

**ULTRA BALM MOISTURIZING PROTECTIVE BALM FOR LIPS SPF 20 NUDE  
CAMEL- octinoxate, zinc oxide stick  
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.*

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**Ultra Balm Moisturizing Protective Balm for lips SPF 20 Nude Caramel**

Active Ingredients Purpose

Octinoxate 7.50% Sunscreen

Zinc Oxide 4.90% Sunscreen

**Uses**

- Helps prevent sunburn.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

**Stop use and ask a doctor if** rash occurs.

**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 damaged or broken skin.

**When using this product** keep out of eyes. Rinse with water to remove.

**Directions**

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

**Inactive ingredients:** octyldodecanol, ethylhexyl palmitate, polyethylene, ozokerite, silica, jojoba esters, copernicia cerifera (carnauba) wax, cetyl peg/ppg-10/1 dimethicone, polyglyceryl-4 isostearate, helianthus annuus (sunflower) seed wax, hexyl laurate, tocopheryl acetate, dipentaerythrityl hexacaprylate/hexacaprate, tridecyl trimellitate, schinus terebinthifolia seed extract, phenoxyethanol, tridecyl stearate, dimethicone, acacia decurrens flower wax, polyglycerin-3, triethoxycaprylylsilane, neopentyl glycol dicaprylate/dicaprate, caprylyl glycol, chlorphenesin, trimethylsiloxysilicate, ceramide np, lecithin.

**may contain:**

mica, titanium dioxide, synthetic fluorphlogopite, iron oxides, yellow 5 lake, red 7 lake, red 6 lake, talc.

**Other information**

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

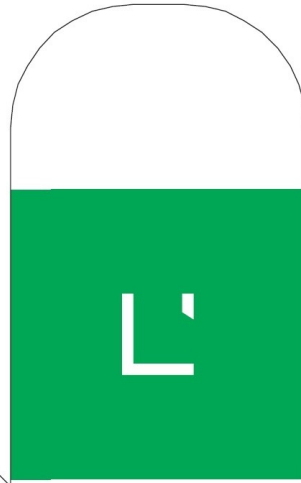
# Ultra Balm SPF 20 Nude Caramel

L'BEL

ULTRA BALM

Moisturizing protective balm for lips SPF 20 Nude Caramel

Net. Wt. 0.14 oz (4 g)



L'BEL

ULTRA  
BALM

Moisturizing  
protective  
balm for lips  
SPF 20

Net Wt. 0.14 oz e (4g)

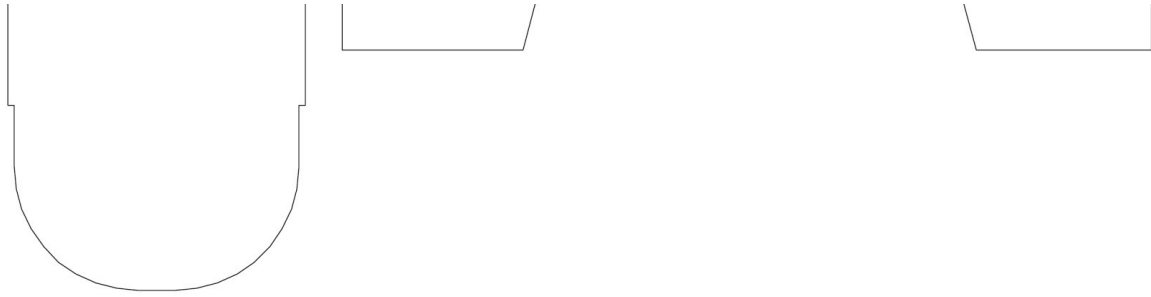
<b>Drug Facts (continued)</b> ■ <b>Stop use and ask a doctor if rash occurs.</b> ■ <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	<b>Drug Facts (continued)</b> sunscreen if swimming or sweating. ■ Children under 6 months of age: Ask a doctor. <b>Other information</b> ■ Protect the product in this container from excessive heat and direct sun <b>Inactive ingredients:</b> octyldodecanol, ethylhexyl palmitate, polyethylene, ozokerite, silica, jojoba
<b>Directions</b> ■ Apply liberally and evenly 15 minutes before sun exposure. ■ Reapply at least every 2 hours. ■ Use a water resistant	

<b>Drug Facts (continued)</b> esters, copernicia cerifera (carnauba) wax, cetyl peg/ppg-10/1 dimethicone, polyglyceryl-4 isostearate, helianthus annuus (sunflower) seed wax, hexyl laurate, tocopheryl acetate, dipentaerythryl hexacaprylate/hexacaprate, tridecyl trimellitate, schinus terebinthifolia seed extract, phenoxyethanol, tridecyl stearate,	<b>Drug Facts (continued)</b> dimethicone, acacia decurrens flower wax, polyglycerin-3, triethoxycaprylsilane, neopentyl glycol dicaprylate/dicaprate, caprylyl glycol, chlorphenesin, trimethylsiloxysilicate, ceramide np, lecithin. <b>May contain:</b> mica, titanium dioxide, synthetic fluorophlogopite, iron oxides, yellow 5 lake, red 7 lake, red 6 lake, talc.
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<b>Drug Facts</b> <b>Active Ingredients</b> Octinoxate 7.50% ..... Sunscreen Zinc Oxide 4.90% ..... Sunscreen	<b>Drug Facts (continued)</b> <b>Alert:</b> 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, <b>not</b> skin cancer or early skin aging. ■ <b>For external use only.</b> ■ <b>Do not use</b> on damaged or broken skin. ■ <b>When using this product</b> keep out of eyes. Rinse with water to remove.
<b>Uses</b> ■ Helps prevent sunburn.	
<b>Warnings</b> ■ Skin Cancer / Skin Aging	

PUERTO RICO: Dist. by Ventura Corp, Ltd., San Juan, Puerto Rico 00926. Made in Colombia. U.S.A.: Dist. by Ventura Int Ltd. DBA Belcorp USA, Miami, FL 33126 Made in Colombia. www.lbel.com

STONE: NUDE CARAMEL



# ULTRA BALM MOISTURIZING PROTECTIVE BALM FOR LIPS SPF 20 NUDE CARAMEL

octinoxate, zinc oxide stick

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:43596-0890
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	4.9 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
<b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8)</b> (UNII: 5041RX63GN)	
<b>POLYGLYCERYL-4 ISOSTEARATE</b> (UNII: 820DPX33S7)	
<b>TRIDECYL STEARATE</b> (UNII: A8OE252M6L)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>MICA</b> (UNII: V8A1AW0880)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>CETYL PEG/PPG-10/1 DIMETHICONE (HLB 1.5)</b> (UNII: V2W71V8T0X)	
<b>HELIANTHUS ANNUUS SEED WAX</b> (UNII: 42DG15CHXV)	
<b>HEXYL LAURATE</b> (UNII: 4CG9F9W01Q)	
<b>BRAZILIAN PEPPER</b> (UNII: SUG822G7CD)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>ACACIA DECURRENS FLOWER WAX</b> (UNII: AU6XZE9IY9)	
<b>MAGNESIUM POTASSIUM ALUMINOSILICATE FLUORIDE</b> (UNII: YK3DC63Y5M)	
<b>DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE</b> (UNII: 554N82UWWV)	
<b>TRIDECYL TRIMELLITATE</b> (UNII: FY36J270ES)	
<b>POLYGLYCERIN-3</b> (UNII: 4A0NCJ6RD6)	

<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE</b> (UNII: VLW429K27K)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>CERAMIDE NP</b> (UNII: 4370DF050B)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)	
<b>OCTYLDODECANOL</b> (UNII: 461N1O614Y)	
<b>HIGH DENSITY POLYETHYLENE</b> (UNII: UG00KM4WR7)	
<b>CERESIN</b> (UNII: Q1LS2UJO3A)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0890-1	4 g in 1 CARTON; Type 0: Not a Combination Product	06/16/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	06/16/2021	

**Labeler** - Ventura Corporation LTD (602751344)

**Registrant** - BEL STAR S A (880160197)

### Establishment

Name	Address	ID/FEI	Business Operations
BEL STAR S A		880160197	manufacture(43596-0890)

Revised: 6/2021

Ventura Corporation LTD