

**ZINKA LIP PROTECTOR SPF 30 LIP BALM- octinoxate, octisalate, octocrylene, oxybenzone stick**  
**Zinka**

*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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**Drug Facts**

**Active ingredient**

Octinoxate (7.5%), Oxybenzone (5.0%), Octisalate (5.0%), Octocrylene (10.0%)

**Purpose**

Sunscreen

**Keep Out of Reach of Children**

If swallowed get medical help or contact a Poison Control Center right away.

**Uses**

Helps prevent sunburn. Helps prevent and temporarily protects dry, chapped or windburned lips.

**Warnings**

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, not skin cancer or early aging.

For external use only: Stop use and ask a doctor: if rash or irritation develops and lasts.

**Directions**

Apply liberally before sun exposure and as needed. Children under 6 months of age: Ask a doctor before use.

**Inactive Ingredients**

Ozokerite, Mineral Oil, Petrolatum, Microcrystalline Wax, Ceresin, Flavor, Caprylic/Capric Triglyceride, Copernicia Cerifera (Carnauba) Wax, Titanium Dioxide (CI 77891), Tocopheryl Acetate, Stearic Acid, Aloe Barbadenis Leaf Extract, Aluminum Hydroxide.

**Package/Label Principal Display Panel**



## ZINKA LIP PROTECTOR SPF 30 LIP BALM

octinoxate, octisalate, octocrylene, oxybenzone stick

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52993-125
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 mg in 1 g
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	5.0 mg in 1 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	10 mg in 1 g
LIGHT MINERAL OIL (UNII: N6K5787QVP)	23.75 mg in 1 g
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	4.00 mg in 1 g

CERESIN (UNII: Q1LS2UJO3A)		27 mg in 1 g		
<b>Product Characteristics</b>				
Color	WHITE	Score		
Shape		Size		
Flavor	COCONUT	Imprint Code		
Contains				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52993-125-02	1 g in 1 CONTAINER		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC mono graph not final	part352	05/09/2014		

**Labeler** - Zinka (153569595)

**Registrant** - Zinka (153569595)

### Establishment

Name	Address	ID/FEI	Business Operations
OraLabs		801824756	MANUFACTURE(52993-125) , LABEL(52993-125)

Revised: 8/2014

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