

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

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**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](http://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<sup>®</sup>

## MINERAL SUNSCREEN

# SPF 30

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

3 FL OZ (89 ML)

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



PI234.00

## SAND CLOUD MINERAL SUNSCREEN

titanium dioxide and zinc oxide lotion

### Product Information

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

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)	
<b>ETHYLHEXYL STEARATE</b> (UNII: EG3PA2K3K5)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>HEXYL LAURATE</b> (UNII: 4CG9F9W01Q)	
<b>HYDROGENATED CASTOR OIL</b> (UNII: ZF94AP8MEY)	
<b>METHYL GLUCOSE DIOLEATE</b> (UNII: FA9KFJ4Z6P)	
<b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)	
<b>OCTYLDODECYL NEOPENTANOATE</b> (UNII: X8725R883T)	
<b>PEG-7 HYDROGENATED CASTOR OIL</b> (UNII: WE09129TH5)	
<b>POLYGLYCERYL-4 ISOSTEARATE</b> (UNII: 820DPX33S7)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITAN MONOOLEATE</b> (UNII: 06XEA2VD56)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>HEXADECYL POVIDONE (4 HEXADECYL BRANCHES/REPEAT)</b> (UNII: AG75W62QYU)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>TRIMETHYLSILOXYSILICATE (M/Q 0.8-1.0)</b> (UNII: 25LXE464L2)	
<b>CETYL DIMETHICONE 25</b> (UNII: U4AS1BW4ZB)	
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)	
<b>ALUMINUM STEARATE</b> (UNII: U6XF9NP8HM)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>CETYL PEG/PPG-10/1 DIMETHICONE (HLB 5)</b> (UNII: 035JKJ76MT)	
<b>EDETATE DISODIUM</b> (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	11/30/2025

### 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)