POLLUTION SHIELD SPF 46 BROAD SPECTRUM SUNSCREEN- titanium dioxide and zinc oxide lotion SENTÉ, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Pollution Shield SPF 46 Broad Spectrum Sunscreen

Drug Facts

Active ingredients	Purpose
Titanium Dioxide 5.3%	Sunscreen
Zinc Oxide 14.5%	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 at least every 2 hours
- Use a water resistant sunscreen if swimming or sweating
- **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 10a.m.-2p.m.
 - Wear long- sleeved shirts, pants, hats, and sunglasses.
 - Children under 6 months of age: Ask a doctor

Inactive ingredients

Water (Aqua), Dicaprylyl Carbonate, Caprylic/Capric Triglyceride, Glycerin, Steareth-2, Cetearyl Alcohol, Polymethylsilsesquioxane, Steareth-21, Silica, Polyhydroxystearic Acid, Hydrolyzed Candida Saitoana Extract, Glycine Max (Soybean) Seed Extract, Yeast Extract, Biosaccharide Gum-4, Dimethicone, Dipotassium Glycyrrhizate, Propanediol, Stearic Acid, Triethoxycaprylylsilane, Sodium Stearoyl Glutamate, 1,2-Hexanediol, Sodium C14-16 Olefin Sulfonate, Caprylhydroxamic Acid, Alumina, Caprylyl Glycol, Xanthan Gum, Disodium EDTA. Iron Oxides (Cl 77491, Cl 77492, Cl

Other information

• Protect the product in this container from excessive heat and direct sun

Questions or comments?

(800) 205-6774

www.sentelabs.com

PRINCIPAL DISPLAY PANEL - 52 g Tube Carton

SENTÉ

Glycosaminoglycans

Pollution Shield

Broad Spectrum SPF 46 Sunscreen

Full Physical

Tinted

PA++++

BOOST

SHIELD

NET WT. 1.8 OZ/52g



Broad Spectrum SPF 46 Sunscreen

Full Physical Tinted

PA++++

BOOST

SHIELD

NET WT. 1.8 OZ/52g



Drug Facts

Active ingredients Purpose

Titanium Dioxide 5.3%.....Sunscreen Zinc Oxide 14.5%.....Sunscreen

Uses

- Helps prevent sunburn
- If used as directed with other sun protection measures (see Directions), decreases the risk of skip capear and

Drug Facts (continued)

Stearic Acid, Triethoxycaprylylsilane, Sodium Stearoyl Glutamate, 1,2-Hexanediol, Sodium C14-16 Olefin Sulfonate, Caprylhydroxamic Acid, Alumina, Caprylyl Glycol, Xanthan Gum, Disodium EDTA, Iron Oxides (CI 77491, CI 77492, CI 77499). 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 at least every 2 hours
- Use a water resistant sunscreen if swimming or sweating
- 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.
- Children under 6 months of age: Ask a doctor

Inactive ingredients

Water (Aqua), Dicaprylyl Carbonate, Caprylic/Capric Triglyceride, Glycerin, Steareth-2, Cetearyl Alcohol, Polymethylsilsesquioxane, Steareth-2, Silica, Polyhydroxystearic Acid, Hydrolyzed Candida Saitoana Extract, Glycine Max (Soybean) Seed Extract, Yeast Extract, Biosaccharide Gum-4, Dimethicone, Dipotassium Glycyrrhizate, Propanediol,

Other information

 Protect the product in this container from excessive heat and direct sun

Questions or comments?

(800) 205-6774 www.sentelabs.com

OIL FREE
NON-COMEDOGENIC
HYPOALLERGENIC
NON-PHOTOTOXIC
PARABEN FREE
FRAGRANCE FREE
NO ANIMAL TESTING

Manufactured for: SENTÉ Carlsbad, CA 92009



POLLUTION SHIELD SPF 46 BROAD SPECTRUM SUNSCREEN

titanium dioxide and zinc oxide lotion

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71398-001	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Titanium Dioxide (UNII: 15FIX9 V2JP) (Titanium Dioxide - UNII:15FIX9 V2JP)	Titanium Dioxide	53 mg in 1 g	
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	145 mg in 1 g	

Inactive Ingredients	
Ingredient Name	Strength
Dicaprylyl Carbonate (UNII: 609A3V1SUA)	
Medium-Chain Triglycerides (UNII: C9H2L21V7U)	
Glycerin (UNII: PDC6A3C0OX)	
Steareth-2 (UNII: V56DFE46J5)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
POLYMETHYLSILSESQUIOXANE (11 MICRONS) (UNII: Z570 VEV8 XK)	
Steareth-21 (UNII: 53J3F32P58)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
Soybean (UNII: L7HT8F1ZOD)	
Yeast, Unspecified (UNII: 3NY3SM6B8U)	
Biosaccharide Gum-4 (UNII: 9XRL057X90)	
Dimethicone (UNII: 92RU3N3Y1O)	
Glycyrrhizinate Dipotassium (UNII: CA2Y0FE3FX)	
Propanediol (UNII: 5965N8W85T)	
Stearic Acid (UNII: 4ELV7Z65AP)	
Triethoxycaprylylsilane (UNII: LDC331P08E)	
Sodium Stearoyl Glutamate (UNII: 65A9F4P024)	
1,2-Hexanediol (UNII: TR046 Y3K1G)	
Sodium C14-16 Olefin Sulfonate (UNII: O9W3D3YF5U)	
Caprylhydroxamic Acid (UNII: UPY805K99W)	
Aluminum Oxide (UNII: LMI26O6933)	
Caprylyl Glycol (UNII: 00 YIU5438 U)	
Xanthan Gum (UNII: TTV12P4NEE)	
Edetate Disodium (UNII: 7FLD91C86K)	
Ferrosoferric Oxide (UNII: XM0M87F357)	
Ferric Oxide Red (UNII: 1K09F3G675)	
Ferric Oxide Yellow (UNII: EX438O2MRT)	

Product Characteristics			
Color	BROWN (Tan)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:71398-001-01	1 in 1 CARTON	06/15/2017		
1		52 g in 1 TUBE; Type 0: Not a Combination Product			
2	NDC:71398-001-04	1 in 1 BLISTER PACK	06/15/2017		
2		2 g in 1 PACKET; Type 0: Not a Combination Product			
3	NDC:71398-001-02	1 in 1 CARTON	06/15/2017		
3		11.3 g in 1 TUBE; Type 0: Not a Combination Product			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part352	06/15/2017		

Labeler - SENTÉ, Inc. (079245446)

Revised: 5/2017 SENTÉ, Inc.