

TINTED MINERAL SUNSCREEN- titanium dioxide, zinc oxide cream
LEILANI VIDAL

DRUG FACTS (continued)

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, Cetareth-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, Triethoxycaprylsilane, Water

OTHER INFORMATION:
• Protect this product from excessive heat and direct sun
• May stain some fabrics

Gentle protection is ideal for daily use
Sheer, lightweight satin finish

MANUFACTURED FOR:
NV Lash Studio
Kailua Kona, HI 96740
808-333-6437
nvhawaii.com

'ĀLOHILOHI
~radiant~

TINTED
MINERAL SUNSCREEN

BROAD SPECTRUM SPF 50
WATER RESISTANT (40 MINUTES)

NET WT. 1.8 OZ /53 G

DRUG FACTS

ACTIVE INGREDIENT:
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 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 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

PRESERVATIVES FREE
FRAGRANCE FREE
DYE FREE
FREE OF CHEMICAL SUNSCREEN FILTERS
NO PARABENS
GLUTEN FREE
NO PHTHALATES
OIL FREE

TINTED MINERAL SUNSCREEN

titanium dioxide, zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85645-258(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)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERIN (UNII: PDC6A3C0OX)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CI 77491 (UNII: 1K09F3G675)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
CI 77499 (UNII: XM0M87F357)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
ETHYLHEXYL HYDROXYSTEARATE BENZOATE (UNII: 3W8F25684B)	
CI 77492 (UNII: EX438O2MRT)	
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)	
ISODODECANE (UNII: A8289P68Y2)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)	
TOCOPHEROL (UNII: R0ZB2556P8)	
TRIETHANOLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
CETEARETH-20 (UNII: YRC528SWJY)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85645-258-50	53 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/05/2024	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	06/05/2024	

Labeler -
LEILANI VIDAL (119708018)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85645-258)

Establishment			
Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing INC		793406000	manufacture(85645-258)

Establishment			
Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85645-258)