcohol, Acrylates/C12-22 Alkyl Methacrylate Copolymer, Phenoxylethanol, Isohexadecane, Caprylyl Glycol, Benzyl Alcohol, Chlorphenesin, Ceteth-10 Phosphate, Dicapryl Phosphate, Fragrance, Polysorbate 60, Xanthan Gum, Coco-Glucoside, Disodium EDTA, Aminomethyl Propanol, Mica, Tocopheryl Acetate, Titanium Dioxide, Panthenol, Aloe Barbadensis Leaf Juice, Silk Amino Acids, Sodium Ascorbyl Phosphate, Psidium Guajava Fruit Extract, Plumeria Acutifolia Flower Extract, Passiflora Incarnata Fruit Extract, Mangifera Indica (Mango) Fruit Extract, Carica Papaya (Papaya) Fruit Extract, Iron Oxides.
Questions or Comments?	Call 1-800-NO UV RAY, Mon-Fri
**for sun protection, use as directed	

HAWAIIAN TROPIC

avobenzone,homosalate,octisalate,octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63354-582
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4.5 g in 100 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	4 g in 100 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	5.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
PANTHENOL (UNII: WW9CM0O67Z)	
GUAVA (UNII: 74O70D6VG0)	
MANGO (UNII: I629I3NR86)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
WATER (UNII: 059QF0KO0R)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
AMINO ACIDS, SILK (UNII: VOL00EX1IA)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
DIISOPROPYL ADIPATE (UNII: P7E6YFV72X)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	

BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CETETH-10 PHOSPHATE (UNII: 4E05O5N49G)	
DIHEXADECYL PHOSPHATE (UNII: 2V6E5WN99N)	
PAPAYA (UNII: KU94FIY6JB)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPA.S AT 1%) (UNII: 86FQE96TZ4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
PLUMERIA RUBRA FLOWER (UNII: 8P7XXY759H)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
COCO GLUCOSIDE (UNII: ICS790225B)	
PASSIFLORA INCARNATA FRUIT (UNII: SF206I8G4P)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
MICA (UNII: V8A1AW0880)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63354-582-11	50 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/23/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	10/23/2020	

Labeler - Edgewell Personal Care Brands, LLC (151179769)