

SPF 50 MINERAL BASED FACIAL SUNSCREEN- titanium dioxide, zinc oxide cream

Hutton, Kathleen MD

DRUG FACTS

ACTIVE INGREDIENTS:

Titanium Dioxide 10%

Zinc Oxide 3%

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 40 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 am-2 pm
 - Wear long-sleeved shirts, pants, hats, and sunglasses

INACTIVE INGREDIENTS:

Bismuth Oxychloride, Capric/Caprylic Triglyceride, Caprylhydroxamic Acid, Caprylyl Glycol, Ceteareth-20, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Disodium EDTA, Ethylhexyl Hydroxystearate Benzoate, Glycerin, Iron Oxides, Isododecane, Isohexadecane, Melissa Officinalis (Balm Mint) Extract, Mica, Microcrystalline Wax, Octyldodecyl Neopentanoate, PEG-30 Dipolyhydroxystearate, Sodium Chloride, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Tocopherol, Triethanolamine, Triethoxycaprylylsilane, Water

OTHER INFORMATION:

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

MANUFACTURED FOR:

Kathleen Hutton MD
Newport Beach, CA 92660

WWW.HUTTONKLEIN.COM

800-909-0060

Principal Display Panel - 53 g Bottle Label

**HUTTON KLEIN
HK
DERMATOLOGISTS**

SPF 50

Mineral Based
Facial Sunscreen

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

Net. Wt. 1.8 oz./ 53 g

DRUG FACTS (cont)

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titanium dioxide, zinc oxide cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:81679-258 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|---------------|
| Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP) | Titanium Dioxide | 100 mg in 1 g |
| Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z) | Zinc Oxide | 30 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| BISMUTH OXYCHLORIDE (UNII: 4ZR792I587) | |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) | |
| CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W) | |

| |
|--|
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) |
| POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY) |
| CYCLOMETHICONE 6 (UNII: XHK3U310BA) |
| CYCLOMETHICONE 5 (UNII: 0THT5PCI0R) |
| DIMETHICONE (UNII: 92RU3N3Y1O) |
| EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM) |
| ETHYLHEXYL HYDROXYSTEARATE BENZOATE (UNII: 3W8F25684B) |
| GLYCERIN (UNII: PDC6A3C0OX) |
| FERRIC OXIDE RED (UNII: 1K09F3G675) |
| FERRIC OXIDE YELLOW (UNII: EX438O2MRT) |
| FERROSFERRIC OXIDE (UNII: XM0M87F357) |
| ISODODECANE (UNII: A8289P68Y2) |
| ISOHEXADECANE (UNII: 918X1OUF1E) |
| MELISSA OFFICINALIS WHOLE (UNII: YF70189L0N) |
| MICA (UNII: V8A1AW0880) |
| MICROCRYSTALLINE WAX (UNII: XOF597Q3KY) |
| OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T) |
| PEG-30 DIPOLYHYDROXYSTEARATE (4000 MW) (UNII: 9713Q0S7FO) |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) |
| TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ) |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) |
| TOCOPHEROL (UNII: ROZB2556P8) |
| TROLAMINE (UNII: 9O3K93S3TK) |
| TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E) |
| WATER (UNII: 059QF0KO0R) |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:81679-258-50 | 53 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 03/25/2024 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M020 | 03/25/2024 | |

Labeler - Hutton, Kathleen MD (792310955)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------|---------|-----------|---------------------|
| Custom Analytics LLC | | 144949372 | ANALYSIS(81679-258) |

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| Name | Address | ID/FEI | Business Operations |
|------|---------|--------|---------------------|
|------|---------|--------|---------------------|

Revised: 3/2024

Hutton, Kathleen MD