

**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,

Tocopheryl Acetate, Triethanolamine, Triethoxycaprylylsilane, Water

**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,  
 Triethoxycaprylylsilane, Water

**OTHER INFORMATION:**

- Protect this product from excessive heat and direct sun

**MANUFACTURED FOR:**

Kathleen Hutton MD  
 Newport Beach, CA 92660

WWW.HUTTONKLEIN.COM

800-909-0060



**SPF 40**  
 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

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:81679-205(NDC:58892-205)
<b>Route of Administration</b>	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

**Inactive Ingredients**

Ingredient Name	Strength
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<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)
<b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 9E4CO0W6C5)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>HYDROGEN DIMETHICONE (20 CST)</b> (UNII: 12Z59IF64N)
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>CYCLOPENTASILOXANE</b> (UNII: 0THT5PCI0R)
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)
<b>DIMETHICONE CROSSPOLYMER</b> (UNII: UF7620L1W6)
<b>PEG-30 DIPOLYHYDROXYSTEARATE</b> (UNII: 9713Q0S7FO)
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)
<b>STEARYL DIMETHICONE (400 MPA.S AT 50C)</b> (UNII: R327X197HY)
<b>TRIETHANOLAMINE</b> (UNII: 9O3K93S3TK)
<b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)
<b>WATER</b> (UNII: 059QF0KO0R)
<b>POLYGLYCERYL-4 ISOSTEARATE</b> (UNII: 820DPX33S7)
<b>C12-15 ALKYL BENZOATE</b> (UNII: A9EJ3J61HQ)
<b>MICROCRYSTALLINE WAX</b> (UNII: XOF597Q3KY)
<b>PEG-10 DIMETHICONE (600 CST)</b> (UNII: 8PR7V1SVM0)
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)
<b>DIMETHICONOL (2000 CST)</b> (UNII: T74O12AN6Y)
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)
<b>CYCLOHEXASILOXANE</b> (UNII: XHK3U310BA)
<b>CAPRYLHYDROXAMIC ACID</b> (UNII: UPY805K99W)
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)
<b>CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4)</b> (UNII: 8INO2K35FA)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81679-205-04	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	Business Operations
Custom Analytics LLC		144949372	analysis(81679-205)

### Establishment

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

## **Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Fallien Cosmeceuticals Ltd.		958388357	relabel(81679-205)

Revised: 12/2025

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