

DAILY DEFENSE TINTED MINERAL SUNSCREEN- titanium dioxide, zinc oxide cream
JKH Aesthetics LLC

DRUG FACTS

ACTIVE INGREDIENTS:
Titanium Dioxide 10%
Zinc Oxide 3%

PURPOSE:
Sunscreen
Sunscreen

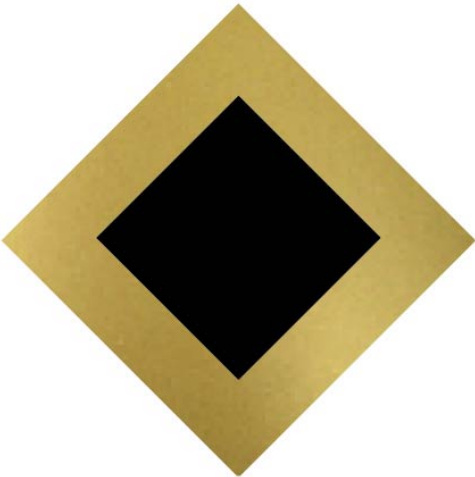
USES:
Helps prevent sunburn. If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun.

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



daily defense tinted
mineral sunscreen

broad spectrum spf 50
water resistant (40 minutes)

 **jkh** AESTHETICS
Mission Viejo, California 92691



net wt. 1.8 oz / 53 g

DAILY DEFENSE TINTED MINERAL SUNSCREEN

titanium dioxide, zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85672-258(NDC:58892-258)
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
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERIN (UNII: PDC6A3C0OX)	
MICA (UNII: V8A1AW0880)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CI 77491 (UNII: 1K09F3G675)	
CI 77499 (UNII: XM0M87F357)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
WATER (UNII: 059QF0KO0R)	
ETHYLHEXYL HYDROXYSTEARATE BENZOATE (UNII: 3W8F25684B)	
CETEARETH-20 (UNII: YRC528SWJY)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
CI 77492 (UNII: EX438O2MRT)	
ISODODECANE (UNII: A8289P68Y2)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TOCOPHEROL (UNII: R0ZB2556P8)	
TRIETHANOLAMINE (UNII: 9O3K93S3TK)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85672-258-50	50 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/30/2024	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	09/30/2024	

Labeler - JKH Aesthetics LLC (129421067)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85672-258)

Establishment			
Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing INC		793406000	manufacture(85672-258)

Establishment			
Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85672-258)

Revised: 12/2025

JKH Aesthetics LLC