TROPIC SUN SPF 50- avobenzone, homosalate, octisalate, octocrylene lotion
Prime Enterprises, 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.

Tropic Sun SPF 50 Sunscreen Lotion Kids

Active ingredients

Avobenzone 3%

Homosalate 10%

Octisalate 5%

Octocrylene 5%

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.

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-sleeve shirts, pants, hats, and sunglasses

children under 6 months: Ask a doctor

Other information

Protect form excessive heat and direct sun.

Inactive ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, C12-15 Alkyl Benzoate, Carbomer, Disodium EDTA, Ethylhexylglycerin, Fragrance, Hydroxypropyl Methylcellulose, Phenoxyethanol, Polyethylene, Polysorbate 20, Propylene Glycol, Sodium Hydroxide, Sorbitan Oleate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Water

Questions or comments?

305-625-4929

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TROPIC SUN SPF 50

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Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58443-0397
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	99.2 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	49.6 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	49.6 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	29.76 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
FRAGRANCE FRESH CITRUS FLORAL ORC1501495 (UNII: OU4GI2R2WB)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
COCOA BUTTER (UNII: 512OYT1CRR)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	white (White to Off White)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0397-4	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/05/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/05/2021	

Labeler - Prime Enterprises, Inc. (101946028)

Registrant - Prime Enterprises, Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises,		101946028	manufacture(58443-0397) , label(58443-0397) , analysis(58443-0397) ,

Inc.		10194602B	pack(58443-0397)