# PROJECT REEF SPF-50- zinc oxide, titanium dioxide cream Project Reef LLC

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**PROJECT REEF SPF-50** 

### **Drug Facts**

### **Active Ingredients**

Zinc Oxide 14.00 %

Titanium Dioxide 6.00 %

### **Purpose**

Sunscreen

#### **Uses:**

• Helps prevent sunburn. • higher SPF gives more sunburn protection • If used as directed with other sun protection measures (see ), decreases the risk of skin cancer and early skin aging caused by the sun

#### **Directions**

### Warnings:

not intended for ingestion. 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 develops and lasts.

### 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 • Children under 6 months of age: ask a doctor. • Reapply at least every 2 hours • Reapply as needed or after towel drying, swimming, or sweating. • Use a water-resistant sunscreen if swimming or sweating •

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 including: • Limit time in the sun, especially from 10 a.m. - 2 p.m. • Wear long-sleeved shirts, pants, hats, and sunglasses.

#### Sun Protection Measures.

#### Other Information:

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

#### **Inactive Ingredients:**

Algae Extract, \*Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Benzyl Alcohol, \*Butyrospermum Parkii (Shea) Butter, \*Camellia Sinensis (Green Tea) Extract, Caprylic/Capric Triglyceride, Citric Acid, Citrus Aurantium Dulcis (Orange) Oil, \*Cocos Nucifera (Coconut) Oil, Decyl Glucoside, Dehydroacetic Acid, Ethyl Vanillin, Fucus Vesiculosus (Seaweed) Extract, \*Glycerin, Glyceryl Stearate, Helianthus Annuus, \*Hippophae Rhamnoides (Sea Buckthorn) Oil, Hydroxyethylcellulose, Lavandula Angustifolia (Lavender) Oil, Polyhydroxystearic Acid, \*Punica Granatum (Pomegranate) Extract, Rubus Idaeus (Raspberry) Extract, Stearic Acid, Tridecyl Salicylate, Xanthan Gum, Zemea (Corn) Propanediol.

#### Questions?

Call 800 914 0146

### Package Labeling:



#### Other Information:

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### **PROJECT REEF SPF-50**

zinc oxide, titanium dioxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81637-179
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	140 mg in 1 mL	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	60 mg in 1 mL	

Inactive Ingredients	
Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SHEA BUTTER (UNII: K49155WL9Y)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
ORANGE OIL (UNII: AKN3KSD11B)	
COCONUT OIL (UNII: Q9L0O73W7L)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	
ETHYL VANILLIN (UNII: YC9ST449YJ)	
FUCUS VESICULOSUS (UNII: 535G2ABX9M)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)	
HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP)	
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
PUNICA GRANATUM ROOT BARK (UNII: CLV24I3T1D)	
RASPBERRY (UNII: 4N14V5R27W)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TRIDECYL SALICYLATE (UNII: AZQ08K38Z1)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CORN (UNII: 0N86727070)	
PROPANEDIOL (UNII: 5965N8W85T)	

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:81637-179- 00	125 mL in 1 TUBE; Type 0: Not a Combination Product	04/05/2021	

Marketing In	Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M020	04/05/2021		

## Labeler - Project Reef LLC (096500461)

Revised: 11/2023 Project Reef LLC