

**LBEL CONCENTRE TOTAL LABIOS GLOBAL PERFECTION SPF 20 MALVA NUDE/RED-
octinoxate and zinc oxide 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.

**L'BEL CONCENTRÉ TOTAL LABIOS LIPSTICK GLOBAL PERFECTION SPF 20 MALVA
NUDE/Red**

Drug Facts

<i>Active Ingredients</i>	<i>Purpose</i>
OCTINOXATE 7.5 %	Sunscreen
ZINC OXIDE 3.92 %	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 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 swallowed, get medical help or contact a Poison Control Center right away.

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

Other information

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

Inactive ingredients

DIISOPROPYL DIMER DILINOLEATE, ISONONYL ISONONANOATE, OZOKERITE, DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE, POLYGLYCERYL-3 DIISOSTEARATE, TRIDECYL TRIMELLITATE, POLYMETHYLSILSESQUIOXANE, POLYETHYLENE, COPERNICIA CERIFERA (CARNAUBA) WAX, HYDROGENATED

POLYCYCLOPENTADIENE, PTFE, BUTYROSPERMUM PARKII (SHEA) BUTTER, TRIDECYL STEARATE, ISODODECANE, SILICA DIMETHYL SILYLATE, TOCOPHERYL ACETATE, MICA, NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE, CAPRYLIC/CAPRIC TRIGLYCERIDE, PHENOXYETHANOL, CETEARYL ETHYLHEXANOATE, METHYLPROPANEDIOL, COCOS NUCIFERA (COCONUT) OIL, ALOE BARBADENSIS LEAF EXTRACT, FRAGRANCE, CERAMIDE 3, CAPRYLYL GLYCOL, SILANEDIOL SALICYLATE, CHLORPHENESIN, TRIETHOXYCAPRYLYLSILANE, TROMETHAMINE, SORBITAN ISOSTEARATE, DIMETHICONE, LIMONIUM GERBERI EXTRACT, GRIFOLA FRONDOSA FRUITING BODY EXTRACT, MALTODEXTRIN, PORTULACA PILOSA EXTRACT, TRIMETHYLSILOXYSILICATE, SUCROSE COCOATE, PALMITOYL TRIPEPTIDE-38, BENZYL BENZOATE, AMYL CINNAMAL, HEXYL CINNAMAL, LINALOOL. **MAY CONTAIN :** TITANIUM DIOXIDE, IRON OXIDES, RED 27 LAKE, RED 21 LAKE, RED 7 LAKE, YELLOW 5 LAKE, RED 30 LAKE, TALC, BLUE 1 LAKE.

Dist. by Ventura Int Ltd.
DBA Belcorp USA, Miami, FL
33126

L'BEL

CONCENTRÉ
TOTAL
LABIOS

lipstick
global
perfection SPF 20

Net Wt. 0.11 oz. e (3,4 g)



LBEL CONCENTRE TOTAL LABIOS GLOBAL PERFECTION SPF 20 MALVA NUDE/RED

octinoxate and zinc oxide lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0169
Route of Administration	TOPICAL		

PUERTO RICO, Dist. by Ventura Corp. Ltd. San Juan, Puerto Rico 00926 Made in Colombia U.S.A.: Dist. by Ventura Int. Ltd. D&A Recorp USA Miami, FL 33126 Made in Colombia

Drug Facts (continued)
 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
Other Information ■ Protect the product in this container from excessive heat and direct sun. ▶

Drug Facts (continued)
 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 ▶

Drug Facts (continued)
 ethylhexanoate, methylpropanediol, cocos nucifera (coconut) oil, aloe barbadensis leaf extract, fragrance, ceramide 3, caprylic glycol, silanediol salicylate, chlorphenesin, triethoxycaprylsilane, tromethamine, sorbitan isostearate, dimethicone, limonium gerani extract, griola frondosa fruiting body extract, maltodextrin, portulaca pilosa extract, trimethylsilylate, sucrose cocate, palmityl tripeptide-38, benzyl benzoate, amy! cinnamal, hexyl cinnamal, linolool. May contain: titanium dioxide, iron oxides, red 27 lake, red 21 lake, red 7 lake, yellow 5 lake, red 30 lake, taic, blue 1 lake.

Drug Facts (continued)
Inactive Ingredients Diisopropyl dimer dilinoleate, isononyl isononanoate, ozokerite, dipentaerythryl hexacaprylate/hexacaprate, polyglyceryl-3 distostearate, triethyl trimellitate, polymethylsilsesquioxane, polyethylene copernicia cerifera (carnauba) wax, hydrogenated polydecylatediene, phe, butyrospermum parkii (shea) butter, triethyl stearate, isododecane, silica dimethyl silylate, tocopheryl acetate, mica, reopentyl glycol dicaprylate/dicaprate, caprylic/capric triglyceride, phenoxethanol, cetearyl ▶

L'BEL

CONCENTRÉ
 TOTAL
 LABIOS
 lipstick
 global
 perfection SPF 20

Net Wt. 0.11 oz. e (3,4 g)

Drug Facts (continued)
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 ▶

Drug Facts
Active Ingredients **Purpose**
 Octinoxate 7.5 % Sunscreen
 Zinc Oxide 3.92 % Sunscreen
Uses ■ Helps prevent sunburn.
Warnings ■ Skin Cancer / Skin Aging ▶

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)	
SHEA BUTTER (UNII: K49155WL9Y)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
ISODODECANE (UNII: A8289P68Y2)	
SILICA DIMETHYL SILYLATE (UNII: EU2PS0G0W)	
MICA (UNII: V8A1AW0880)	
NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CETEARYL ETHYLHEXANOATE (UNII: 9M64UO4C25)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CERAMIDE NP (UNII: 4370DF050B)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SILANEDIOL SALICYLATE (UNII: C054DF30K0)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
TROMETHAMINE (UNII: 023C2WHX2V)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SUCROSE COCOATE (UNII: 3H18P0UK73)	
PALMITOYL LYSYLDIOXYMETHIONYLLYSINE (UNII: T7A529FB8O)	
BENZYL BENZOATE (UNII: N863NB338G)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
.ALPHA.-HEXYL CINNAMALDEHYDE (UNII: 7X6O37OK2I)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TALC (UNII: 7SEV7J4R1U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0169-2	1 in 1 BOX	10/19/2018	
1	NDC:43596-0169-1	3.4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	10/19/2018	

Labeler - VENTURA CORPORATION LTD (602751344)**Establishment**

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(43596-0169)

Revised: 12/2019

VENTURA CORPORATION LTD