

SUN SHADES SPORT PLUS- avobenzone, homosalate, octisalate, octocrylene spray
Melaleuca, 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.

Sun Shades Sport 45+ Content of Label

Active ingredients

Avobenzone 3%, Homosalate 15%, Octisalate 5%, Octocrylene 10%

Purpose

Sunscreen

Uses

- provides high protection against sunburn
- higher SPF gives more sunburn protection
- retains SPF after 80 minutes of activity in the water or sweating

Warnings

For External use only

Flammable: do not use near heat, flame, or while smoking

When using this product

- keep out of eyes. Rinse with water to remove.
- do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120°F.

Stop use and ask a doctor if rash or irritation develops and lasts

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- shake well before first use
- apply evenly and liberally to all exposed areas before sun exposure
- do not spray directly on face. Spray on hands to apply to face.
- use in well-ventilated area
- reapply after 80 minutes of swimming or sweating and after towel drying. Otherwise, reapply at least every 2 hours.
- children under 6 months of age: ask a doctor

Other information

- do not store at temperatures below 32°F (0°C) or above 120°F (49°C)
- Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreen may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun
- may stain some fabrics

Inactive ingredients

acrylates/octylacrylamide copolymer, aleurites moluccana seed oil, ascorbyl palmitate, bisabolol, bixa orellana seed extract, C12-15 alkyl benzoate, caprylic/capric triglyceride, disodium lauriminodipropionate tocopheryl phosphates, macadamia ternifolia seed oil, parfum, phenyl trimethicone, polyester-10, propylene glycol dibenzoate, SD alcohol 40-B, tocopherol


SUN SHADES™

SPORT
SUNSCREEN

SPF 45+

UVA/UVB
PROTECTION

Very Water/Sweat Resistant
Fast & Even Coverage

6 FL OZ (177 mL)

Shake Well Before Using

Ultra Sun Protection for Any Physical Activity

Sun Shades Sport Sunscreen provides no-rub, spray-and-go, UVA/UVB sun protection. This advanced sweat-resistant and water-resistant formula also combines vitamins and botanicals that fight off free radicals and help prevent the appearance of premature skin aging and skin tone loss.

Drug Facts

Active Ingredients	Purpose
Azobenzene 3%, Homosalate 15%, Octisalate 5%, Octocrylene 10%	Sunscreen

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Other Information

- Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreen may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun
- may stain some fabrics
- do not store at temperatures below 32°F (0°C) or above 120°F (48°C)

Inactive Ingredients

acrylates/octylacrylamide copolymer, aloe/tea moluccana seed oil, ascorbyl palmitate, bisabolol, bixa orellana seed extract, C12-15 alkyl benzoate, caprylic/capric triglyceride, diiodium laureth-9 propionate tocopheryl phosphates, macadamia ternifolia seed oil, parifun, phenyl trimethicone, polyester-10, propylene glycol dibenzoate, SD alcohol 40-5, tocopherol



Dist. by: Metolucce, Inc., Idaho Falls, ID 83402-0003

To order: 1-800-282-3000 • www.metolucce.com

Dist. by: Metolucce Southeast Asia (Singapore) Pte Ltd, 10 Eunos Rd 8,

#14-03 Singapore Post Centre, Singapore 409600, SG 1800 800 8080

Product of USA #2145 05/09 U/S/G



NOT FOR RESALE IN CANADA

avobenzone, homosalate, octisalate, octocrylene spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54473-212
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	4.7106 g in 177 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	25.553 g in 177 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	7.851 g in 177 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	15.702 g in 177 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
BIXA ORELLANA SEED (UNII: O87354RZ5A)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
KUKUI NUT OIL (UNII: TP11QR7B8R)	
LEVOMENOL (UNII: 24WE03BX2T)	
MACADAMIA OIL (UNII: 515610SU8C)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
PROPYLENE GLYCOL DIBENZOATE (UNII: EQY32Z1AN4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54473-212-06	177 mL in 1 CAN		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	04/30/2011	

Labeler - Melaleuca, Inc. (139760102)