

HAWAIIAN TROPIC- avobenzene, octocrylene, oxybenzone stick
Edgewell Personal Care 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

Avobenzene 1%, Octocrylene 10%, Oxybenzone 6%

Purpose

Sunscreen

Uses

helps prevent sunburn

Warnings

For external use only

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 sunburn, not skin cancer or early skin aging.

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 • reapply after eating or drinking • Children under 6 months: Ask a doctor

Inactive Ingredients

Ozokerite, Ethylhexyl Palmitate, Caprylic/Capric Triglyceride, Diisobutyl Adipate, Cetyl Alcohol,

Cyclopentasiloxane, Theobroma Cacao (Cocoa)Seed Butter, Adipic Acid/Diglycol Crosspolymer, Dimethicone, Flavor, Isostearyl Linoleate, cyclohexasiloxane, PEG-8, Silica, Sodium Saccharin, Propylparaben, BHT, Mineral Oil, PEG-8 Dimethicone, Cocos Nucifera (Coconut) Oil, Aloe Barbadensis Leaf Extract, 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, Octyldodecanol, Retinyl Palmitate, Tocopheryl Acetate, Ascorbic Acid, Sodium Propoxyhydroxypropyl Thiosulfate Silica.

Other Information

protect this product from excessive heat and direct sun

Questions/Comments ?

1-800 NO UV RAY

TRPOICAL Flavor

HAWAIIAN

Tropic

LIP BALM

Sunscreen Stick

Water Resistant (80 minutes)

SPF

45



HAWAIIAN TROPIC

avobenzone, octocrylene, oxybenzone stick

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:63354-300

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	6 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 g in 100 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PLUMERIA RUBRA FLOWER (UNII: 8P7XXY759H)	
SODIUM PROPOXYHYDROXYPROPYL THIOSULFATE SILICA (UNII: 208G222332)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
ADIPIC ACID/DIGLYCOL CROSSPOLYMER (20000 MPA.S) (UNII: R9TPS68K19)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
MINERAL OIL (UNII: T5L8T28FGP)	
PEG-8 DIMETHICONE (UNII: GIA7T764OD)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
COLOCASIA ESCULENTA ROOT (UNII: H7B71Q0G0D)	
MANGIFERA INDICA WHOLE (UNII: U34MFR958F)	
PASSIFLORA INCARNATA FRUIT (UNII: SF206I8G4P)	
PSIDIUM GUAJAVA WHOLE (UNII: 4J570BB45U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
COCOS NUCIFERA WHOLE (UNII: 245J88W96L)	
DIISOBUTYL ADIPATE (UNII: 8OPY05ZY7S)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
THEOBROMA CACAO WHOLE (UNII: EB048G1S9J)	
ISOSTEARYL LINOLEATE (UNII: 4778M3HR0N)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
PAPAYA (UNII: KU94FIY6JB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63354-300-63	4 g in 1 BLISTER PACK; Type 0: Not a Combination Product	01/11/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/11/2012	

Labeler - Edgewell Personal Care LLC (021718141)

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Edgewell Personal Care LLC