

**CALIFORNIA TAN BROAD SPECTRUM SPF 45- avobenzene, 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.*

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**Active ingredients**

Avobenzene 3 %, Homosalate 10 %, Octisalate 5 %, Octocrylene 2.7 %, and 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

**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, 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)

**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®

**Drug Facts**

Active Ingredients	Purpose
Avobenzone 3% Homosalate 10% Octisalate 5% Octocrylene 2.75% Oxybenzone 2%	Sunscreen

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Call toll free 1-800-SUNCARE

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 Tempe, AZ 85284 • 800-SUNCARE  
 www.californiatan.com  
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**SUNSCREEN LOTION**

Broad Spectrum SPF 45

Water Resistant  
(80 Minutes)

**CLEANTOUCH™  
TECHNOLOGY**

133 mL / 4.5 Fl Oz

CALIFORNIA TAN

CT

45

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 133 mL / 4.5 Fl Oz

## CALIFORNIA TAN BROAD SPECTRUM SPF 45

avobenzone, homosalate, octisalate, octocrylene, and oxybenzone lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58443-0097
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	29.9 mg in 1 mL
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	99.8 mg in 1 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	49.9 mg in 1 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	27.5 mg in 1 mL
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	19.9 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>POLYSILICONE-15</b> (UNII: F8DRP5BB29)	
<b>POTASSIUM CETYL PHOSPHATE</b> (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: 059QF0KO0R)	
<b>CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: 71DD5V995L)	
<b>ADENOSINE CYCLIC PHOSPHATE</b> (UNII: E0399OZS9N)	
<b>ADENOSINE TRIPHOSPHATE</b> (UNII: 8L70Q75FXE)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>3-BUTYLPHthalide</b> (UNII: 822Q956KGM)	
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>PLECTRANTHUS BARBATUS ROOT</b> (UNII: V5741391RG)	

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)
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
OMEGA-3 FATTY ACIDS (UNII: 71M78END5S)
AMINO ACIDS (UNII: 0O72R8RF8A)

### Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0097-3	133 mL in 1 TUBE; Type 0: Not a Combination Product	04/04/2013	

### Marketing Information

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

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

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

### Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	label(58443-0097) , pack(58443-0097) , manufacture(58443-0097) , analysis(58443-0097)