

BALI BLOC SPF 30 COCOA 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%

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 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 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

Virgin coconut oil* (Cocos nucifera seed oil), beeswax* (cera alba), cocoa powder*

(Theobroma cacao seed powder)

* certified organic by USDA/NOP **non-nano, uncoated, French Process zinc oxide

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:73369-0008
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
COCOA (UNII: D9108TZ9KG)	15 g in 100 g
YELLOW WAX (UNII: 2ZA36H0S2V)	15 g in 100 g
COCONUT OIL (UNII: Q9L0O73W7L)	45 g in 100 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73369-0008-1	110 g in 1 TUBE; Type 0: Not a Combination Product	10/08/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	10/08/2014	

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(73369-0008)

Revised: 10/2023

Kabana Skin Care LLC