

MINERAL LIP SUNSCREEN- titanium dioxide, zinc oxide stick
HALEM DERMATOLOGY PLLC

Mineral Lip Sunscreen **Broad Spectrum SPF 45**
Water Resistant (80 minutes)
Net Wt. .14 oz / (4.5 g)

MINERAL LIP SUNSCREEN TINTED
BROAD SPECTRUM SPF 45
Water Resistant (80 minutes)
Net Wt. .14 oz. / (4.5 g)

MONICA HALEM M.D.
NEW YORK

DRUG FACTS:
ACTIVE INGREDIENTS: Titanium Dioxide 4.09%, Sunscreen, Zinc Oxide 5.596
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. 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 the reach of children. Get medical help or contact a Poison Control Center right away.

DIRECTIONS: Apply liberally 15 minutes before sun exposure. Reapply after 80 minutes of swimming or sweating, immediately after towel drying, and at least every 2 hours • Children under 6 months: Ask a doctor

MANUFACTURED FOR: Monica Halem MD | New York, NY 10075 • 212-988-2400
NDC 385413212456

MINERAL LIP SUNSCREEN

titanium dioxide, zinc oxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85413-212(NDC:58892-212)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	55 mg in 1 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	40 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM STEARATE (UNII: U6XF9NP8HM)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
PEG/PPG-15/15 DIMETHICONE (UNII: 184IZ28A2G)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CI 77491 (UNII: 1K09F3G675)	
CI 77492 (UNII: EX438O2MRT)	
CI 77499 (UNII: XM0M87F357)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ZINGIBER OFFICINALE (GINGER) ROOT OIL (UNII: SAS9Z1SVUK)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CETEARYL ISONONANOATE (UNII: P5O01U99NI)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
CERESIN (UNII: Q1LS2UJO3A)	
HEXYLDECANOL (UNII: 151Z7P1317)	
ALUMINA (UNII: LMI26O6933)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
CETYL DIMETHYLBUTYL ETHER (UNII: 7LAB1GXG9G)	
CITRIC ACID (UNII: 2968PHW8QP)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
DIPROPYLENE GLYCOL CAPRATE/CAPRYLATE DIESTER (UNII: R6G12EY23X)	
TOCOPHEROL (UNII: R0ZB2556P8)	
HELIANTHUS ANNUUS (SUNFLOWER) SEED WAX (UNII: 42DG15CHXV)	
HEXYLDECYL LAURATE (UNII: 0V595C1P6M)	
PEG-8 (UNII: B697894SGQ)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	LIME, KIW	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85413-212-45	1 in 1 CYLINDER	01/11/2023	
1		4.5 g in 1 CYLINDER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	01/11/2023	

Labeler - HALEM DERMATOLOGY PLLC (096071438)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85413-212)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(85413-212)

Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85413-212)

Revised: 12/2025

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