

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

Active Ingredients

Avobenzone 1.5%, Homosalate 3.0%, Octisalate 4.5%, Octocrylene 3.0%

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

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

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 value 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

Inactive Ingredients

Water, Cetearyl Alcohol, VP/Eicosene Copolymer, Diisopropyl Adipate, C12-15 Alkyl Benzoate, Glycerin, Neopentyl Glycol Diheptanoate, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Coco-Glucoside, Dimethicone, Polymethylsilsesquioxane, Sodium Hydroxide, Ceteth-10 Phosphate, Dicetyl Phosphate, Propylene Glycol Dibenzoate, Disodium EDTA, Paraffin, Xanthan Gum, Butyrospermum Parkii (Shea) Butter, Jojoba Alcohol, Potassium Jojobate, Simmondsia Chinensis (Jojoba) Butter, Mangifera Indica (Mango) Seed Butter, Propanediol, Tocopheryl Acetate, Carica Papaya (Papaya) Fruit Extract, Colocasia Antiquorum Root Extract, Mangifera Indica (Mango) Fruit Extract, Passiflora Incarnata Fruit Extract, Plumeria Acutifolia Flower Extract, Psidium Guajava Fruit Extract, Panthenol, Aloe Barbadensis Leaf Juice, Sodium Ascorbyl Phosphate, Phenoxyethanol, Propylparaben, Fragrance, Mica, Titanium Dioxide.

Other Information

Protect this product from excessive heat and direct sun

Questions or comments ?

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

HAWAIIAN

Tropic

Sheer Touch

Lotion Sunscreen

ULTRA RADIANCE

PROTECTS, SOFTENS,

LEAVES SKIN RADIANT

15

BROAD SPECTRUM

SPF 15

UVA & UVB protection

non-greasy

oil free

water resistant

(80 minutes)



HAWAIIAN TROPIC

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63354-016
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	3 g in 100 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1.5 g in 100 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	3 g in 100 g

OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)

OCTISALATE

4.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
PROPANEDIOL (UNII: 5965N8W85T)	
MANGIFERA INDICA SEED BUTTER (UNII: 40XD9M35X2)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PARAFFIN (UNII: I9O0E3H2ZE)	
SHEA BUTTER (UNII: K49155WL9Y)	
JOJOBA BUTTER (UNII: XIA46H803R)	
MANGO (UNII: I629I3NR86)	
PLUMERIA RUBRA FLOWER (UNII: 8P7XXY759H)	
PAPAYA (UNII: KU94FIY6JB)	
PSIDIUM GUAJAVA WHOLE (UNII: 4J570BB45U)	
PASSIFLORA INCARNATA FRUIT (UNII: SF206I8G4P)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJK51DR)	
DIHEXADECYL PHOSPHATE (UNII: 2V6E5WN99N)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PANTHENOL (UNII: WV9CM0O67Z)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYMETHYLSILSESQUOXANE (11 MICRONS) (UNII: Z570VEV8XK)	
COCO GLUCOSIDE (UNII: ICS790225B)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIISOPROPYL ADIPATE (UNII: P7E6YFV72X)	
CETETH-10 PHOSPHATE (UNII: 4E05O5N49G)	
WATER (UNII: 059QF0K00R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
VINYLPYRROLIDONE/EICOSENE COPOLYMER (UNII: 035MV9S1C3)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
COLOCASIA ESCULENTA ROOT (UNII: H7B71Q0G0D)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
PROPYLENE GLYCOL DIBENZOATE (UNII: EQY32Z1AN4)	
POTASSIUM HYDROLYZED JOJOBA ESTERS (UNII: CH428W5O62)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63354-016-56	236 g in 1 BOTTLE; Type 0: Not a Combination Product	10/15/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/15/2018	

Labeler - Edgewell Personal Care Brands LLC (151179769)

Revised: 10/2018

Edgewell Personal Care Brands LLC