

**GREEN SCREEN SPF 31 NUDE 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

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**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-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](http://www.kabanaskincare.com)

### ***Drug Facts***

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**GREEN SCREEN SPF 31 NUDE SUNSCREEN**

zinc oxide cream

## Product Information

|                                |                |                           |                |
|--------------------------------|----------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:73369-0004 |
| <b>Route of Administration</b> | TOPICAL        |                           |                |

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

| <b>Ingredient Name</b>                  | <b>Strength</b>  |
|---|------------------|
| JOJOBA OIL (UNII: 724GKU717M)           | 3.75 g in 100 g  |
| FERROSO FERRIC OXIDE (UNII: XM0M87F357) | 0.08 g in 100 g  |
| ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)     | 1.38 g in 100 g  |
| POLYSORBATE 60 (UNII: CAL22UVI4M)       | 1.125 g in 100 g |
| WATER (UNII: 059QF0K00R)                | 35 g in 100 g    |
| SHEA BUTTER (UNII: K49155WL9Y)          | 1.93 g in 100 g  |
| FERRIC OXIDE RED (UNII: 1K09F3G675)     | 0.15 g in 100 g  |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)  | 1.125 g in 100 g |
| OLIVE OIL (UNII: 6UYK2W1W1E)            | 24.65 g in 100 g |
| FERRIC OXIDE YELLOW (UNII: EX438O2MRT)  | 0.27 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:73369-0004-1 | 115 g in 1 TUBE; Type 0: Not a Combination Product | 01/11/2013           |                    |
| 2 | NDC:73369-0004-2 | 30 g in 1 TUBE; Type 0: Not a Combination Product  | 01/11/2013           |                    |

## Marketing Information

| <b>Marketing Category</b> | <b>Application Number or Monograph Citation</b> | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|---------------------------|---|-----------------------------|---------------------------|
| OTC monograph final       | part352   | 01/11/2013                  |                           |

**Labeler** - Kabana Skin Care LLC (080237112)

**Registrant** - Kabana Skin Care LLC (080237112)

**Establishment**

| <b>Name</b>          | <b>Address</b> | <b>ID/FEI</b> | <b>Business Operations</b> |
|----------------------|----------------|---------------|----------------------------|
| Kabana Skin Care LLC |                | 080237112     | manufacture(73369-0004)    |

Revised: 10/2023

Kabana Skin Care LLC