

SAND CLOUD MINERAL SUNSCREEN- titanium dioxide and zinc oxide lotion
Sand Cloud Holdings, LLC

Sand Cloud Mineral Sunscreen

Active ingredients

Titanium Dioxide 5%

Zinc Oxide 10%

Purpose

Sunscreen

Uses

- helps prevent sunburn

Warnings

For external use only

Do not use

- on damaged or broken skin

When using this product

- keep out of eyes. Rinse with water to remove

Stop use and ask a doctor if

- rash occurs

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away

Directions

- shake well prior to use
- apply liberally 15 minutes before sun exposure
- children under 6 months of age: 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
 - reapply :

- after 40 minutes of swimming or sweating
- immediately after towel drying
- at least every 2 hours

Other information

- protect the product in this container from excessive heat and direct sun
- may stain some fabrics

Inactive ingredients

Alumina, Aluminum Stearate, Beeswax, C12-15 Alkyl Benzoate, Caprylyl Glycol, Cetyl Dimethicone, Cetyl PEG/PPG-10/1 Dimethicone, Chlorphenesin, Dimethicone, Disodium EDTA, Ethylhexyl Palmitate, Ethylhexyl Stearate, Hexyl Laurate, Hydrogenated Castor Oil, Methyl Glucose Dioleate, Octyldodecyl Neopentanoate, PEG-7 Hydrogenated Castor Oil, Phenoxyethanol, Polyglyceryl-4 Isostearate, Polyhydroxystearic Acid, Propanediol, Purified Water, Sorbitan Oleate, Stearic Acid, Tocopheryl Acetate (Vitamin E), Triethoxycaprylylsilane, Trimethylsiloxysilicate, VP Hexadecene Copolymer

Questions?

Call **619-693-8397** or visit www.sandcloud.com

Sand Cloud Mineral Sunscreen 3oz

SAND CLOUD

MINERAL SUNSCREEN

SPF 30

BROAD SPECTRUM SPF 30

WATER RESISTANT

(40 MINUTES)

FRAGRANCE FREE

P12234.00



SAND CLOUD[®]

MINERAL SUNSCREEN

SPF 30

BROAD SPECTRUM SPF 30
WATER RESISTANT
(40 MINUTES)
FRAGRANCE FREE

3 FL OZ (89 ML)

Drug Facts

Active ingredients

Titanium Dioxide 5%
Zinc Oxide 10%

Purpose

Sunscreen
Sunscreen

Uses

• helps prevent sunburn

Warnings

For external use only

- **Do not use** • on damaged or broken skin
- **When using this product** • keep out of eyes. Rinse with water to remove
- **Stop use and ask a doctor if** • rash occurs
- **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away

Directions

- shake well prior to use • apply liberally 15 minutes before sun exposure
- children under 6 months of age: 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
 - reapply:
 - after 40 minutes of swimming or sweating
 - immediately after towel drying
 - at least every 2 hours

Other information • protect the product in this container from excessive heat and direct sun • may stain some fabrics

Inactive ingredients

Alumina, Aluminum Stearate, Beeswax, C12-15 Alkyl Benzoate, Caprylyl Glycol, Cetyl Dimethicone, Cetyl PEG/PPG-10/1 Dimethicone, Chlorphenesin, Dimethicone, Disodium EDTA, Ethylhexyl Palmitate, Ethylhexyl Stearate, Hexyl Laurate, Hydrogenated Castor Oil, Methyl Glucose Dioleate, Octyldodecyl Neopentanoate, PEG-7 Hydrogenated Castor Oil, Phenoxyethanol, Polyglyceryl-4 Isostearate, Polyhydroxystearic Acid, Propanediol, Purified Water, Sorbitan Oleate, Stearic Acid, Tocopheryl Acetate (Vitamin E), Triethoxycaprylylsilane, Trimethylsilyoxysilicate, VP Hexadecene Copolymer

Questions? Call 619-693-8397 or visit www.sandcloud.com

Distributed by:
Sand Cloud Holdings LLC
San Diego, Ca. 92109



PI234.00

SAND CLOUD MINERAL SUNSCREEN

titanium dioxide and zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83081-2045
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	54 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	108 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
METHYL GLUCOSE DIOLEATE (UNII: FA9KFJ4Z6P)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
PEG-7 HYDROGENATED CASTOR OIL (UNII: WE09129TH5)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPANEDIOL (UNII: 5965N8W85T)	
WATER (UNII: 059QF0KO0R)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
HEXADECYL POVIDONE (4 HEXADECYL BRANCHES/REPEAT) (UNII: AG75W62QYU)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TRIMETHYLSILOXYSILICATE (M/Q 0.8-1.0) (UNII: 25LXE464L2)	
CETYL DIMETHICONE 25 (UNII: U4AS1BW4ZB)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
ALUMINUM STEARATE (UNII: U6XF9NP8HM)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 5) (UNII: 035JKJ76MT)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83081-2045-3	89 mL in 1 TUBE; Type 0: Not a Combination Product	06/30/2023	
2	NDC:83081-2045-5	148 mL in 1 TUBE; Type 0: Not a Combination Product	06/30/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	06/30/2023	

Labeler - Sand Cloud Holdings, LLC (042484924)