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 SUNSCREEN

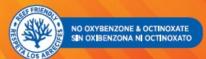
with ZINC OXIDE • con ÓXIDO DE ZINC

SPF 30+ UVA

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**



€ 6 FL OZ (177 mL)

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Inactive ingredients

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Melaleuca, Inc., Idaho Falls, ID 83402 203–534–3000, Helaleuca.com Dist, by: Medaleuca of Europe (Germany) GmbH, EU: Hessenring 13b, 64546 Mörfelden-Walldorf, Germany, UK: c/o Haines Watts, Bridge House Ashley Road, Hale, Albrincham, Chesire, WAI4 2UT. 3 • 49 (0) 6105 980 2800, eu.metaleura.com Made im tje 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

Ingredient Name 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)	ngth
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CETYL ALCOHOL (UNII: 936JST6JCN)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
DIHEXADECYL PHOSPHATE (UNII: 2V6E5WN99N)	
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)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
YELLOW WAX (UNII: 2ZA36H0S2V)	

Product Characteristics		
Color	Score	
Shape	Size	
Flavor	Imprint Code	
Contains		

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
,	NDC:54473-218-	177 mL in 1 TUBE; Type 0: Not a Combination	01/01/2010	

OT/OT/SOTO **Product**



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MINERAL SUNSCREEN

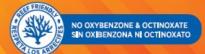
with ZINC OXIDE • con ÓXIDO DE ZINC

SPF 30+ UVA

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NOT FOR RESALE





Melaleuca, Inc., Idaho Falls, ID 83402 208-534-3000, Melaleuca.com Dist, by: Molaleura of Europe (Germany) GmbiH. RU: Hessenring ISD, 64545 Worldeben-Wallburd, Germany, UK: ob Haines Walts, Bridge House Ashley Road, Hale, Allrincham, Chesine, WAIA 2UL. 3 • 49 (0) 6105 980 2000, et.melaileura.com Made im tie USA with US and imported components Product of USA N° 2144 06/22 U/EU

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	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.