

**CETAPHIL SHEER MINERAL SUNSCREEN SPF 50- titanium dioxide, zinc oxide lotion**

**Galderma Laboratories, L.P.**

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**Cetaphil Sheer Mineral Sunscreen Broad Spectrum SPF 50**

**Active Ingredients**

Titanium Dioxide 4.9%

Zinc Oxide 4.7%

**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 skin aging caused by the sun

**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**

- apply liberally 15 minutes before sun exposure
- reapply:

- after 80 minutes of swimming or sweating
- immediately after towel drying
- at least every 2 hours
- 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

### **Other Information**

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

### **Inactive Ingredients**

alumina, arachidyl alcohol, arachidyl glucoside, ascorbic acid, avena sativa (oat) kernel extract, beeswax, behenyl alcohol, benzyl alcohol, bisabolol, butylene glycol, butyloctyl salicylate, calendula officinalis flower extract, camellia sinensis leaf extract, carbomer, ceramide AP, ceramide EOP, ceramide NP, cetyl dimethicone, chamomilla recutita (matricaria) flower extract, cholesterol, dimethicone, dimethicone PEG-8 laurate, dipotassium glycyrrhizate, disodium EDTA, ethylhexylglycerin, glycerin, glyceryl stearate, hydrated silica, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, isohexadecane, maltodextrin, methicone, panthenol, pantothenic acid, PEG-100 stearate, PEG-8, phytosphingosine, polyaminopropyl biguanide, polymethyl methacrylate, polysorbate 60, potassium sorbate, propylene glycol, sodium lauroyl lactylate, stearic acid, styrene/acrylates copolymer, tocopheryl acetate(vitamin E), triethoxycaprylylsilane, trimethylsiloxysilicate, trisiloxane, VP/eicosene copolymer, water, xanthan gum.

### **Questions or comments?**

1-866-735-4137

**PRINCIPAL DISPLAY PANEL - 3 FL OZ TUBE**

NEW



DERMATOLOGIST RECOMMENDED BRAND

# Sheer Mineral Sunscreen

Broad Spectrum SPF 50

# 50

Formulated for Sensitive Skin  
Microbiome Gentle  
Contains prebiotics and Vitamin E

Water Resistant (80 minutes)

Paraben and Fragrance Free

3 FL OZ (89 mL)

PS-4713-0

### Drug Facts

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Zinc Oxide 4.7%	Sunscreen

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Dist. by: Galderma Laboratories, L. P.  
Fort Worth, TX 76177 USA  
1-866-735-4137

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cetaphil.com



NEW

**Cetaphil®**  
Dermatologist Recommended Brand

# Sheer Mineral Sunscreen

Broad Spectrum SPF 50  
50

Formulated for Sensitive Skin

Microbiome Gentle

Contains prebiotics and Vitamin E

Water Resistant (80 minutes)

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3 FL OZ (89 mL)

Distributed by:

Galderma Laboratories, L.P.

Fort Worth, TX 76177 USA

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cetaphil.com

P54713-0

## CETAPHIL SHEER MINERAL SUNSCREEN SPF 50

titanium dioxide, zinc oxide lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0299-4112
<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	49 mg in 1 mL
<b>Zinc Oxide</b> (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	47 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
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<b>Aluminum Hydroxide</b> (UNII: 5QB0T2IUN0)	
<b>Arachidyl Alcohol</b> (UNII: 1QR1QRA9BU)	
<b>Arachidyl Glucoside</b> (UNII: 6JVM35JOOJ)	
<b>Ascorbic Acid</b> (UNII: PQ6CK8PD0R)	
<b>Oat</b> (UNII: Z6J799EAJK)	
<b>Yellow Wax</b> (UNII: 2ZA36H0S2V)	
<b>Docosanol</b> (UNII: 9G1OE216XY)	
<b>Benzyl Alcohol</b> (UNII: LKG8494WBH)	
<b>Levomenol</b> (UNII: 24WE03BX2T)	
<b>Butylene Glycol</b> (UNII: 3XUS85K0RA)	
<b>Butyloctyl Salicylate</b> (UNII: 2EH13UN8D3)	
<b>Calendula Officinalis Flower</b> (UNII: P0M7O4Y7YD)	
<b>Green Tea Leaf</b> (UNII: W2ZU1RY8B0)	
<b>Carbomer Homopolymer, Unspecified Type</b> (UNII: 0A5MM307FC)	
<b>Ceramide Ap</b> (UNII: F1X8L2B00J)	
<b>Ceramide 1</b> (UNII: 5THT33P7X7)	
<b>Ceramide Np</b> (UNII: 4370DF050B)	
<b>Cetyl Dimethicone 150</b> (UNII: 5L694Y0T22)	
<b>Chamomile</b> (UNII: FGL3685T2X)	
<b>Cholesterol</b> (UNII: 97C5T2UQ7J)	
<b>Dimethicone</b> (UNII: 92RU3N3Y1O)	
<b>Dimethicone Peg-8 Laurate</b> (UNII: 72MF9C2A18)	
<b>Glycyrrhizinate Dipotassium</b> (UNII: CA2Y0FE3FX)	
<b>Edetate Disodium</b> (UNII: 7FLD91C86K)	
<b>Ethylhexylglycerin</b> (UNII: 147D247K3P)	
<b>Glycerin</b> (UNII: PDC6A3C0OX)	
<b>Glyceryl Monostearate</b> (UNII: 230OU9XXE4)	
<b>Hydrated Silica</b> (UNII: Y6O7T4G8P9)	
<b>Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer (100000 Mpa.S At 1.5%)</b> (UNII: 86FQE96TZ4)	
<b>Isohexadecane</b> (UNII: 918X1OUF1E)	
<b>Maltodextrin</b> (UNII: 7CVR7L4A2D)	
<b>Methicone (20 Cst)</b> (UNII: 6777U11MKT)	
<b>Panthenol</b> (UNII: WW9CM0O67Z)	
<b>Pantothenic Acid</b> (UNII: 19F5HK2737)	
<b>Peg-100 Stearate</b> (UNII: YD01N1999R)	
<b>Polyethylene Glycol 400</b> (UNII: B697894SGQ)	
<b>Phytosphingosine</b> (UNII: GIN46U9Q2Q)	
<b>Polihexanide</b> (UNII: 322U039GMF)	
<b>Poly(Methyl Methacrylate; 450000 Mw)</b> (UNII: Z47NNT4J11)	
<b>Polysorbate 60</b> (UNII: CAL22UVI4M)	
<b>Potassium Sorbate</b> (UNII: 1VPU26JZZ4)	
<b>Propylene Glycol</b> (UNII: 6DC9Q167V3)	
<b>Sodium Lauroyl Lactylate</b> (UNII: 7243K85WFO)	
<b>Stearic Acid</b> (UNII: 4ELV7Z65AP)	
<b>Styrene/Acrylamide Copolymer (500000 Mw)</b> (UNII: 5Z4DPO246A)	
<b>.Alpha.-Tocopherol Acetate</b> (UNII: 9E8X80D2L0)	
<b>Triethoxycaprylylsilane</b> (UNII: LDC331P08E)	
<b>Trimethylsiloxysilicate (M/Q 0.6-0.8)</b> (UNII: 5041RX63GN)	
<b>Trisiloxane</b> (UNII: 9G1ZW13R0G)	
<b>Vinylpyrrolidone/Eicosene Copolymer</b> (UNII: 035MV9S1C3)	

**Water** (UNII: 059QF0KO0R)

**Xanthan Gum** (UNII: TTV12P4NEE)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0299-4112-00	89 mL in 1 TUBE; Type 0: Not a Combination Product	11/01/2020	
2	NDC:0299-4112-05	10 mL in 1 TUBE; Type 0: Not a Combination Product	11/01/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/01/2020	

**Labeler** - Galderma Laboratories, L.P. (047350186)

### Establishment

Name	Address	ID/FEI	Business Operations
Fruit of The Earth Research Laboratories, Inc.		008193513	manufacture(0299-4112)

### Establishment

Name	Address	ID/FEI	Business Operations
Fruit of The Earth, Inc.		080086802	manufacture(0299-4112)

Revised: 12/2023

Galderma Laboratories, L.P.