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

Active ingredients

Avobenzone 2 %, Octisalate 5 %, and Octocrylene 2.75 %

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 $120~^{0}\text{TF}$

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 well-ventilated area
- reapply
 - o 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

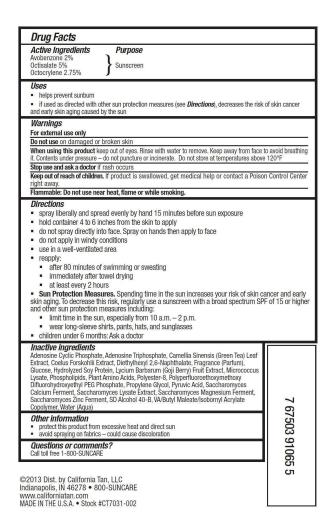
Adenosine Cyclic Phosphate, Adenosine Triphosphate, Camellia Sinensis (Green Tea) Leaf Extract, Coelus Forskohlii Extract, Diethylhexyl 2,6-Naphthalate, Fragrance (Parfum), Glucose, Hydrolyzed Soy Protein, Lycium Barbarum (Goji Berry) Fruit Extract, Micrococcus Lysate, Phospholipids, Plant Amino Acids, 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)

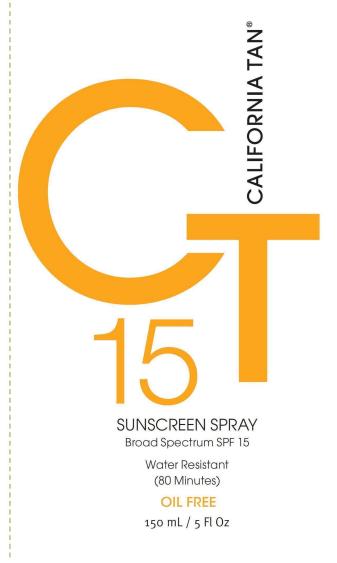
Other information

- protect this product from excesive heat and direct sun
- avoid spraing on fabrics could cause discoloration

Questions or Comments?
Call toll free 1-800-SUNCARE

PRINCIPAL DISPLAY PANEL - 150 mL Can Label





CT 15 SUNSCREEN SPRAY Broad Spectrum SPF 15 Water Resistant

CALIFORNIA TAN

(80 Minutes)

OIL FREE

150 mL/5 Fl Oz

CALIFORNIA TAN BROAD SPECTRUM SPF 15

avobenzone, octisalate and octocrylene spray

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:13630-0064

TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	16 mg in 1 mL		
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	40.3 mg in 1 mL		
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	22.2 mg in 1 mL		

Inactive Ingredients	
Ingredient Name	Strength
DIETHYLHEXYL 2,6-NAPHTHALATE (UNII: 10 DQJ7YGXM)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
LYCIUM BARBARUM FRUIT (UNII: 930626MWDL)	
POLYESTER-8 (1400 MW, CYANO DIPHENYLPRO PENO YL CAPPED) (UNII: T9296U138P)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
ALCOHOL (UNII: 3K9958V90M)	
ADENO SINE TRIPHO SPHATE (UNII: 8L70 Q75FXE)	
PYRUVIC ACID (UNII: 8558G7RUTR)	
ADENO SINE CYCLIC PHO SPHATE (UNII: E0399OZS9N)	
DEXTROSE (UNII: IY9 XDZ35W2)	
OMEGA-3 FATTY ACIDS (UNII: 71M78END5S)	
SACCHAROMYCES LYSATE (UNII: R85W246Z1C)	
DIBUTYL MALEATE (UNII: 4X371TMK9K)	

Product Characteristics			
Color	ye llo w	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:13630-0064-3	150 mL in 1 CAN; Type 0: Not a Combination Product	12/28/2011	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/28/2011	

Labeler - Prime Packaging, Inc. (805987059)

Registrant - Prime Packaging, Inc. (805987059)

Establishment			
Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		10 19 46 0 28	manufacture(13630-0064), analysis(13630-0064)

Establishment			
Name	Address	ID/FEI	Business Operations
Prime Packaging, Inc.		805987059	label(13630-0064), pack(13630-0064)

Revised: 1/2020 Prime Packaging, Inc.