

OUTER REEF MINERAL SUNSCREEN SPF 30- titanium dioxide cream
Coral Reef Park Co., 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.

OUTER REEF MINERAL SUNSCREEN SPF 30

Drug Facts

Active Ingredient

Titanium Dioxide 8.00%

Purpose

Sunscreen

Uses:

• Helps prevent sunburn • Higher SPF gives more sunburn protection • Retains SPF after 80 minutes of swimming or sweating • 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 not intended for ingestion.

Do Not Use:

• on damaged or broken skin.

When using this product

keep out of eyes. Rinse with water to remove. • stop use and consult physician if irritation or rash develops.

Keep out of reach of children.

If product is swallowed, get medical attention or contact poison control center immediately.

Directions:

- Apply liberally 15-minutes before sun exposure.
- Children under 6-months of age: ask a doctor.
- 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 the risk, regularly use a sunscreen with broad spectrum SPF of 15 or higher and other sun protection measures
 - Limit time in the sun, especially between 10am and 2pm.
 - Wear long sleeve shirts, pants, hats and sunglasses.

Other Information:

- Protect this product from excessive heat and direct sunlight.

Inactive Ingredients:

*Aloe Barbadensis Leaf (Aloe Vera gel) Juice, Aqua (Deionized Water), Butyloctyl Salicylate, *Camellia Sinensis (Green Tea) Extract, Caprylic/Capric Triglyceride, Cetearyl Alcohol, Cetearyl Oliviate, Cetyl Palmitate, Citrullus Lanatus (Watermelon) Extract, *Cocos Nucifera (coconut) Oil, Daucus Carota Sativa (Carrot) Extract, Dodecane, *Glycerin, Glyceryl Caprylate, Glyceryl Stearate, Glyceryl Undecylenate, *Helianthus Annuus (Sunflower) Oil, Hydrogenated Castor Oil, Hydroxymethylcellulose, Magnesium Aluminum Silicate, Polyhydroxystearic Acid, Silica, Sorbitan Oliviate, Stearic Acid, Tocopherol (Vitamin E), Tridecyl Salicylate. *Denotes certified organic ingredient.

Package Labeling:

Non Printing Area



REEF SAFE

Non-Nano
Biodegradable
Antioxidants
Water-resistant (80 Min)



**UVA | UVB
BROAD SPECTRUM SPF 30**

3.4 FL OZ (100 mL)



Please help us protect our Beautiful but Fragile Coral Reefs by using only Mineral-based Sunscreens.

Randy Pegrum
FOUNDER

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Comments & Suggestions:
outerreef30@gmail.com

Visit us:
outerreef.us

Distributed by: Coral Reef Park Co. Key Largo, FL 33037
MADE IN THE USA



Non Printing Area

OUTER REEF MINERAL SUNSCREEN SPF 30

titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73691-047
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	80 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
WATERMELON (UNII: 231473QB6R)	
COCONUT OIL (UNII: Q9L0O73W7L)	
CARROT (UNII: L56Z1JK48B)	
DODECANE (UNII: 11A386X1QH)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
GLYCERYL 1-UNDECYLENATE (UNII: B68LJT9544)	
HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
HYDROXYMETHYL CELLULOSE (UNII: 273FM27VK1)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TOCOPHEROL (UNII: R0ZB2556P8)	
TRIDECYL SALICYLATE (UNII: AZQ08K38Z1)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73691-047-00	100 mL in 1 TUBE; Type 0: Not a Combination Product	03/10/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph not final	part352	03/10/2020	

Labeler - Coral Reef Park Co., Inc. (786852207)