

CALIFORNIA TAN SPF 45 SUNSCREEN- avobenzone, homosalate, octisalate, octocrylene and oxybenzone 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 45 Sunscreen Lotion

Active Ingredients

Avobenzone 3%

Homosalate 10%

Octisalate 5%

Octocrylene 2.75%

Oxybenzone 2%

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

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, 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 Lysate Extract, Saccharomyces/Calcium Ferment, 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 45 Sunscreen Lotion

CALIFORNIA TAN®

Drug Facts

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Inactive ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Adenosine Cyclic Phosphate, Adenosine Triphosphate, Butylated Hydroxytoluene, Butylphthalimide, Camellia Sinensis (Green Tea) Leaf Extract, Cetyl Alcohol, Coelus Forskohlii Extract, Disodium EDTA, Fragrance (Parfum), Glucose, Hydrolyzed Soy Protein, Isopropylphthalimide, Lycium Barbarum (Goji Berry) Fruit Extract, Methylisothiazolinone, Methylparaben, Micrococcus Lysate, Phenyl Trimethicone, Phospholipids, Plant Amino Acids, Polyethylene, Polyperfluoroethoxymethoxy Difluorohydroxyethyl PEG Phosphate, Polysilicone-15, Potassium Cetyl Phosphate, Potassium Hydroxide, Propylene Glycol, Propylparaben, Pyruvic Acid, Saccharomyces Calcium Ferment, Saccharomyces Lysate Extract, Saccharomyces Magnesium Ferment, Saccharomyces Zinc Ferment, Silica, Stearyl Alcohol, Styrene/Acrylates Copolymer, Water (Aqua)

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Call toll free 1-800-SUNCARE

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 Tempe, AZ 85284 • 800-SUNCARE
 www.californiantan.com
 MADE IN THE U.S.A. • Stock #CT7029-001



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SUNSCREEN LOTION
 Broad Spectrum SPF 45

Water Resistant
 (80 Minutes)

CLEANTOUCH™
 TECHNOLOGY

133 mL / 4.5 Fl Oz

CALIFORNIA TAN SPF 45 SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene and oxybenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58 443-016 1
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	20 mg in 1 mL

AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	27.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
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)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
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: HIE492ZZ3T)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
POLYSILICONE-15 (UNII: F8DRP5BB29)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DEXTROSE (UNII: IY9XDZ35W2)	
N-BUTYLPHTHALIMIDE (UNII: 5TH1DKT35E)	
(C10-C30)ALKYL METHACRYLATE ESTER (UNII: XH2FQZ38D8)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
COLEUS FORSKOHLII ROOT OIL (UNII: 5NXR7DJ9WO)	
SOY PROTEIN (UNII: R44IWB3RN5)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ISOPROPYLPHTHALIMIDE (UNII: 1J1MM83329)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0161-3	133 mL in 1 TUBE; Type 0: Not a Combination Product	11/11/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	11/11/2013	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0161) , manufacture(58443-0161) , label(58443-0161) , analysis(58443-0161)

Revised: 1/2020

Prime Enterprises Inc.