

CALIFORNIA TAN SPF 30 BROAD SPECTRUM SUNSCREEN- avobenzone, homosalate, octisalate, and octocrylene aerosol, foam
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 3 %, Homosalate 10%, Octisalate 5 %, and Octocrylene 2.75 %

Purpose

Sunscreen

Uses

- helps prevent sunburn
- if use 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. 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.

Use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.

Directions

- apply liberally and spread evenly by hand 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

Adenosine Cyclic Phosphate, Adenosine Triphosphate, Aloe Barbadensis Leaf Juice, Camellia Sinensis (Green Tea) Leaf Extract, Cetareth-20, Cetaryl Alcohol, Coleus Forskohlii Root Extract, Disodium EDTA, EDTA, Fragrance (Parfum), Glucose, Hydrolyzed Soy Protein, Isostearic Acid, Lycium Barbarum (Goji Berry) Fruit Extract, Methylisothiazolinone, Methylparaben, Micrococcus Lysate, Phenoxyethanol, Phenyl Trimethicone, Phospholipids, Plant Amino Acids, Polyperfluoroethoxymethoxy Difluoroethyl PEG Phosphate, Polysorbate 20, Polysorbate 60, Propane, Propylene Glycol, Pyruvic Acid, Quaternium-15, Saccharomyces/Calcium Ferment, Saccharomyces Lysate Extract, Saccharomyces/Magnesium Ferment, Saccharomyces/Zinc Ferment, Sodium Polyacrylate, Stearic Acid, Styrene/Acrylates Copolymer, Tocopheryl Acetate, Triethanolamine, VP/Hexadecene, Water (Aqua)

Other Information

- 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

PRINCIPAL DISPLAY PANEL - 170 g Can Label

GT

CALIFORNIA TAN®

30 BODY MOUSSE

SUNSCREEN MOUSSE
Broad Spectrum SPF 30

Water Resistant
(80 Minutes)

OIL-FREE
Net Wt. 6 oz (170g)

Drug Facts	
Active Ingredients	Purpose
Avobenzone 3% Homosalate 10% 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. 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.	
Use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.	
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Inactive ingredients	
Adenosine Cyclic Phosphate, Adenosine Triphosphate, Aloe Barbardensis Leaf Juice, Butane, Camellia Sinensis (Green Tea) Leaf Extract, Ceteareth-20, Cetearyl Alcohol, Coleus Forskohlii Root Extract, Disodium EDTA, EDTA, Fragrance (Parfum), Glucose, Hydrolyzed Soy Protein, Isostearic Acid, Lycium Barbarum (Goji Berry) Fruit Extract, Methylisothiazolinone, Methylparaben, Micrococcus Lysate, Phenoxymethanol, Phenyl Trimethicone, Phospholipids, Plant Amino Acids, Polyperfluoroethylmethoxy Dimethacrylate, Polyisobutyl PEG Phosphate, Polysorbate 20, Polysorbate 80, Propane, Propylene Glycol, Pyruvic Acid, Quaternium-15, Saccharomyces / Calcium Ferment, Saccharomyces Lysate Extract, Saccharomyces / Magnesium Ferment, Saccharomyces / Zinc Ferment, Sodium Polyacrylate, Stearic Acid, Styrene/Acrylates Copolymer, Tocopheryl Acetate, Triethanolamine, VP/Hexadecene Copolymer, Water (Aqua)	
Other information	
<ul style="list-style-type: none"> protect this product from excessive heat and direct sun avoid contact with fabrics – could cause discoloration 	
Questions or comments?	
Call toll free 1-800-SUNCARE	



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California Tan
GT
30
Body
Mousse
Sunscreen Mousse
Broad Spectrum SPF 30
Water Resistant
(80 Minutes)
OIL FREE

Net Wt. 6 oz (170g)

CALIFORNIA TAN SPF 30 BROAD SPECTRUM SUNSCREEN

avobenzone, homosalate, octisalate, and octocrylene aerosol, foam

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13630-0079
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	300 g in 1 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	1000 g in 1 g
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	500 g in 1 g
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	275 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BUTANE (UNII: 6LV4FOR43R)	
PROPANE (UNII: T75W9911L6)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
LYCIUM BARBARUM FRUIT (UNII: 930626MWDL)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CETEARETH-22 (UNII: 28VZG1E234)	
STYRENE/ACRYLAMIDE COPOLYMER (MW 500000) (UNII: 5Z4DPO246A)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
VINYLPYRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)	
EGG PHOSPHOLIPIDS (UNII: 1Z74184RGV)	
AMINO ACIDS (UNII: 0O72R8RF8A)	
SACCHAROMYCES LYSATE (UNII: R85W246Z1C)	
SOY PROTEIN (UNII: R44IWB3RN5)	
CALCIUM (UNII: SY7Q814VUP)	
MAGNESIUM (UNII: I38ZP9992A)	
ZINC (UNII: J41CSQ7QDS)	

COLEUS FORSKOHLII ROOT OIL (UNII: 5NXR7DJ9WO)	
CATALASE (MICROCOCCUS LUTEUS) (UNII: 7TXA8K9WAE)	
DEXTROSE (UNII: IY9XDZ35W2)	
ADENOSINE CYCLIC PHOSPHATE (UNII: E0399OZS9N)	
PYRUVIC ACID (UNII: 8558G7RUTR)	
ADENOSINE TRIPHOSPHATE (UNII: 8L70Q75FXE)	
QUATERNIUM-15 (UNII: E40U03LEM0)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
WATER (UNII: 059QF0K00R)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13630-0079-4	170 g in 1 CAN; Type 0: Not a Combination Product	12/30/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/30/2013	

Labeler - Prime Packaging, Inc. (805987059)

Registrant - Prime Packaging, Inc. (805987059)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	manufacture(13630-0079) , analysis(13630-0079)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Packaging, Inc.		805987059	label(13630-0079) , pack(13630-0079)