# GREEN SCREEN SPF 31 PEACH SUNSCREEN- zinc oxide cream Kabana Skin Care LLC

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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# **Active Ingredients**

Zinc Oxide\*\* USP 25%

# **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 if used as directed with other sun protection measures

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 product is swallowed, get medical help or contact a Poison Control Center right away

- apply liberally 15 minutes before sun exposure
- use a water resistant sunscreen if swimming or sweating
- reapply:
- after 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 A.M. 2 P.M.
- wear long-sleeve shirts, pants, hats, and sunglasses
- children under 6 months: Ask a Doctor

# Inactive Ingredients

Eldorado Springs Artesian Water (aqua), extra virgin olive oil\* (Oleo europaea fruit oil), jojoba oil\* (Simmondsia chinensis oil), vegetable glycerin# (glycerin), shea butter\* (Butyrospermum parkii seed oil), vegetable emulsifying wax NF # (cetearyl alcohol and polysorbate 60), vegetable vitamin e # (tocopherol), iron oxide (iron oxides)

\*Certified Organic by USDA/NOP \*\*non-nano, uncoated, French Process zinc oxide #Non-GMO

#### Other Information

• protect this product from excessive heat and direct sun

# Questions or comments?

Call Kabana Skin Care toll free at 1-888-517-0414 or visit www.kabanaskincare.com

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# zinc oxide cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73369-0003	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	Strength		
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	25 g in 100 g		

Inactive Ingredients				
Ingredient Name	Strength			
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	1.38 g in 100 g			
JOJOBA OIL (UNII: 724GKU717M)	3.75 g in 100 g			
WATER (UNII: 059QF0KO0R)	35 g in 100 g			
FERRIC OXIDE RED (UNII: 1K09F3G675)	0.15 g in 100 g			
POLYSORBATE 60 (UNII: CAL22UVI4M)	1.125 g in 100 g			
FERRIC OXIDE YELLOW (UNII: EX43802MRT)	0.85 g in 100 g			
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	1.125 g in 100 g			
SHEA BUTTER (UNII: K49155WL9Y)	1.93 g in 100 g			
OLIVE OIL (UNII: 6UYK2W1W1E)	25.95 g in 100 g			
GLYCERIN (UNII: PDC6A3C0OX)	3.75 g in 100 g			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73369- 0003-1	115 g in 1 TUBE; Type 0: Not a Combination Product	01/11/2013	
2	NDC:73369- 0003-2	30 g in 1 TUBE; Type 0: Not a Combination Product	01/11/2013	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part352	01/11/2013		

# Labeler - Kabana Skin Care LLC (080237112)

# Registrant - Kabana Skin Care LLC (080237112)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>

Kabana Skin Care LLC	080237112	manufacture(73369-0003)
Rabana Skin Care EEC	000237112	manaractar c(75505 0005)

Revised: 10/2023 Kabana Skin Care LLC