

**ESIKA EXTREME MOISTURIZING SPF 16- octinoxate and oxybenzone lipstick
Ventura Corporation (San Juan, P.R)**

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.

**ē sika
Extreme
Moisturizing Lipstick
SPF 16**

Active Ingredients

Octinoxate 6.64%, Oxybenzone 1.51%

Use

Helps prevent sunburn.

Warnings

For external use only.

Stop use if skin rash occurs.

Keep out of reach of children.

Directions

Apply evenly before sun exposure and as needed. Apply lipstick following the curves of natural lip line.

Inactive Ingredients

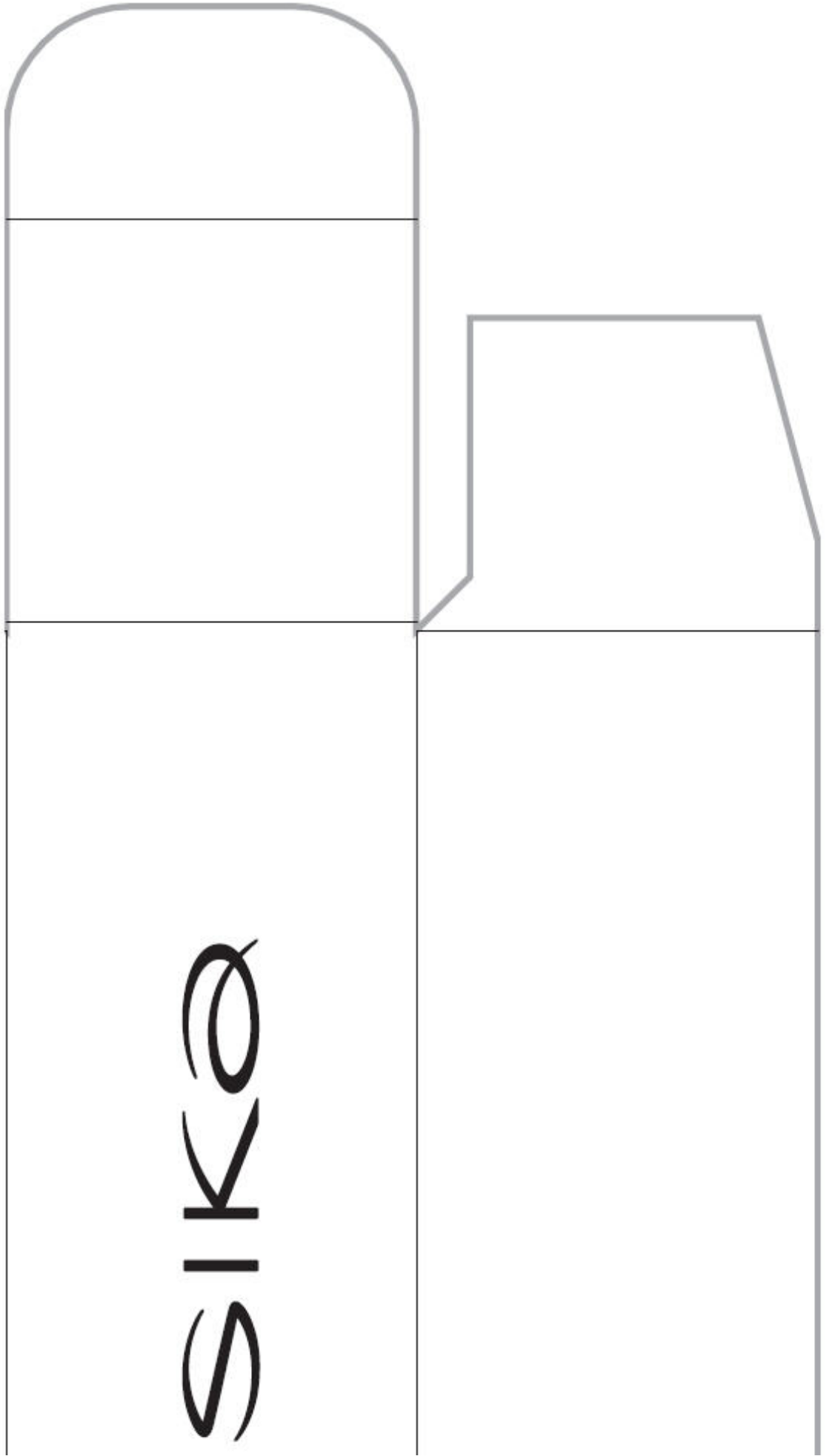
Dipentaerythrityl hexacaprylate/hexacaprate, tridecyl trimellitate, ethylhexyl palmitate, ozokerite, polyethylene, polymethyl methacrylate, aqua (water), polyglyceryl-3 diisostearate, tridecyl stearate, glycerin, neopentyl glycol dicaprylate/dicaprate, copernicia cerifera cera (copernicia cerifera (carnauba) wax), kaolin, octyldodecanol , phenoxyethanol, sodium starch octenylsuccinate, tocopheryl acetate, microcristallina cera (microcrystalline wax), parfum (fragrance), methylparaben, petrolatum, phospholipids, propylparaben, cholesterol, glycine soja oil (glycine soja (soybean) oil), butyrospermum parkii butter (butyrospermum parkii (shea) butter), butylparaben, ethylparaben, bht, candelilla cera (euphorbia cerifera (candelilla) wax), cera alba (beeswax), cetearyl alcohol, cetearyl glucoside, polyglyceryl-2 dipolyhydroxystearate, isobutylparaben, tocopherol, glycosphingolipids, magnesium chloride, potassium chloride, sodium chloride, silica, ci 19140 (yellow 5 lake), ci 15850 (red 7 lake), ci 77891 (titanium dioxide), ci 77019 (mica), ci 45410 (red 27 lake), ci 77491 (iron oxides), ci 77492 (iron oxides), ci 77499 (iron oxides), ci 75470 (carmine), ci 45380 (red 21 lake), ci 42090 (blue 1 lake), ci 77163 (bismuth oxychloride), chitosan, talc.

PRINCIPAL DISPLAY PANEL - 4 g Carton

**ē sika
Extreme
Moisturizing Lipstick**

SPF 16

4 g e (.14 oz.)



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Extreme
Moisturizing Lipstick
SPF 16

4 g e (.14 oz.)

... of natural lip line.
... hexyl palmitate,
... tridecyl stearate,
... (carnauba) wax),
... crocristallina cera
... aben, cholesterol,
... (shea) butter), ▶

... alba (beeswax),
... en, tocopherol,
... ntain: CI 19140
... (red 27 lake), CI
...) (red 21 lake), CI

... ia.

Active Ingredients: Octinoxate 6.64%, Oxybenzone 1.51%.

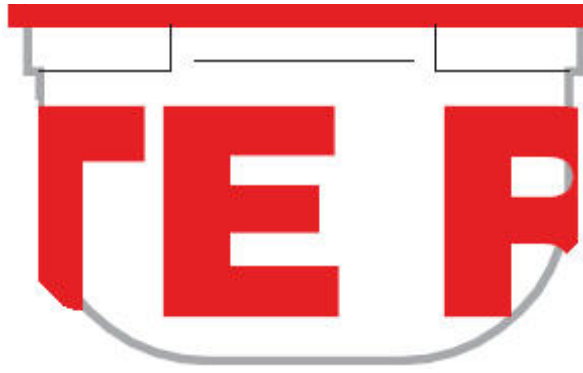
Uses: Helps prevent sunburn.

Warnings: For external use only. Stop use if skin rash occurs. **Keep out of reach of children.**

Directions: Apply evenly before sun exposure and as needed. Apply lipstick following the curves
Inactive Ingredients: Dipentaerythryl hexacaprylate/hexacaprate, tridecyl trimellitate, ethyl
ozokerite, polyethylene, polymethyl methacrylate, aqua (water), polyglyceryl-3 diisostearate,
glycerin, neopentyl glycol dicaprylate/dicaprate, copernicia cerifera cera (copernicia cerifera
kaolin, octyldodecanol, phenoxyethanol, sodium starch octenylsuccinate, tocopheryl acetate, microcrystalline wax), parfum (fragrance), methylparaben, petrolatum, phospholipids, propylparaben, butyrospermum parkii butter (butyrospermum parkii oil), butyrospermum parkii butter (butyrospermum parkii oil)

butylparaben, ethylparaben, bht, candelilla cera (euphorbia cerifera (candelilla) wax), cera
cetearyl alcohol, cetearyl glucoside, polyglyceryl-2 dipolyhydroxystearate, isobutylparat
glycosphingolipids, magnesium chloride, potassium chloride, sodium chloride, silica. **May contain**
(yellow 5 lake), CI 15850 (red 7 lake), CI 77891 (titanium dioxide), CI 77019 (mica), CI 45410
77491 (iron oxides), CI 77492 (iron oxides), CI 77499 (iron oxides), CI 75470 (carmine), CI 4538C
42090 (blue 1 lake), CI 77163 (bismuth oxychloride), chitosan, talc.

PUERTO RICO: Distributed by Ventura Corporation, Ltd. San Juan, Puerto Rico 00926. Made in Colombia



ESIKA EXTREME MOISTURIZING SPF 16

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-303
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0664 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0151 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	
WATER (UNII: 059QF0K00R)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
GLYCERIN (UNII: PDC6A3C0OX)	
NEOPENTYL GLYCOL DICAPRATE (UNII: 77T908SE82)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
KAOLIN (UNII: 24H4NWX5CO)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PETROLATUM (UNII: 4T6H12BN9U)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
SOYBEAN OIL (UNII: 241ATL177A)	
SHEA BUTTER (UNII: K49155WL9Y)	
BUTYL PARABEN (UNII: 3QP1IU3FV8)	
ETHYL PARABEN (UNII: 14255EXE39)	

BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
CANDELILLA WAX (UNII: WL0328HX19)
YELLOW WAX (UNII: 2ZA36H0S2V)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)
ISOBUTYL PARABEN (UNII: 0QQJ25X58G)
TOCOPHEROL (UNII: R0ZB2556P8)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98110)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
MICA (UNII: V8A1AW0880)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
COCHINEAL (UNII: TZ8Z31B35M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)
TALC (UNII: 7SEV7J4R1U)
ALUMINUM OXIDE (UNII: LM26O6933)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-303-02	1 in 1 BOX		
1	NDC:13537-303-01	4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	05/17/2011	

Labeler - Ventura Corporation (San Juan, P.R) (602751344)

Establishment

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