DAILY TINTED ANTIOXIDANT MINERAL SUNSCREEN- zinc oxide cream MONIKA G KIRIPOLSKY MD INC.

Active Ingredients

Zinc Oxide 16%

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 broken or damaged skin. Stop use and ask a doctor if rash occurs. When using this product, keep out of eyes. Rinse with water to remove. Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

Warning

Keep out of reach of children

Directions

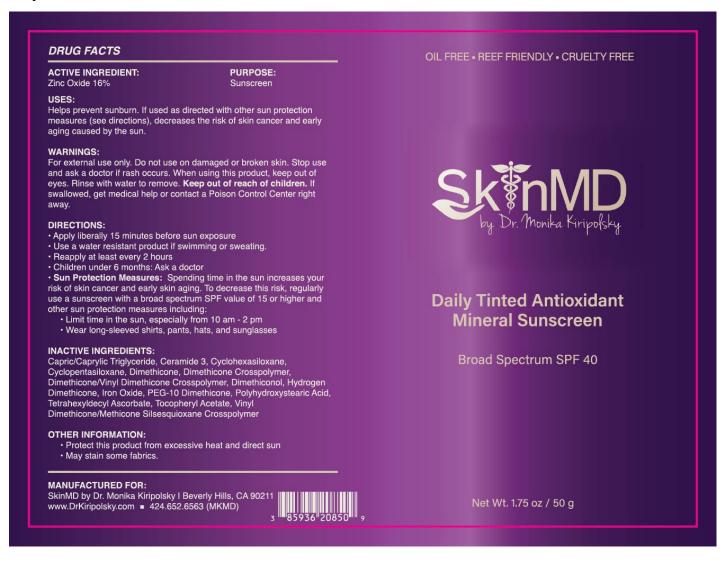
Apply liberally 15 minutes before sun exposure. Use a water-resistant product if swimming or sweating. Reapply at least every 2 hours. Children under 6 months: Ask a doctor. Sun Protection Measures: Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad-Spectrum SPF value 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-sleeved shirts, pants, hats and sunglasses.

Inactive Ingredients

Capric/Caprylic Triglyceride, Ceramide 3, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Iron Oxide, Hydrogen Dimethicone, PEG-10 Dimethicone, Polyhydroxystearic Acid, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Vinyl Dimethicone/Methicone Silsesquioxane Crosspolymer

Other Information

Protect this product from excessive heat and direct sun May stain some fabrics



DAILY TINTED ANTIOXIDANT MINERAL SUNSCREEN

zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85936-208
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	160 mg in 1 g		

Ingredient Name	Strength
CI 77491 (UNII: 1K09F3G675)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	
CI 77492 (UNII: EX438O2MRT)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
CI 77499 (UNII: XM0M87F357)	
CERAMIDE 3 (UNII: 4370DF050B)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:85936- 208-50	50 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/13/2021		

Marketing Information				
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M020	07/13/2021		

Labeler - MONIKA G KIRIPOLSKY MD INC. (037790167)

Establishment				
Name	Address	ID/FEI	Business Operations	
Fragrance Manufacturing Inc		793406000	manufacture(85936-208)	

Establishment				
Name	Address	ID/FEI	Business Operations	
Custom Analytics LLC		144949372	analysis (85936-208)	

Revised: 7/2025 MONIKA G KIRIPOLSKY MD INC.