## CALIFORNIA TAN CONTINUOUS SUNSCREEN BROAD SPECTRUM SPF 30- avobenzone, homosalate, octisalate, octocrylene, and oxybenzone spray Prime Packaging 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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#### California Tan Continuous Sunscreen Broad Spectrum SPF 30

#### **Active Ingredients**

Avobenzone 2%

Homosalate 7.5%

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

#### **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. Keep away from face to avoid breathing it

Contents under pressure - do not puncture or incinerate. Do not store at temperatures above 120°F

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.

Flammable: Do not use near heat, flame or while smoking.

#### Directions

- spray liberally and spread evenly by hand 15 minutes before sun exposure
- hold container 4 to 6 inches from the skin to apply
- do not spray directly into face. Spray on hands then apply to face
- do not apply in windy conditions
- use in a well-ventilated area
- reapply:
- after 80 minutes of swimming and 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

Adenosine Cyclic Phosphate, Adenosine Triphosphate, Camellia Sinensis (Green Tea) Leaf Extract, Coleus Forskohlii Extract, Diethylhexyl 2,6-Naphthalate, Fragrance (Parfum), Glucose, Hydrolyzed Soy Protein, Lycium Barbarum (Goji Berry) Fruit Extract, Micrococcus Lysate, Phospholipids, Plant Amino Acids, Polyester-8, Polyperfluoroethoxymethoxy Difluorohydroxyethyl PEG Phosphate, Propylene Glycol, Pyruvic Acid, Saccharomyces Calcium Ferment, Saccharomyces Lysate Extract, Saccharomyces Magnesium Ferment, Saccharomyces Zinc Ferment, Alcohol Denat., VA/Butyl Maleate/Isobornyl Acrylate Copolymer, Water (Aqua)

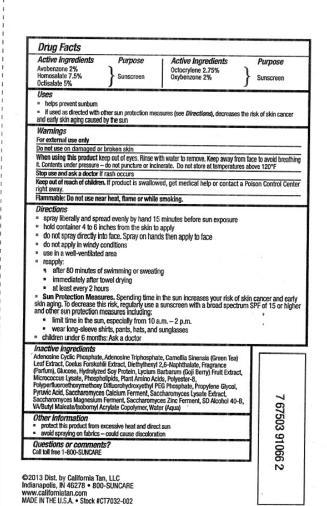
#### Other Information

- protect this product from excessive heat and direct sun
- avoid spraying on fabrics could cause discoloration

#### Question or comments?

Call toll free 1-800 SUNCARE

California Tan Contiuous Sunscreen Broad Spectrum SPF 30





#### CALIFORNIA TAN CONTINUOUS SUNSCREEN BROAD SPECTRUM SPF 30

avobenzone, homosalate, octisalate, octocrylene, and oxybenzone spray

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:13630-0112 Route of Administration TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength

AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	16.5 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	62 mg in 1 mL
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	41.3 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	22.7 mg in 1 mL
OXYBENZONE (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	OXYBENZONE	16.5 mg in 1 mL

Inactive Ingredients				
Ingredient Name	Strength			
OMEGA-3 FATTY ACIDS (UNII: 71M78 END5S)				
SACCHAROMYCES CEREVISIAE (UNII: 978 D8 U419 H)				
ADENO SINE TRIPHO SPHATE (UNII: 8L70 Q75FXE)				
ALCOHOL (UNII: 3K9958V90M)				
ADENOSINE CYCLIC PHOSPHATE (UNII: E0399OZS9N)				
POLYESTER-8 (1400 MW, CYANO DIPHENYLPRO PENO YL CAPPED) (UNII: T9296 U138 P)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
HYDROLYZED SOY PROTEIN (ENZYMATIC; 2000 MW) (UNII: 1394NXB9L6)				
PLECTRANTHUS BARBATUS ROOT (UNII: V5741391RG)				
AMINO ACIDS (UNII: 0 O72R8 RF8 A)				
GREEN TEA LEAF (UNII: W2ZU1RY8B0)				
DIETHYLHEXYL 2,6-NAPHTHALATE (UNII: 10 DQJ7YGXM)				
DEXTROSE (UNII: IY9 XDZ35W2)				
LYCIUM BARBARUM FRUIT (UNII: 930626MWDL)				
WATER (UNII: 059QF0KO0R)				
PYRUVIC ACID (UNII: 8558G7RUTR)				
SACCHAROMYCES LYSATE (UNII: R85W246Z1C)				
DIBUTYL MALEATE (UNII: 4X371TMK9K)				
MICRO CO CCUS LUTEUS (UNII: LV6L29Z6AX)				

Product Characteristics			
Color	yello w	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging					
ı	#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
l	1 NI	DC:13630-0112-4	150 mL in 1 CAN; 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		

### Registrant - Prime Packaging Inc. (805987059)

Establishment			
Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc		101946028	manufacture(13630-0112), analysis(13630-0112)

Establishment			
Name	Address	ID/FEI	Business Operations
Prime Packaging Inc.		805987059	pack(13630-0112), label(13630-0112)

Revised: 1/2020 Prime Packaging Inc.