

**CALIFORNIA TAN SPF 45 FACE 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.*

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**Active ingredients**

Avobenzone 3 %, Homosalate 15%, 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**

Acrylates/C12-22 Alkyl Methacrylate Copolymer, Adenosine Cyclic Phosphate, Adenosine Triphosphate, Allantoin, Aloe Barbadensis Leaf Juice, Butane, Butylene Glycol, Camellia Sinensis (Green Tea) Leaf Extract, Cetareth-20, Cetearyl Alcohol, Chamomilla Recitita (Matricaria) Flower Extract, Coleus Forskohlii Root Extract, Disodium EDTA, EDTA, 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, 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 - 142 g Can Label**

**CALIFORNIA TAN®**

**GT**

**45**

**FACE MOUSSE**

**SUNSCREEN MOUSSE**  
Broad Spectrum SPF 45

Water Resistant  
(80 Minutes)

**OIL-FREE • FRAGRANCE-FREE**

Net Wt. 5 oz (142g)

**Drug Facts**

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**Inactive ingredients**  
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**Questions or comments?**  
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California Tan  
 CT  
 45  
 Face  
 Mousse  
 Sunscreen Mousse  
 Broad Spectrum SPF 45  
 Water Resistant  
 (80 Minutes)  
 OIL FREE • FRAGRANCE-FREE  
 Net Wt. 5 oz (142g)

**CALIFORNIA TAN SPF 45 FACE SUNSCREEN**  
 avobenzone, homosalate, octisalate, and octocrylene aerosol, foam

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:13630-0078
<b>Route of Administration</b>	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	1500 g in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	500 g in 1 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	275 g in 1 g

### Inactive Ingredients

Ingredient Name	Strength
(C10-C30)ALKYL METHACRYLATE ESTER (UNII: XH2FQZ38D8)	
ALLANTOIN (UNII: 344S277G0Z)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BUTANE (UNII: 6LV4FOR43R)	
PROPANE (UNII: T75W9911L6)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ISO STEARIC ACID (UNII: X33R8U0062)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
MATRICARIA CHAMOMILLA FLOWERING TOP OIL (UNII: SA8AR2W4ER)	
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)	
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)	

<b>PYRUVIC ACID</b> (UNII: 8558G7RUTR)	
<b>ADENOSINE TRIPHOSPHATE</b> (UNII: 8L70Q75FXE)	
<b>QUATERNIUM-15</b> (UNII: E40U03LEM0)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>WATER</b> (UNII: 059QF0K00R)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13630-0078-4	142 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(13630-0078) , analysis(13630-0078)

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Name	Address	ID/FEI	Business Operations
Prime Packaging, Inc.		805987059	label(13630-0078) , pack(13630-0078)

Revised: 12/2018

Prime Packaging, Inc.