

**TROPICAL SANDS SPF-30 BROAD SPECTRUM SUNSCREEN- titanium dioxide,
zinc oxide cream
Elements Brands, Inc.**

Tropical Sands SPF-30 Broad Spectrum Sunscreen

DRUG FACTS

Active Ingredients

Titanium Dioxide (6.0%)

Zinc Oxide (6.0%)

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 or irritation occurs.

Keep out of reach of children.

If product is 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 • 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 of 15 or

higher and other sun protection measures including: •Limit time in the sun, especially from 10 am – 2 pm. •Wear long sleeve shirts, pants, hats and sunglasses. •For children under 6 months: consult a physician. **Sun Protection Measures:**

Inactive Ingredients:

Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Butyrospermum Parkii (Shea) Butter, Camellia Sinensis (Green Tea) Extract, Cocos Nucifera (Coconut) Oil, Dehydroxanthan Gum, Gluconolactone, Glycerin, Glycine Soja (Soybean) Oil, Helianthus Annuus (Sunflower) Oil, Lecithin, Mangifera Indica (Mango) Butter, Sodium Benzoate, Sodium Laurylglucosides Hydroxypropylsulfonate, Styrene/Acrylates Copolymer, Tocopheryl (Vitamin E), Xanthan Gum

Other Information:

Protect this product from excessive heat and direct sun.

Package Labeling:



TROPICAL SANDS

ALL NATURAL

SPF 30

BROAD SPECTRUM SUNSCREEN

UVA/UVB PROTECTION

WATER RESISTANT (80 MINUTES)

CORAL REEF SAFE

BABY & KID SAFE

BIODEGRADABLE

NON-NANO ★ NON-ALLERGENIC
WITH GREEN TEA ★ KID SAFE

8 FL OZ (236 ml)

Apply 15 minutes before sun exposure (a little goes a long way).

DRUG FACTS

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Titanium Dioxide (6.0%)	Sunscreen
Zinc Oxide (6.0%)	Sunscreen

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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 • 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 of 15 or higher and other sun protection measures including:
 • Limiting time in the sun, especially from 10 am – 2 pm.
 • Wearing long-sleeve shirts, pants, hats and sunglasses
 • Children under 6 months: Ask a doctor

Inactive Ingredients: Aloe Barbadosis (Aloe Vera Gel) Juice, Aqua (Deionized Water), Butyrospermum Parkii (Shea) Butter, Camellia Sinensis (Green Tea) Extract, Cocos Nucifera (Coconut) Oil, Dehydroxanthan Gum, Gluconolactone, Glycerin, Glycine Soja (Soybean) Oil, Helianthus Annuus (Sunflower) Oil, Lecithin, Mangifera Indica, (Mango) Butter, Sodium Benzoate, Sodium Laurylglucosides Hydroxypropylsulfonate, Styrene/Acrylates Copolymer, Tocopheryl (Vitamin E), Xanthan Gum.

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TROPICAL SANDS SPF-30 BROAD SPECTRUM SUNSCREEN

titanium dioxide, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71221-796
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	60 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	60 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
COCONUT OIL (UNII: Q9L0O73W7L)	
DEHYDROXANTHAN GUM (UNII: 63ZP7I1BQO)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
GLYCERIN (UNII: PDC6A3C0OX)	
SOYBEAN OIL (UNII: 241ATL177A)	
HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP)	
MANGO (UNII: I629I3NR86)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71221-796-08	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/24/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	02/24/2017	

Labeler - Elements Brands, Inc. (006166707)