

SUNTONE SPORT SUNSCREEN BROAD SPECTRUM SPF 50- avobenzone, homosalate, octisalate, octocrylene, oxybenzone 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.

Suntone Sport Sunscreen Continuous Spray Broad Spectrum SPF 50

Active Ingredients

Avobenzone 3%

Homosalate 10%

Octisalate 5%

Octocrylene 2.75%

Oxybenzone 4%

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 a well-ventilated area
- reapply:
- after 80 minutes of swimming and 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

Fragrance (Parfum), SD Alcohol 40-B (Alcohol Denat.), Tocopheryl Acetate, VA/Butyl Maleate/Isobornyl Acrylate Copolymer

Other information

- protect this product from excessive heat and direct sun
- avoid spraying on fabrics - could cause discoloration

Question or comments?

Biocycle laboratories, Inc. 16363 NW 49 Avenuw, Miami, FL 33014

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Drug Facts

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Questions or comments? Biocycle Laboratories, Inc. 16363 NW 49 Avenue, Miami, FL 33014

Distributed by: Biocycle Laboratories, Inc. | Miami, FL 33014
MADE IN USA FROM US AND IMPORTED MATERIALS



Suntone
Fit for the Sun
SPORT

Sunscreen
CONTINUOUS SPRAY

BROAD SPECTRUM SPF 50

Water Resistant (80 minutes)

Non-Greasy Formula

50

Net WT 5.5 OZ (155g)

SUNTONE SPORT SUNSCREEN BROAD SPECTRUM SPF 50

avobenzone, homosalate, octisalate, octocrylene, oxybenzone spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13630-0130
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	25.5 mg in 1 mL

OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	42.5 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	23.38 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	34 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	85 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
VINYL ACETATE (UNII: L9MK238N77)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
DIBUTYL MALEATE (UNII: 4X371TMK9K)	
ISOBORNYL ACRYLATE (UNII: IX0PRH184P)	
ALCOHOL (UNII: 3K9958V90M)	

Product Characteristics

Color	yellow (Light yellow)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13630-0130-4	177 mL in 1 CAN; Type 0: Not a Combination Product	04/16/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	04/16/2018	

Labeler - Prime Packaging Inc. (805987059)

Registrant - Prime Packaging Inc. (805987059)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc		101946028	manufacture(13630-0130) , analysis(13630-0130)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Packaging Inc.		805987059	pack(13630-0130) , label(13630-0130)