# MINERAL BASED FACIAL SUNSCREEN- zinc oxide cream KATHLEEN P. HUTTON, M.D., INC. A PROFESSIONAL CORPORATION

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### Active Ingredients:

Zinc Oxide 20%

### **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.

#### Warnings:

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:**

C12-15 Alkyl Benzoate, Caprylhydroxamic Acid, Caprylyl Glycol, Cetyl PEG/PPG-10/1 Dimethicone, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Disodium EDTA, Glycerin, Hydrogen Dimethicone, Microcrystalline Wax, PEG-10 Dimethicone, PEG-30 Dipolyhydroxystearate, Polyglyceryl-4 Isostearate, Polyhydroxystearic Acid, Polysorbate 20, Sodium Chloride, Stearyl Dimethicone, Tetrahexyldecyl Ascorbate,

#### Other Information:

Protect this product from excessive heat and direct sun

DRUG FACTS (cont)

INACTIVE INGREDIENTS:

C12-15 Alkyl Benzoate, Caprylhydroxamic Acid, Caprylyl Glycol, Cetyl PEG/PPG 10/1 Dimethicone, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone

Crosspolymer, Dimethicone/Vinyl

Dimethicone Crosspolymer,

Dimethiconol, Disodium EDTA, Glycerin,

Hydrogren Dimethicone, Microcrystalline Wax, PEG-10

Dimethicone, PEG-30

Dipolyhydroxystearate, Polyglyceryl-4

Isostearate, Polyhydroxystearic Acid, Polysorbate 20, Sodium Chloride, Stearyl

Dimethicone, Tetrahexyldecyl

Ascorbate, Tocopheryl Acetate, Triethanolamine,

Triethoxyca prylylsilane, Water

OTHER INFORMATION:

 Protect this product from excessive. heat and direct sun

MANUFACTURED FOR:

Kathleeen Flutton MD Newport Beach, CA 92660

WWW.HUTTONKLEIN.COM

800-909-0060



Mineral Based Facial Sunscreen

- Free of Chemical Sunscreens
- Water-Resistant (40 Minutes)
- Broad Spectrum
- Oil and PABA Free



Net. Wt. 4 oz./ 113 g

# MINERAL BASED FACIAL SUNSCREEN

zinc oxide cream

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Prod	LICT	Inform	ation

**Product Type** HUMAN OTC DRUG Item Code (Source) NDC:81679-205

**Route of Administration TOPICAL** 

#### **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	200 mg in 1 g

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**Ingredient Name** Strength

TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y10)	
STEARYL DIMETHICONE (400 MPA.S AT 50C) (UNII: R327X197HY)	
TRIETHANOLAMINE (UNII: 903K93S3TK)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4) (UNII: 8INO2K35FA)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		113 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/10/2025	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M020	09/10/2025		

# **Labeler -** KATHLEEN P. HUTTON, M.D., INC. A PROFESSIONAL CORPORATION (792310955)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
Fragrance Manufacturing Inc.		793406000	manufacture(81679-205)

# **Establishment**

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(81679-205)

Revised: 9/2025

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