

**TROPICAL SANDS SPF-30 BROAD SPECTRUM SUNSCREEN (COCONUT)- titanium dioxide, zinc oxide cream  
Elements Brands, 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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**Tropical Sands SPF-30 Broad Spectrum Sunscreen (Coconut)**

**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 • **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:

- 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.

**Inactive Ingredients:**

Aqua (Deionized Water), Butyrospermum Parkii (Shea) Butter, Camellia Sinensis (Green Tea) Extract, Carthamus Tinctorius (Safflower) Oleosomes, Cetearyl Alcohol, Cetearyl Glucoside, Cetearyl Oliviate, Cocos Nucifera (Coconut) Oil, Eucalyptus Globulus (Eucalyptus) Oil, Gluconolactone, Glycerin, Helianthus Annuus (Sunflower) Seed Oil, Lecithin, Simmondsia Chinensis (Jojoba) Oil, Sorbitan Oliviate, Tocopheryl (Vitamin E), Xanthan Gum, Coconut-Derived Natural Fragrance.

***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

**COCONUT SCENTED**

**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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**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 • 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:** Aqua (Deionized Water), Butyrospermum Parkii (Shea) Butter, Camellia Sinensis Leaf (Green Tea) Extract, Carthamus Tinctorius (Safflower) Oleosomes, Cetearyl Alcohol, Cetearyl Glucoside, Cetearyl Oliviate, Cocos Nucifera (Coconut) Oil, Eucalyptus Globulus (Eucalyptus) Oil, Gluconolactone, Glycerin, Helianthus Annuus (Sunflower) Seed Oil, Helianthus Annuus (Sunflower) Wax, Lecithin, Simmondsia Chinensis (Jojoba) Oil, Sorbitan Oliviate, Tocopherol (Vitamin-E), Xanthum Gum, Coconut-Derived Natural Fragrance.

**Other Information:** Protect this product from excessive heat and direct sun.

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**TROPICAL SANDS SPF-30 BROAD SPECTRUM SUNSCREEN (COCONUT)**

titanium dioxide, zinc oxide cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71221-793
<b>Route of Administration</b>	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
WATER (UNII: 059QF0KO0R)	
SHEA BUTTER (UNII: K49155WL9Y)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CARTHAMUS TINCTORIUS SEED OLEOSOMES (UNII: 9S60Q72309)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
COCONUT OIL (UNII: Q9L0O73W7L)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
GLYCERIN (UNII: PDC6A3C0OX)	
HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
XANTHAN GUM (UNII: TTV12P4NEE)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71221-793-08	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/22/2017	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	02/22/2017	

**Labeler** - Elements Brands, Inc. (006166707)

Revised: 2/2017

Elements Brands, Inc.