

**ESIKA MAXIMUM COLOR LIPSTICK SPF 18- octinoxate and oxybenzone lipstick
Ventura Corporation LTD.**

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.

ēsika Maximum Color Lipstick SPF 18

Drug Facts

Active Ingredients

Octinoxate 7.3 %, Oxybenzone 1.65%

Purpose

Sunscreen

Uses

- Helps prevent sunburn.

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 help prevent sunburn, not skin cancer or early skin aging.
- For external use only.
- Do not use on damage 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 swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally and evenly 15 minutes before sun exposure.
- Children under 6 months of age: Ask a doctor.
- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating.

Other information

- Protect the product in this container from excessive heat and direct sun.

Inactive Ingredients

diisopropyl dimer dilinoleate, ethylhexyl palmitate, ozokerite, copernicia cerifera (carnauba) wax, polyethylene, butyrospermum parkii (shea) butter, silica, octyldodecanol, water, phenoxyethanol,

microcrystalline wax, petrolatum, phospholipids, methylparaben, fragrance, bht, cholesterol, butylparaben, ethylparaben, euphorbia cerifera (candelilla) wax, beeswax, cetearyl alcohol, cetearyl glucoside, polyglyceryl-2 dipolyhydroxystearate, isobutylparaben, propylparaben, glycosphingolipids, maltodextrin, zea mays (corn) starch, sodium hyaluronate. **May contain:** red 7 lake, red 27 lake, iron oxides, mica, yellow 5 lake, titanium dioxide, red 6 lake, isononyl isononanoate, talc, isopropyl myristate, blue 1 lake, carmine, isopropyl titanium triisostearate, triethoxycaprylylsilane, stealkonium hectorite, C9-15 fluoroalcohol phosphate, polyhydroxystearic acid, propylene carbonate.

Dist. by Ventura Corporation, Ltd.
San Juan, Puerto Rico 00926.

PRINCIPAL DISPLAY PANEL - 4 g Tube Carton

ēsika

Maximum Color
Lipstick SPF 18

4 g e (.14 oz.)



ESIKA MAXIMUM COLOR LIPSTICK SPF 18

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-442
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.073 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.0165 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
diisopropyl dilinoleate (UNII: 5323S7S2LR)	
ethylhexyl palmitate (UNII: 2865993309)	
carnauba wax (UNII: R12CBM0EIZ)	
high density polyethylene (UNII: UG00KM4WR7)	
shea butter (UNII: K49155WL9Y)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
octyldodecanol (UNII: 461N1O614Y)	
water (UNII: 059QF0K00R)	
phenoxyethanol (UNII: HIE492ZZ3T)	
microcrystalline wax (UNII: XOF597Q3KY)	
petrolatum (UNII: 4T6HI2BN9U)	
methylparaben (UNII: A218C7HI9T)	
butylated hydroxytoluene (UNII: 1P9D0Z171K)	
cholesterol (UNII: 97C5T2UQ7J)	
butylparaben (UNII: 3QP1U3FV8)	
ethylparaben (UNII: 14255EXE39)	
candelilla wax (UNII: WL0328HX19)	
yellow wax (UNII: 2ZA36H0S2V)	
cetostearyl alcohol (UNII: 2DMT128M1S)	
cetearyl glucoside (UNII: 09FUA47KNA)	
polyglyceryl-2 dipolyhydroxystearate (UNII: 9229XJ4V12)	
isobutylparaben (UNII: 0QQJ25X58G)	
propylparaben (UNII: Z8IX2SC1OH)	
maltodextrin (UNII: 7CVR7L4A2D)	
starch, corn (UNII: O8232NY3SJ)	
hyaluronate sodium (UNII: YSE9PPT4TH)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
mica (UNII: V8A1AW0880)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
titanium dioxide (UNII: 15FIX9V2JP)	
D&C RED NO. 6 (UNII: 481744A140)	
isononyl isononanoate (UNII: S4V5BS6GCX)	
talc (UNII: 7SEV7J4RIU)	
isopropyl myristate (UNII: 0RE8K4LNJS)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

isopropyl titanium triisostearate (UNII: 949E3KBJ1D)	
triethoxycaprylylsilane (UNII: LDC331P08E)	
propylene carbonate (UNII: 8D08K3S51E)	
aluminum oxide (UNII: LMI26O6933)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-442-02	1 in 1 BOX		
1	NDC:13537-442-01	4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	12/06/2012	

Labeler - Ventura Corporation LTD. (602751344)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(13537-442)

Establishment

Name	Address	ID/FEI	Business Operations
Yobel Supply Chain Management S.A. (Peru)		934116930	MANUFACTURE(13537-442)

Revised: 12/2012

Ventura Corporation LTD.