# INVISIBLE SHIELD FULL PHYSICAL TINTED SPF 52 BROAD SPECTRUM SUNSCREENtitanium 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.

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# Invisible Shield Full Physical Tinted SPF 52 Broad Spectrum Sunscreen

## **Drug Facts**

Active ingredients	Purpose
Titanium Dioxide 5.75%	Sunscreen
Zinc Oxide 11.15%	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 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), Caprylic/Capric Triglyceride, Shea Butter Ethyl Esters, Caprylyl Methicone, Acetamidoethoxyethanol, Steareth-2, Polyhydroxystearic Acid, Steareth-21, Glycerin, Biosaccharide Gum-4, Fructose, Withania Somnifera Root Extract, Yeast Extract, Hydrolyzed Candida Saitoana Extract, Cichorium Intybus (Chicory) Root Extract, Batyl Alcohol, Stearic Acid, Alumina, Triethoxycaprylylsilane, Xanthan Gum, Phytic Acid, Sodium Hydroxide, Propanediol, Caprylyl Glycol, Caprylhydroxamic Acid, 1,2-Hexanediol, Disodium EDTA, Iron Oxides (CI 77491, CI 77492, CI

# 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

Invisible Shield

Full Physical

Tinted

**Broad Spectrum** 

SPF 52 Sunscreen

PA++++

**SHIELD** 

NET WT. 1.8 OZ/52 g

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## Active ingredients

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#### Inactive ingredients

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#### Drug Facts (continued)

Polyhydroxystearic Acid, Steareth-21, Glycerin, Biosaccharide Gum-4. Fructose, Withania Somnifera Root Extract, Yeast Extract, Hydrolyzed Candida Saitoana Extract, Cichorium Intybus (Chicory) Root Extract, Batyl Alcohol, Stearic Acid, Alumina, Triethoxycaprylylsilane, Xanthan Gum, Phytic Acid, Sodium Hydroxide, Propanediol, Caprylyl Glycol, Caprylhydroxamic Acid, 1,2-Hexanediol, Disodium EDTA, Iron Oxides (CI 77491, CI 77492, CI 77499).

#### Other information

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#### Questions or comments?

(800) 205-6774 www.sentelabs.com

NON-COMEDOGENIC DERMATOLOGIST-TESTED NON-PHOTOTOXIC OIL FREE PARABEN FREE FRAGRANCE FREE

Manufactured for: SENTÉ® Carlsbad, CA 92009 Questions? (800) 205-6774 www.sentelabs.com

U20025-00



# Invisible Shield Full Physical

Tinted

**Broad Spectrum** SPF 52 Sunscreen

PA++++

SHIELD

NET WT. 1.8 OZ/52g

The Skin Cancer Foundation recommends this product as an effective broad spectrum sunscreen.



**DAILY USE** 



# INVISIBLE SHIELD FULL PHYSICAL TINTED SPF 52 BROAD SPECTRUM SUNSCREEN

titanium dioxide and zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71398-012
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	57.5 mg in 1 g	
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	111.5 mg in 1 g	

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Medium-Chain Triglycerides (UNII: C9H2L21V7U)	
Caprylyl Trisiloxane (UNII: Q95M2P1KJL)	
Steareth-2 (UNII: V56DFE46J5)	
POLYHYDRO XYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
Steareth-21 (UNII: 53J3F32P58)	
Glycerin (UNII: PDC6 A3C0 OX)	
Biosaccharide Gum-4 (UNII: 9XRL057X90)	
Fructose (UNII: 6YSS42VSEV)	
Withania Somnifera Root (UNII: V038D626IF)	
Yeast, Unspecified (UNII: 3NY3SM6B8U)	
CICHORIUM INTYBUS (CHICORY) ROOT OLIGOSACCHARIDES (UNII: 38 AFY41EAR)	
Batilol (UNII: 39 YR661C4U)	
Stearic Acid (UNII: 4ELV7Z65AP)	
Aluminum Oxide (UNII: LMI26O6933)	
Triethoxycaprylylsilane (UNII: LDC331P08E)	
Xanthan Gum (UNII: TTV12P4NEE)	
Fytic Acid (UNII: 7IGF0 S7R8 I)	
Propanediol (UNII: 5965N8W85T)	
Caprylyl Glycol (UNII: 00 YIU5438 U)	
Caprylhydroxamic Acid (UNII: UPY805K99W)	
1,2-Hexanediol (UNII: TR046 Y3K1G)	
Edetate Disodium (UNII: 7FLD91C86K)	
Ferrosoferric Oxide (UNII: XM0 M87F357)	
Ferric Oxide Red (UNII: 1K09F3G675)	
Ferric Oxide Yellow (UNII: EX438O2MRT)	

Product Characteristics			
Color	BROWN	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

]	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:71398-012-01	1 in 1 CARTON	05/15/2019			
1		52 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	05/15/2019	

# **Labeler -** SENTÉ, Inc. (079245446)

Revised: 2/2019 SENTÉ, Inc.