

# **CALIFORNIA TAN BROAD SPECTRUM SPF 15- avobenzone, octisalate, and 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.*

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## **Active ingredients**

Avobenzone 2 %, Octisalate 5 %, and Octocrylene 1.85 %

## **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

## **Inactive Ingredients**

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 Difluorohydroxyethyl 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

**PRINCIPAL DISPLAY PANEL - 133 mL Tube Label**

CALIFORNIA TAN®

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**Drug Facts**

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SUNSCREEN LOTION  
Broad Spectrum SPF 15

Water Resistant  
(80 Minutes)

CLEANTOUCH™  
TECHNOLOGY

4.5 FL Oz (133 mL)

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CT  
15  
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 4.5 FL Oz (133 mL)

## CALIFORNIA TAN BROAD SPECTRUM SPF 15

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### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58443-0095
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	19.3 mg in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	48.2 mg in 1 mL
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	26.5 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
(C10-C30)ALKYL METHACRYLATE ESTER (UNII: XH2FQZ38D8)	
ADENOSINE CYCLIC PHOSPHATE (UNII: E0399OZS9N)	
ADENOSINE TRIPHOSPHATE (UNII: 8L70Q75FXE)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
N-BUTYLPHthalimide (UNII: 5TH1DKT35E)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
COLEUS FORSKOHLII ROOT OIL (UNII: 5NXR7DJ9WO)	
N,N-DIMETHYL-2-OCTADECANAMINE (UNII: C358MC5735)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
DEXTROSE (UNII: IY9XDZ35W2)	
SOY PROTEIN (UNII: R44IWB3RN5)	
ISOPROPYLPHthalimide (UNII: 1J1MM83329)	
LYCIUM BARBARUM FRUIT (UNII: 930626MWDL)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MICROCOCCUS LUTEUS (UNII: LV6L29Z6AX)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
OMEGA-3 FATTY ACIDS (UNII: 71M78END5S)	
AMINO ACIDS (UNII: 0O72R8RF8A)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSILICONE-15 (UNII: F8DRP5BB29)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	

<b>POTASSIUM HYDROXIDE</b> (UNII: WZH3C48M4T)
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)
<b>PYRUVIC ACID</b> (UNII: 8558G7RUTR)
<b>CALCIUM</b> (UNII: SY7Q814VUP)
<b>SACCHAROMYCES LYSATE</b> (UNII: R85W246Z1C)
<b>MAGNESIUM</b> (UNII: I38ZP9992A)
<b>ZINC</b> (UNII: J41CSQ7QDS)
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)
<b>STYRENE</b> (UNII: 44LJ2U959V)
<b>WATER</b> (UNII: 059QF0K00R)

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0095-3	133 mL in 1 TUBE; Type 0: Not a Combination Product	04/01/2013	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	04/01/2013	

**Labeler** - Prime Enterprises, Inc. (101946028)

**Registrant** - Prime Enterprises, Inc. (101946028)

### Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	label(58443-0095) , pack(58443-0095) , manufacture(58443-0095) , analysis(58443-0095)