

**SUN SHADES MINERAL PLUS SUNSCREEN WITH ZINC OXIDE- octisalate 5%, octocrylene 3%, zinc oxide 10.5% lotion
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 Plus Sunscreen with Zinc Oxide

Active ingredients

Octisalate 5%, Octocrylene 3%, Zinc Oxide 10.5%

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.

Stop use and ask a doctor if rash occurs

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

Directions

- apply liberally and spread evenly by hand 15 minutes before sun exposure
- reapply:
 - after 80 minutes of swimming or 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 signs of aging. To decrease this risk, regularly use a sunscreen with a

broad-spectrum SPF value of 15 or higher and other sun protection measures including:

- limit time in the sun, especially from 10 AM-2 PM
- wear long-sleeve shirts, pants, hats, and sunglasses
- children under 6 months of age: ask a doctor

Other information

- protect this product from excessive heat and direct sun
- do not store at temperatures below 32°F (0°C) or above 120°F (49°C)

Inactive ingredients

aleurites meluccana seed oil, ascorbyl palmitate, bisabolol, butyrospermum parkii (shea butter), C12-15 alkyl benzoate, caprylic/capric triglyceride, cetearyl alcohol, ceteth-10 phosphate, cetyl alcohol, dicaprylyl carbonate, dicetyl phosphate, disodium lauriminodipropionate tocopheryl phosphates, glycerin, hydrogenated palm glycerides, isoeicosane, isostearic acid, lecithin, macadamia ternifolia seed oil, neopentyl glycol diheptanoate, fragrance, pentylene glycol, phenoxyethanol, phenyl trimethicone, polyester-7, polyglyceryl-3 polyricinoleate, polyhydroxystearic acid, potassium cetyl phosphate, potassium sorbate, sodium chloride, sucrose distearate, tocopherol, water, xanthan gum, ethylhexyl salicylate, beeswax, trisodium ethylenediamine disuccinate, sodium hydroxide



MINERAL^{PLUS} SUNSCREEN

with ZINC OXIDE • con ÓXIDO DE ZINC

SPF
FPS | 30⁺ | UVA
UVB

BROAD-SPECTRUM PROTECTION
DE AMPLIO ESPECTRO
FACTOR DE PROTECCIÓN SOLAR ALTO

WATER RESISTANT (80 MINUTES)
VITAMIN & BOTANICAL BLEND
IDEAL FOR SENSITIVE SKIN

RESISTENTE AL AGUA DURANTE 80 MINUTOS
CONTIENE VITAMINAS E INGREDIENTES DE ORIGEN VEGETAL
APTO PARA PIELES SENSIBLES



NO OXYBENZONE & OCTINOXATE
SIN OXIBENZONA NI OCTINOXATO

6 FL OZ (177 mL)

Drug Facts

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Octisalate 5%, Octocrylene 3%, Zinc Oxide 10.5%,.....Sunscreen

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Other information

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Inactive ingredients

water (aqua/eau), caprylic/capric triglyceride, cetearyl alcohol, isoeicosane, C12-15 alkyl benzoate, glycerin, dicaprylyl carbonate, polyester-7, butyrospermum parkii (shea) butter, pentylene glycol, phenyl trimethicone, phenoxyethanol, neopentyl glycol diheptanoate, beeswax (cera alba), ceteth-10 phosphate, dicetyl phosphate, sucrose distearate, alleurites moluccana seed oil, cetyl alcohol, sodium chloride, potassium cetyl phosphate, xanthan gum, fragrance (parfum), potassium sorbate, isostearic acid, lecithin, polyglyceryl-3 polyricinoleate, polyhydroxystearic acid, hydrogenated palm glycerides, trisodium ethylenediamine disuccinate, bisabolol, disodium lauriminodipropionate tocopheryl phosphates, macadamia ternifolia seed oil, sodium hydroxide, ascorbyl palmitate, tocopheryl acetate, benzyl salicylate, coumarin, linalool



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2UL, UK +49 (0) 6105 980 2800, eu.melaleuca.com
Made in the USA with US and imported components
Product of USA N° 2144 06/22 U/EU

NOT FOR RESALE

SUN SHADES MINERAL PLUS SUNSCREEN WITH ZINC OXIDE

octisalate 5%, octocrylene 3%, zinc oxide 10.5% lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54473-218
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	9.225 g in 177 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	5.535 g in 177 mL

ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	18.45 g in 177 mL
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Inactive Ingredients

Ingredient Name	Strength
TRISODIUM ETHYLENEDIAMINE DISUCCINATE (UNII: YA22H34H9Q)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
CETETH-10 PHOSPHATE (UNII: 4E05O5N49G)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
DIHEXADECYL PHOSPHATE (UNII: 2V6E5VN99N)	
DISODIUM LAURIMINODIPROPIONATE TOCOPHERYL PHOSPHATES (UNII: 0K5Y9U1P6M)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGENATED PALM GLYCERIDES (UNII: YCZ8EM144Q)	
ISOEICOSANE (UNII: AR294KAG3T)	
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)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SHEANUT OIL (UNII: O88E196QRF)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SUCROSE DISTEARATE (UNII: 33X4X4B90S)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
YELLOW WAX (UNII: 2ZA36H0S2V)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54473-218-	177 mL in 1 TUBE; Type 0: Not a Combination	01/01/2018	



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FPS | 30⁺ | UVA
UVB

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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/27/2012	

Labeler - Melaleuca Inc. (139760102)

Registrant - Melaleuca Inc. (079711683)

Establishment

Name	Address	ID/FEI	Business Operations
Melaleuca Inc.		079711683	manufacture(54473-218)

Revised: 1/2023

Melaleuca Inc.