

**CYZONE CY PERLIPS LABIAL HIDRATANTE CON PERLAS DE LUZ Y FPS 20- octinoxate and oxybenzone cream**

**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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**CYZONE**

**CY PERLIPS Labial Hidratante con perlas de luz y FPS 20**

***Drug Facts***

**Active Ingredients**

OCTINOXATE 7.0 % , OXYBENZONE 2.5 %

**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**

RICINUS COMMUNIS SEED OIL (RICINUS COMMUNIS (CASTOR) SEED OIL),

CAPRYLIC/CAPRIC TRIGLYCERIDE, POLYETHYLENE, CERA ALBA (BEESWAX), CANDELILLA CERA (EUPHORBIA CERIFERA (CANDELILLA) WAX), HYDROGENATED VEGETABLE OIL, BUTYROSPERMUM PARKII BUTTER (BUTYROSPERMUM PARKII (SHEA) BUTTER), SILICA DIMETHYL SILYLATE, GLYCERIN, OCTYLDODECANOL, PARFUM (FRAGRANCE), GLYCERYL ISOSTEARATE, ISOSTEARYL ALCOHOL, HELIANTHUS ANNUUS SEED OIL (HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL), SODIUM SACCHARIN, PROPYLPARABEN, MICROCRISTALLINA CERA (MICROCRYSTALLINE WAX), BETA-SITOSTEROL, PETROLATUM, BHT, TOCOPHERYL ACETATE, PHOSPHOLIPIDS, CHOLESTEROL, CETEARYL ALCOHOL, CETEARYL GLUCOSIDE, COPERNICIA CERIFERA CERA (COPERNICIA CERIFERA (CARNAUBA ) WAX), POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE, GLYCOSPHINGOLIPIDS. **May contain:** CI 77742 (MANGANESE VIOLET), CI 15850 (RED 7 LAKE), CI 77492 (IRON OXIDES), CI 77891 (TITANIUM DIOXIDE ), SYNTHETIC FLUORPHLOGOPITE, CI 19140 (YELLOW 5 LAKE), CI 73360 (RED 30).

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

### **PRINCIPAL DISPLAY PANEL - 4 g Stick Label**

***perlips***

labial hidratante con  
perlas de luz y FPS 20

**cy°**

**cy°zone**

4 g e (.14 oz.)

perlips  
labial hidratante con  
perlas de luz y FPS 20

cy°

cy°zone

### Drug Facts

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### Other information



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

### Drug Facts (continued)

In this container from excessive heat and direct sun.

### Inactive ingredients

ricinus communis seed oil (ricinus communis (castor) seed oil), caprylic/capric triglyceride, polyethylene, cera alba (beeswax), candelilla cera (euphorbia cerifera (candelilla) wax), hydrogenated vegetable oil, butyrospermum parkii butter (butyrospermum parkii (shea) butter), silica dimethyl silylate, glycerin, octyldodecanol, parum (fragrance), glyceryl isostearate, isostearyl alcohol, helianthus annuus seed oil (helianthus annuus (sunflower) seed oil), sodium saccharin, propylparaben, microcristallina cera (microcristalline wax), beta-sitosterol, petrolatum, bht, tocopheryl acetate, phospholipids, cholesterol, cetearyl alcohol, cetearyl glucoside, copernicia cerifera cera (copernicia cerifera (carnauba) wax), polyglyceryl-2 dipolyhydroxystearate, glycosphingolipids. **may contain:** ci 77742 (manganese violet), ci 15850 (red 7 lake), ci 77492 (iron oxides), ci 77891 (titanium dioxide), synthetic fluorphlogopite, ci 19140 (yellow 5 lake), ci 73360 (red 30 lake), ci 77491 (iron oxides), ci 77499 (iron oxides), talc, ci 77019 (mica), tin oxide.

4 g e (.14 oz.)

**CYZONE CY PERLIPS LABIAL HIDRATANTE CON PERLAS DE LUZ Y FPS 20**

octinoxate and oxybenzone cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:13537-432
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>Octinoxate</b> (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.07 g in 1 g
<b>Oxybenzone</b> (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.025 g in 1 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>CASTOR OIL</b> (UNII: D5340Y2I9G)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>HIGH DENSITY POLYETHYLENE</b> (UNII: UG00KM4WR7)	
<b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)	
<b>CANDELILLA WAX</b> (UNII: WL0328HX19)	
<b>SHEA BUTTER</b> (UNII: K49155WL9Y)	
<b>SILICA DIMETHYL SILYLATE</b> (UNII: EU2PSP0G0W)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>OCTYLDODECANOL</b> (UNII: 461N1O614Y)	
<b>GLYCERYL ISOSTEARATE</b> (UNII: HYE7O27HAO)	
<b>ISOSTEARYL ALCOHOL</b> (UNII: Q6130CQ44Y)	
<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)	
<b>SACCHARIN SODIUM DIHYDRATE</b> (UNII: SB8ZUX40TY)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>MICROCRYSTALLINE WAX</b> (UNII: XOF597Q3KY)	
<b>.BETA.-SITOSTEROL</b> (UNII: S347WMO6M4)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>CHOLESTEROL</b> (UNII: 97C5T2UQ7J)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>CETEARYL GLUCOSIDE</b> (UNII: 09FUA47KNA)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE</b> (UNII: 9229XJ4V12)	
<b>MANGANESE VIOLET</b> (UNII: 72M48QQV8Q)	
<b>D&amp;C RED NO. 7</b> (UNII: ECW0LZ41X8)	

ALUMINUM OXIDE (UNII: LM26O6933)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 30 (UNII: 2S42T2808B)	

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-432-01	4 g in 1 TUBE, WITH APPLICATOR		

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/13/2012	

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

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(13537-432)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Yobel Supply Chain Management S.A. (Peru)		934116930	MANUFACTURE(13537-432)

Revised: 7/2012

Ventura Corporation LTD.