

MINERAL LIP SUNSCREEN- titanium dioxide, zinc oxide stick
Hutton, Kathleen MD

DRUG FACTS

Active Ingredients:

Titanium Dioxide 4.0%

Zinc Oxide 5.5%

Purpose:

Sunscreen

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
- 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 10:00 a.m.-2:00 p.m.
- Wear long-sleeved shirts, pants, hats, and sunglasses

Inactive Ingredients:

Alumina, Aluminum Hydroxide, Aluminum Stearate, Asorbic Acid, Ascorbyl Palmitate, C₁₂₋₁₅ Alkyl Benzoate, Cetearyl Isononanoate, Cetyl PEG/PPG-15/15 Butyl Ether Dimethicone, Citric Acid, Dipropylene Glycol Dicaprylate-Caprato, Ethylhexyl Palmitate, Flavor, Helianthus Annuus (Sunflower) Seed Wax, Hexyldecanol, Hexyldecyl Laurate, Iron Oxide, Lecithin, Ozokerite, PEG-8, Polyglyceryl-3 Diisostearate, Polyhydroxystearic Acid, Stearic Acid, Tocopherol, Tocopheryl Acetate, Zingiber Officinale (Ginger) Root Oil

Other Information:

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

Not tested on animals

Principal Display Panel - 4.5 g Tube Label

HUTTON KLEIN

**HK
DERMATOLOGISTS**

Mineral Lip
Sunscreen

SPF 45

broad spectrum

water resistant

(80 mins)

Tinted

Net. Wt. .14 oz./ 4.5 g



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Sunscreen

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water resistant
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Kathleen Hutton, MD
Newport Beach, CA 92660



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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81679-212
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	40 mg in 1 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	55 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM OXIDE (UNII: LMI26O6933)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
ALUMINUM STEARATE (UNII: U6XF9NP8HM)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CETEARYL ISONONANOATE (UNII: P5O01U99NI)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4) (UNII: 8INO2K35FA)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
DIPROPYLENE GLYCOL CAPRYLATE (UNII: CJ981S4H3T)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CITRUS AURANTIIFOLIA FRUIT OIL (UNII: 7937R189CB)	
KIWI FRUIT OIL (UNII: 66086CWP3Q)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
HEXYLDECANOL (UNII: 151Z7P1317)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)	
CERESIN (UNII: Q1LS2UJO3A)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TOCOPHEROL (UNII: R0ZB2556P8)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
GINGER OIL (UNII: SAS9Z1SVUK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:81679-212-45	4.5 g in 1 TUBE; Type 0: Not a Combination Product	12/18/2023	
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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	02/17/2017	

Labeler - Hutton, Kathleen MD (792310955)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	ANALYSIS(81679-212)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc. (FMI)		793406000	MANUFACTURE(81679-212) , PACK(81679-212)

Revised: 12/2023

Hutton, Kathleen MD