SUNTONE BROAD SPECTRUM SPF 4- avobenzone, octocrylene lotion
Prime Enterprises, 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 1 %, Octocrylene 0.85 %

Purpose

Sunscreen

Uses

- helps prevent sunburn

Warnings

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, **not** skin cancer or early skin aging.

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.

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.

Directions

- apply liberally 15 minutes before sun exposure
- reapply:
  - after 80 minutes of swimming or sweating
  - immediately after towel drying
  - at least every 2 hour
- children under 6 months: Ask a doctor

Inactive Ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, Butylphthalimide, C12-15 Alkyl Benzoate, Carbomer, Disodium EDTA, Fragrance (Parfum), Hydroxypropyl Methylcellulose, Isopropylphthalimide, Methylisothiazolinone, Methylparaben, Polyethylene, Polysorbate 20, Propylene Glycol, Propylparaben, Sorbitan Oleate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Triethanolamine, Water (Aqua)

Other information

- protect this product from excesive heat and direct sun

Questions or Comments?

Biocycle Laboratories, Inc.

16363 NW 49 Avenue, Miami, FL 33014

PRINCIPAL DISPLAY PANEL - 177 mL Can Label

Suntone

Fit for the sun

Sunscreen Lotion

Broad Spectrum SPF 4

Water Resistant (80 minutes)

Non-Greasy Formula

4

6 FL. OZ /177mL

SUNTONE BROAD SPECTRUM SPF 4

avobenzone, octocrylene lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58443-0100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	9.9 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	8.4 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
3-BUTYLPHTHALIDE (UNII: 822Q956KGM)	
ISOPROPYLPHTHALIMIDE (UNII: 1J1MM83329)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0100-4	177 mL in 1 CAN; Type 0: Not a Combination Product	02/04/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/04/2013	

Labeler - Prime Enterprises, Inc. (101946028)

Registrant - Prime Enterprises, Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	label(58443-0100) , pack(58443-0100) , manufacture(58443-0100) , analysis(58443-0100)

Revised: 1/2020 Prime Enterprises, Inc.