

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

Galderma Laboratories, L.P.

Cetaphil Sheer Mineral Sunscreen Broad Spectrum SPF 50

Active Ingredients

Titanium Dioxide 9.0%

Zinc Oxide 7.0%

OTC - PURPOSE SECTION

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

WATER, ISOHEXADECANE, BUTYLOCTYL SALICYLATE, CETYL DIMETHICONE, STYRENE/ACRYLATES COPOLYMER, OLIVE OIL POLYGLYCERYL-6 ESTERS, SORBITAN OLIVATE, SODIUM STEAROYL LACTYLATE, VP/EICOSENE COPOLYMER, CETEARYL ALCOHOL, CETEARYL OLIVATE, CETYL PALMITATE, SORBITAN PALMITATE, DIMETHICONE PEG-8 LAURATE, CERAMIDE NP, CERAMIDE AP, CERAMIDE EOP, CHOLESTEROL, PHYTOSPHINGOSINE, HYDROLYZED HYALURONIC ACID, BENZYL ALCOHOL, BISABOLOL, DIPOTASSIUM GLYCYRRHIZATE, PROPANEDIOL, XANTHAN GUM, ALUMINUM HYDROXIDE, SODIUM LAUROYL LACTYLATE, CARBOMER, TOCOPHERYL ACETATE, DISODIUM EDTA, STEARIC ACID, TRIETHOXYCAPRYLYLSILANE, CITRIC ACID, MALTODEXTRIN, PHENOXYETHANOL, CAPRYLOYL GLYCINE, UNDECYLENOYL GLYCINE

Questions or comments?

1-866-735-4137

PRINCIPAL DISPLAY PANEL - 3 FL OZ TUBE

#1 DOCTOR RECOMMENDED
SENSITIVE SKINCARE BRAND



SUN 50

Sheer Mineral Sunscreen
Broad Spectrum SPF 50

Formulated for sensitive skin
Microbiome gentle formula
nourishes sensitive skin while
providing hydrating,
chemical-free sun protection
Water resistant (80 minutes)
Prebiotics & Vitamin E



3 FL OZ (89 mL)

Drug Facts

Active ingredients	Purpose
Titanium Dioxide 9.0%	Sunscreen
Zinc Oxide 7.0%	Sunscreen

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When using this product ■ keep out of eyes. Rinse with water to remove.
Stop use and ask a doctor if ■ rash occurs.
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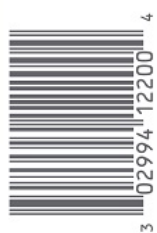
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Inactive ingredients: WATER, ISOHEXADECANE, BUTYLOCTYL SALICYLATE, CETYL DIMETHICONE, STYRENE/ACRYLATES COPOLYMER, OLIVE OIL POLYGLYCERYL-6 ESTERS, SORBITAN OLIVATE, SODIUM STEAROYL LACTYLATE, VP/ECOSENE COPOLYMER, CETEARYL ALCOHOL, CETEARYL OLIVATE, CETYL PALMITATE, SORBITAN PALMITATE, DIMETHICONE PEG-8 LAURATE, CERAMIDE NP, CERAMIDE AP, CERAMIDE EOP, CHOLESTEROL, PHYTOSPHINGOSINE, HYDROLYZED HYALURONIC ACID, BENZYL ALCOHOL, BISABOLOL, DIPHOSPHATE, PROPANEDIOL, XANTHAN GUM, ALUMINUM HYDROXIDE, SODIUM LAUROYL LACTYLATE, CARBOMER, TOCOPHERYL ACETATE, DISODIUM EDTA, STEARIC ACID, TRIETHOXYCAPRYLYLSILANE, CITRIC ACID, MALTODEXTRIN, PHENOXYETHANOL, CAPRYLYL GLYCINE, UNDECYLENOL, GLYCINE

Questions or comments?
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GALDERMA
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#1 Doctor Recommended

Sensitive Skincare Brand

Cetaphil®

SUN

50

Sheer Mineral Sunscreen

Broad Spectrum SPF 50

Formulated for sensitive skin

Microbiome gentle formula

nourishes sensitive skin while
providing hydrating,
chemical-free sun protection

Water resistant (80 minutes)

Prebiotics & Vitamin E

National Eczema Association logo

3 FL OZ (89 mL)

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Fort Worth, TX 76177 USA

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CETAPHIL SHEER MINERAL SUNSCREEN SPF 50

titanium dioxide, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0299-4122
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	90 mg in 1 mL
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	70 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0K00R)	
Isohexadecane (UNII: 918X1OUF1E)	
Butyloctyl Salicylate (UNII: 2EH13UN8D3)	
Cetyl Dimethicone 150 (UNII: 5L694Y0T22)	
Styrene/Acrylamide Copolymer (500000 Mw) (UNII: 5Z4DPO246A)	
Olive Oil Polyglyceryl-6 Esters (UNII: 4KDO9AFM9I)	
Sorbitan Olivatate (UNII: MDL271E3GR)	
Sodium Stearoyl Lactylate (UNII: IN99IT31LN)	
Vinylpyrrolidone/Eicosene Copolymer (UNII: 035MV9S1C3)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
Cetearyl Olivatate (UNII: 58B69Q84JO)	
Cetyl Palmitate (UNII: 5ZA2S6B08X)	
Sorbitan Monopalmitate (UNII: 77K6Z421KU)	
Dimethicone Peg-8 Laurate (UNII: 72MF9C2A18)	
Ceramide Np (UNII: 4370DF050B)	
Ceramide Ap (UNII: F1X8L2B00J)	
Ceramide 1 (UNII: 5THT33P7X7)	
Cholesterol (UNII: 97C5T2UQ7J)	
Phytosphingosine (UNII: GIN46U9Q2Q)	
Benzyl Alcohol (UNII: LKG8494WBH)	
Levomenol (UNII: 24WE03BX2T)	
Glycyrrhizinate Dipotassium (UNII: CA2Y0FE3FX)	
Propanediol (UNII: 5965N8W85T)	
Xanthan Gum (UNII: TTV12P4NEE)	
Aluminum Hydroxide (UNII: 5QB0T2IUN0)	
Sodium Lauroyl Lactylate (UNII: 7243K85WFO)	
Carbomer Homopolymer, Unspecified Type (UNII: 0A5MM307FC)	
.Alpha.-Tocopherol Acetate (UNII: 9E8X80D2L0)	
Edetate Disodium (UNII: 7FLD91C86K)	
Stearic Acid (UNII: 4ELV7Z65AP)	
Triethoxycaprylylsilane (UNII: LDC331P08E)	
Citric Acid Monohydrate (UNII: 2968PHW8QP)	
Maltodextrin (UNII: 7CVR7L4A2D)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Capryloyl Glycine (UNII: 8TY5YO42NJ)	
Undecylenoyl Glycine (UNII: 4D20464K2J)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0299-4122-00	89 mL in 1 TUBE; Type 0: Not a Combination Product	10/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	10/01/2021	

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

Establishment

Name	Address	ID/FEI	Business Operations
Fruit of The Earth Research Laboratories, Inc.		008193513	manufacture(0299-4122)

Establishment

Name	Address	ID/FEI	Business Operations
Fruit of The Earth, Inc.		080086802	manufacture(0299-4122)

Revised: 11/2023

Galderma Laboratories, L.P.