

**CYZONE BETTER LIPS BALM- octinoxate, oxybenzone, 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.*

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cy°  
cy°zone  
better lips balm

**Active Ingredients**

Octinoxate 7%, Oxybenzone 2%, Zinc Oxide 1%.

**Purpose**

Sunscreen.

**Uses**

Helps prevent sunburn.

**Warnings**

Stop use if skin rash occurs.

**Inactive ingredients**

Caprylic/capric triglyceride, diisopropyl dimer dilinoleate, ricinus communis seed oil (ricinus communis (castor) seed oil), octyldodecanol, hydrogenated polyisobutene, polyethylene, candelilla cera (euphorbia cerifera (candelilla) wax), cera alba (beeswax), copernicia cerifera cera (copernicia cerifera (carnauba) wax), CI 77019 (mica), parfum (fragrance), dipalmitoyl hydroxyproline, glyceryl isostearate, isostearyl alcohol, glycerin, butyrospermum parkii (butyrospermum parkii (shea butter), bertholletia excelsa seed oil, orbignya oleifera seed oil, tocopheryl acetate, beta-sitosterol, sodium saccharin, silica dimethyl silylate, cetearyl ethylhexanoate, propylparaben, cera microcristallina (microcrystalline wax), bht, butyl methoxydibenzoylmethane, petrolatum, cetyl alcohol, phospholipids, hydrogenated coconut oil, ethylhexyl salicylate, cholesterol, oleyl alcohol, triethoxycaprylylsilane, ozokerite, dimethicone, polyglyceryl-2 dipolyhydroxystearate, cetearyl glucoside, cetearyl alcohol, cetyl ricinoleate, glycosphingolipids, trimethylsiloxysilicate. **May Contain:** Calcium aluminum borosilicate, CI 77891 (titanium dioxide), CI 45380 (red 21 lake), CI 15850 (red 7 lake), CI 45410 (red 27 lake), CI 16035 (red 40 lake), CI 77491 (iron oxides), CI 77492 (iron oxides), silica, CI 19140 (yellow 5 lake), talc, CI 77499 (iron oxides), tin oxide, CI 75470 (carmine), palmitic acid, methylparaben, butylparaben.

**P.R.:** Dist. by Ventura Corporation, Ltd., San Juan, Puerto Rico 00926.

**PRINCIPAL DISPLAY PANEL - 4,5 g Label**

**better lips balm**

Humectante para labios  
con color **FPS 18 UVA UVB**

cy°

**cy<sup>o</sup>zone**

4,5 g e (.15 oz.)

# better lips balm

Humectante para labios  
con color **FPS 18 UVA UVB**

**Active Ingredients:** Octinoxate 7%, Oxybenzone 2%, Zinc Oxide 1%.

**Purpose:** Sunscreen.

**Uses:** Helps prevent sunburn.

**Warnings:** Stop use if skin rash occurs.

**Inactive ingredients:** Caprylic/capric triglyceride, diisopropyl dimer dilinolate, ricinus communis seed oil (ricinus communis (castor) seed oil), octyldodecanol, hydrogenated polyisobutene, polyethylene, candelilla cera (euphorbia cerifera (candelilla) wax), cera alba (beeswax), copernicia cerifera (copernicia cerifera (carnauba) wax), CI 77019 (mica), parfum (fragrance), dipalmitoyl hydroxyproline, glyceryl isostearate, isostearyl alcohol, glycerin, butyrospermum parkii (butyrospermum parkii (shea butter), bertholletia excelsa seed oil, orbignya olifera seed oil, tocopheryl acetate, beta-sitosterol, sodium saccharin, silica dimethyl silylate, cetearyl ethylhexanoate, propylparaben, cera microcristalina (microcrystalline wax), bht, butyl methoxydibenzoylmethane, petrolatum, cetyl alcohol, phospholipids, hydrogenated coconut oil, ethylhexyl salicylate, cholesterol, oleyl alcohol, triethoxycaprylylsilane, ozokerite, dimethicone, polyglyceryl-2 dipolyhydroxystearate, cetearyl glucoside, cetearyl alcohol, cetyl ricinoleate, glycosphingolipids, trimethylsiloxyethylsilicate. **May Contain:** Calcium aluminum borosilicate, CI 77891 (titanium dioxide), CI 45380 (red 21 lake), CI 15850 (red 7 lake), CI 45410 (red 27 lake), CI 16035 (red 40 lake), CI 77491 (iron oxides), CI 77492 (iron oxides), silica, CI 19140 (yellow 5 lake), talc, CI 77499 (iron oxides), tin oxide, CI 75470 (carmine), palmittic acid, methylparaben, butylparaben.

P.R.: Dist. by Ventura Corporation, Ltd., San Juan, Puerto Rico 00926.  
Made in Colombia

cy°

cy°zone  
4,5 g e (.15 oz.)

## CYZONE BETTER LIPS BALM

octinoxate, oxybenzone, and zinc oxide lipstick

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:13537-300
<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	70 mg in 1 g
<b>Oxybenzone</b> (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	20 mg in 1 g
<b>Zinc Oxide</b> (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	10 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>CASTOR OIL</b> (UNII: D5340Y2I9G)	
<b>OCTYLDODECANOL</b> (UNII: 461N1O614Y)	
<b>CANDELILLA WAX</b> (UNII: WL0328HX19)	
<b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>MICA</b> (UNII: V8A1AW0880)	
<b>DIPALMITOYL HYDROXYPROLINE</b> (UNII: E6AHA53N1H)	
<b>GLYCERYL ISOSTEARATE</b> (UNII: HYE7O27HAO)	
<b>ISOSTEARYL ALCOHOL</b> (UNII: Q613OCQ44Y)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SHEA BUTTER</b> (UNII: K49155WL9Y)	
<b>BRAZIL NUT OIL</b> (UNII: 0G89T29HO6)	
<b>BABASSU OIL</b> (UNII: 8QSB4M5477)	
<b>.BETA.-SITOSTEROL</b> (UNII: S347WMO6M4)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>CETEARYL ETHYLHEXANOATE</b> (UNII: 9M64UO4C25)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	

<b>MICROCRYSTALLINE WAX</b> (UNII: XOF597Q3KY)
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)
<b>AVOBENZONE</b> (UNII: G63QQF2NOX)
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)
<b>HYDROGENATED COCONUT OIL</b> (UNII: JY81OXM1OM)
<b>OCTISALATE</b> (UNII: 4X49Y0596W)
<b>CHOLESTEROL</b> (UNII: 97C5T2UQ7J)
<b>OLEYL ALCOHOL</b> (UNII: 172F2WN8DV)
<b>TRIETHOXYCAPRYLSILANE</b> (UNII: LDC331P08E)
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)
<b>CETEARYL GLUCOSIDE</b> (UNII: 09FUA47KNA)
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)
<b>D&amp;C RED NO. 21</b> (UNII: 08744Z6JNY)
<b>D&amp;C RED NO. 7</b> (UNII: ECW0LZ41X8)
<b>D&amp;C RED NO. 27</b> (UNII: 2LRS185U6K)
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)
<b>ALUMINUM OXIDE</b> (UNII: LM26O6933)
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)
<b>TALC</b> (UNII: 7SEV7J4R1U)
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)
<b>STANNIC OXIDE</b> (UNII: KM7N50LOS6)
<b>PALMITIC ACID</b> (UNII: 2V16EO95H1)
<b>METHYL PARABEN</b> (UNII: A2I8C7HI9T)
<b>BUTYL PARABEN</b> (UNII: 3QPI1U3FV8)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-300-01	1 in 1 BOX		
1	NDC:13537-300-02	4.5 g in 1 TUBE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	02/28/2011	

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