

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 excessive heat and direct sun

Questions or Comments?

Biocycle Laboratories, Inc.

16363 NW 49 Avenue, Miami, FL 33014

PRINCIPAL DISPLAY PANEL - 177 mL Can Label

The image shows a can label for Suntone Sunscreen Lotion. The top half of the label features a stylized sun with a dotted pattern, transitioning from orange to yellow. Below the sun, the brand name "Suntone" is written in a bold, blue, sans-serif font, with the tagline "Fit for the Sun" in a smaller, orange, script font underneath. The bottom half of the label is a solid blue color with white and yellow text. It prominently displays "Sunscreen Lotion" in white, followed by "Broad Spectrum SPF 4", "Water Resistant (80 minutes)", and "Non-Greasy Formula" in yellow. A large white number "4" is positioned to the right of these claims. At the bottom left, it says "6 FL. OZ. / 177mL". On the right side of the label, there is a white rectangular "Drug Facts" panel with a blue border. This panel contains detailed information about the product's ingredients, uses, warnings, directions, and other information. A barcode is located at the bottom right of the label, with the number "0 87524 97001 9" printed below it. The entire label is set against a background of stylized blue and white waves.

Suntone
Fit for the Sun

Sunscreen Lotion

Broad Spectrum SPF 4
Water Resistant (80 minutes)
Non-Greasy Formula

4

6 FL. OZ. / 177mL

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Biocycle Laboratories, Inc.
16363 NW 49 Avenue, Miami, FL 33014

0 87524 97001 9

Distributed by: Biocycle Laboratories, Inc. | Miami, FL 33014 MADE IN USA

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 HOMO POLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL PARABEN (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.