

CALIFORNIA TAN SPF 15 SUNSCREEN- avobenzone, 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.

California Tan SPF 15 Sunscreen

Active Ingredients

Avobenzone 2%

Octisalate 5%

Octocrylene 1.85%

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

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 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

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Adenosine Cyclic Phosphate, Adenosine Triphosphate, Butylphthalimide, C12-15 Alkyl Benzoate, Camellia Sinensis (Green Tea) Leaf Extract, Cetyl Alcohol, Coleus Forskohlii Root Extract, Disodium EDTA, Fragrance (Parfum), Glucose, Hydrolyzed Soy Protein, Isopropylphthalimide, Lycium Barbarum (Goji Berry) Fruit Extract, Methylisothiazolinone, Micrococcus Lysate, Phenoxyethanol, Phenyl Trimethicone, Phospholipids, Plant Amino Acids, Polyethylene, Polyperfluoroethoxymethoxy Difluoroethyl PEG Phosphate, Polysilicone-15, Potassium Cetyl Phosphate, Potassium Hydroxide, Propylene Glycol, Pyruvic Acid,

Saccharomyces/Calcium Ferment, Saccharomyces Lysate Extract, Saccharomyces/Magnesium Ferment, Saccharomyces/Zinc Ferment, Silica, Stearyl Alcohol, Styrene/Acrylates Copolymer, Tocopheryl Acetate, Water (Aqua)

Other Information

- protect this product from excessive heat and direct sun

Questions or Comments?

Call toll free 1-800-SUNCARE

California Tan SPF 15 Sunscreen Lotion

Drug Facts

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 Indianapolis, IN 46278 • 800-SUNCARE
 www.californiatan.com
 MADE IN THE U.S.A. • Stock #CT7027-002

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SUNSCREEN LOTION
 Broad Spectrum SPF 15

Water Resistant
 (80 Minutes)

CLEANTOUCH™
 TECHNOLOGY

4.5 FL Oz (133 mL)



CALIFORNIA TAN SPF 15 SUNSCREEN			
avobenzone, octisalate, octocrylene lotion			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58 443-0 169
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	20 mg in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	50 mg in 1 mL
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	18.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
STYRENE/ACRYLAMIDE COPOLYMER (MW 500000) (UNII: 5Z4DPO246A)	
SACCHAROMYCES CEREVISIAE (UNII: 978D8U419H)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SACCHAROMYCES LYSATE (UNII: R85W246Z1C)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PYRUVIC ACID (UNII: 8558G7RUTR)	
AMINO ACIDS (UNII: 0O72R8RF8A)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
MICROCOCCUS LUTEUS (UNII: LV6L29Z6AX)	
LYCIUM BARBARUM FRUIT (UNII: 930626MWDL)	
ADENOSINE CYCLIC PHOSPHATE (UNII: E0399OZS9N)	
ADENOSINE TRIPHOSPHATE (UNII: 8L70Q75FXE)	
PHENOXYETHANOL (UNII: HE492ZZ3T)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
POLYSILICONE-15 (UNII: F8DRP5BB29)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DEXTROSE (UNII: IY9XDZ35W2)	
(C10-C30)ALKYL METHACRYLATE ESTER (UNII: XH2FQZ38D8)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
N-BUTYLPHTHALIMIDE (UNII: 5TH1DKT35E)	
COLEUS FORSKOHLII ROOT OIL (UNII: 5NXR7DJ9WO)	
SOY PROTEIN (UNII: R44IWB3RN5)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ISOPROPYLPHTHALIMIDE (UNII: 1J1MM83329)	
WATER (UNII: 059QF0KO0R)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0169-4	133 mL in 1 TUBE; Type 0: Not a Combination Product	12/30/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/30/2015	

Labeler - Prime Enterprises Inc. (101946028)**Registrant** - Prime Enterprises Inc. (101946028)**Establishment**

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0169) , manufacture(58443-0169) , label(58443-0169) , analysis(58443-0169)

Revised: 1/2020

Prime Enterprises Inc.