

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 °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 well-ventilated area
- 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

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 excessive 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

Drug Facts		
Active Ingredients	Purpose	
Avobenzone 2% Octisalate 5% Octocrylene 2.75%	} Sunscreen	
Uses		
<ul style="list-style-type: none"> 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		
<ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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, SD Alcohol 40-B, VA/Butyl Maleate/Isobornyl Acrylate Copolymer, Water (Aqua)		
Other information		
<ul style="list-style-type: none"> protect this product from excessive heat and direct sun avoid spraying on fabrics – could cause discoloration 		
Questions or comments?		
Call toll free 1-800-SUNCARE		

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www.californiantan.com
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SUNSCREEN SPRAY
Broad Spectrum SPF 15

Water Resistant
(80 Minutes)

OIL FREE

150 mL / 5 Fl Oz

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CALIFORNIA TAN BROAD SPECTRUM SPF 15

avobenzone, octisalate and octocrylene spray

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:13630-0064

Route of Administration 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: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	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: I0DQJ7YGXM)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
LYCIUM BARBARUM FRUIT (UNII: 930626MWDL)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENYL CAPPED) (UNII: T9296U138P)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
ALCOHOL (UNII: 3K9958V90M)	
ADENOSINE TRIPHOSPHATE (UNII: 8L70Q75FXE)	
PYRUVIC ACID (UNII: 8558G7RUTR)	
ADENOSINE CYCLIC PHOSPHATE (UNII: E0399OZS9N)	
DEXTROSE (UNII: IY9XDZ35W2)	
OMEGA-3 FATTY ACIDS (UNII: 71M78END5S)	
SACCHAROMYCES LYSATE (UNII: R85W246Z1C)	
DIBUTYL MALEATE (UNII: 4X371TMK9K)	

Product Characteristics

Color	yellow	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 1946028	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.