

MINERAL LIP SUNSCREEN- titanium dioxide, zinc oxide stick
Helen's Haven

**MINERAL
LIP SUNSCREEN**

SPF 45
BROAD SPECTRUM
WATER RESISTANT
(80 MINS)

.14 oz | 4.5 g



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DRUG FACTS:

ACTIVE INGREDIENTS/PURPOSE: Titanium Dioxide 4.0%, Sunscreen, Zinc Oxide 5.5%, 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. If swallowed, 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 • **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 am-2 pm • Wear long-sleeved shirts, pants, hats, and sunglasses
MANUFACTURED FOR: Helen's Haven Integrative Med Spa • Honolulu, HI 96816
www.skintechskincare.com • 808-739-0400

NDC: 8558121245



MINERAL LIP SUNSCREEN

titanium dioxide, zinc oxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85581-212(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 HYDROXIDE (UNII: 5QB0T2IUN0)				
CETYL DIMETHYLBUTYL ETHER (UNII: 7LAB1GXG9G)				
CI 77491 (UNII: 1K09F3G675)				
SOYBEAN LECITHIN (UNII: 1DI56QDM62)				
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)				
ASCORBIC ACID (UNII: PQ6CK8PD0R)				
ALUMINA (UNII: LMI26O6933)				
ASCORBYL PALMITATE (UNII: QN83US2B0N)				
ETHYLHEXYL PALMITATE (UNII: 2865993309)				
TOCOPHEROL (UNII: R0ZB2556P8)				
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)				
CERESIN (UNII: Q1LS2UJO3A)				
CETEARYL ISONONANOATE (UNII: P5O01U99NI)				
PEG/PPG-15/15 DIMETHICONE (UNII: 184IZ28A2G)				
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)				
HEXYLDECANOL (UNII: 151Z7P1317)				
HEXYLDECYL LAURATE (UNII: 0V595C1P6M)				
ZINGIBER OFFICINALE (GINGER) ROOT OIL (UNII: SAS9Z1SVUK)				
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)				
CITRIC ACID (UNII: 2968PHW8QP)				
CI 77492 (UNII: EX438O2MRT)				
CI 77499 (UNII: XM0M87F357)				
PEG-8 (UNII: B697894SGQ)				
ALUMINUM STEARATE (UNII: U6XF9NP8HM)				
DIPROPYLENE GLYCOL CAPRATE/CAPRYLATE DIESTER (UNII: R6G12EY23X)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
Product Characteristics				
Color		Score		
Shape		Size		
Flavor	LIME, KIWI	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85581-212-45	1 in 1 CARTON	12/01/2020	
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	12/01/2020	

Labeler - Helen's Haven (947935946)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85581-212)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing INC		793406000	manufacture(85581-212)

Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85581-212)

Revised: 12/2025

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