

MINERAL SUNSCREEN- 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:
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, Triethoxycaprylsilane, Water

OTHER INFORMATION:

- Protect this product from excessive heat and direct sun

Gentle enough for all skin types, even the most sensitive; appropriate for post-procedure use

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



‘ĀLOHILOHI

~radiant~



**NON-TINTED
SUNSCREEN**

BROAD SPECTRUM SPF 40
WATER RESISTANT (40 MINUTES)





NET WT. 4 OZ / 113 G

DRUG FACTS

ACTIVE INGREDIENT: 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 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

MINERAL SUNSCREEN

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85645-205(NDC:58892-205)
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

Inactive Ingredients

Ingredient Name	Strength
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	

CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)
GLYCERIN (UNII: PDC6A3C0OX)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
DIMETHICONE (UNII: 92RU3N3Y1O)
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)
TRIETHANOLAMINE (UNII: 9O3K93S3TK)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
WATER (UNII: 059QF0K00R)
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4) (UNII: 8INO2K35FA)
CYCLOHEXASILOXANE (UNII: XHK3U310BA)
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)
STEARYL DIMETHICONE (400 MPA.S AT 50C) (UNII: R327X197HY)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85645-205-04	113 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(85645-205)

Establishment

Name	Address	ID/FEI	Business Operations
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Fragrance Manufacturing INC		793406000	manufacture(85645-205)
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Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85645-205)

Revised: 12/2025

LEILANI VIDAL