

GREEN SCREEN SPF 31 BRONZE 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.

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

Directions

- 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:73369-0005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	25 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
POLYSORBATE 60 (UNII: CAL22UVI4M)	1.125 g in 100 g
OLIVE OIL (UNII: 6UYK2W1W1E)	24.65 g in 100 g
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	1.9 g in 100 g
GLYCERIN (UNII: PDC6A3C0OX)	3.75 g in 100 g
SHEA BUTTER (UNII: K49155WL9Y)	1.93 g in 100 g
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	1.125 g in 100 g
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	1.38 g in 100 g
JOJOBA OIL (UNII: 724GKU717M)	3.75 g in 100 g
FERRIC OXIDE RED (UNII: 1K09F3G675)	0.24 g in 100 g
FERROSFERRIC OXIDE (UNII: XM0M87F357)	0.16 g in 100 g
WATER (UNII: 059QF0KOOR)	35 g in 100 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73369-0005-1	115 g in 1 TUBE; Type 0: Not a Combination Product	01/11/2013	
2	NDC:73369-0005-2	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	Business Operations
Kabana Skin Care LLC		080237112	manufacture(73369-0005)

Revised: 10/2023

Kabana Skin Care LLC