

**SUN SHADES MINERAL PLUS SUNSCREEN- octisalate and zinc oxide cream
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 Mineral SPF 30+ Content of Label

Active ingredient

Octisalate 5%, Zinc oxide 10%

Purpose

Sunscreen

Uses

- helps prevent sunburn
- higher SPF gives more sunburn protection
- for skin highly sensitive to sunburn
- retains SPF after 80 minutes of activity in the water or sweating

Warnings

For external use only

When using this product keep out of the eyes. Rinse with water to remove.

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

- apply liberally and evenly to all exposed areas before sun exposure
- 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

Inactive ingredients

aleurites moluccana seed oil, ascorbyl palmitate, bisabolol, bixa orellana seed extract, butyrospermum parkii (shea butter), C12-15 alkyl benzoate, caprylic/capric triglyceride, cera alba, cetearyl alcohol, ceteth-10 phosphate, cetyl alcohol, cetyl ethylhexanoate, dicaprylyl carbonate, dicetyl phosphate, disodium EDTA, disodium lauriminodipropionate tocopheryl phosphates, glycerin, hydrogenated palm glycerides, isoeicosane, isostearic acid, macadamia ternifolia seed oil, neopentyl glycol diheptanoate, parfum, pentylene glycol, phenoxyethanol, phenyl trimethicone, polyester-7, polyhydroxystearic acid, potassium cetyl phosphate, potassium sorbate, sodium chloride, sucrose distearate, tocopherol, triethanolamine, water, xanthan gum

SUN SHADES™

MINERAL PLUS SUNSCREEN
WITH ZINC OXIDE

SPF 30+

UVA/UVB PROTECTION

Very Water/Sweat Resistant
Vitamin & Botanical Blend
Protects Against Signs of Aging
Ideal for Sensitive Skin

6 FL OZ (177 mL)

Naturally Advanced Sun Protection
Sun Shades Mineral Plus Sunscreen uses naturally derived micronized zinc oxide to provide a high level of broad-spectrum UVA/UVB protection. This advanced, water-resistant formula dries sheer without leaving a white film and helps prevent moisture loss. It also combines a rich blend of natural, free-radical-fighting vitamins and antioxidants.

Drug Facts	
Active ingredient	Purpose
Octisalate 5%, Zinc oxide 10%	Sunscreen
Uses	
<ul style="list-style-type: none"> helps prevent sunburn higher SPF gives more sunburn protection for skin highly sensitive to sunburn retains SPF after 80 minutes of activity in the water or sweating 	
Warnings	
For external use only	
When using this product keep out of eyes. Rinse with water to remove.	
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	
<ul style="list-style-type: none"> apply liberally and evenly to all exposed areas before sun exposure 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 	
Inactive ingredients	
aleurites moluccana seed oil, ascorbyl palmitate, bisabolol, bixa orellana seed extract, butyrospermum parkii (shea butter), C12-15 alkyl benzoate, caprylic/capric triglyceride, cera alba, cetearyl alcohol, ceteth-10 phosphate, cetyl alcohol, cetyl ethylhexanoate, dicaprylyl carbonate, dicetyl phosphate, disodium EDTA, disodium lauriminodipropionate tocopheryl phosphates, glycerin, hydrogenated palm glycerides, isoicosane, isostearic acid, macadamia ternifolia seed oil, neopentyl glycol diheptanoate, parfum, pentylene glycol, phenoxyethanol, phenyl trimethicone, polyester-7, polyhydroxystearic acid, potassium cetyl phosphate, potassium sorbate, sodium chloride, sucrose distearate, tocopherol, triethanolamine, water, xanthan gum	

Melaleuca, Inc., Idaho Falls, ID 83402-6003
 Tel order: 1-800-282-3000 • www.melaleuca.com
 Dist. by: Melaleuca Southeast Asia (Singapore) Pte Ltd, 10 Eunos Rd 8, #14-03 Singapore Post Centre, Singapore 408600, SG 1800 800 8080
 Product of USA #2144 05/09 USG
 NOT FOR RESALE IN CANADA

SUN SHADES MINERAL PLUS SUNSCREEN

octisalate and zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54473-164
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	9.225 g in 177 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC - UNII:J41CSQ7QDS)	ZINC OXIDE	18.45 g in 177 mL

Inactive Ingredients

Ingredient Name	Strength
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
BIXA ORELLANA SEED (UNII: O87354RZ5A)	

C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)
CETYL ALCOHOL (UNII: 936JST6JCN)
CETYL ETHYLHEXANOATE (UNII: 134647WMX4)
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)
DIHEXADECYL PHOSPHATE (UNII: 2V6E5WN99N)
EDETATE DISODIUM (UNII: 7FLD91C86K)
GLYCERIN (UNII: PDC6A3C0OX)
ISOSTEARIC ACID (UNII: X33R8U0062)
KUKUI NUT OIL (UNII: TP11QR7B8R)
LEVOMENOL (UNII: 24WE03BX2T)
MACADAMIA OIL (UNII: 515610SU8C)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)
PENTYLENE GLYCOL (UNII: 50C1307PZG)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
SHEA BUTTER (UNII: K49155WL9Y)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
TROLAMINE (UNII: 9O3K93S3TK)
WATER (UNII: 059QF0KO0R)
XANTHAN GUM (UNII: TTV12P4NEE)
YELLOW WAX (UNII: 2ZA36H0S2V)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54473-164-06	177 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	05/01/2009	

Labeler - Melaleuca, Inc. (139760102)

Establishment

Name	Address	ID/FEI	Business Operations
Melaleuca, Inc.		139760102	manufacture