

**ESIKA MAXIMUM COLOR SPF 18- 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.*

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**ēsika**  
**Maximum Color**  
**Lipstick SPF 18**

**Active Ingredients**

Octinoxate 7.3%, Oxybenzone 1.65%

**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**

Diisopropyl dimer dilinoleate, ethylhexyl palmitate, ozokerite, copernicia cerifera cera (copernicia cerifera (carnauba ) wax), polyethylene, butyrospermum parkii butter (butyrospermum parkii (shea) butter), silica, octyldodecanol, aqua (water), phenoxyethanol, microcristallina cera (microcrystalline wax), petrolatum, phospholipids, methylparaben, parfum (fragrance), bht, cholesterol, butylparaben, ethylparaben, candelilla cera (euphorbia cerifera (candelilla) wax), cera alba (beeswax), cetearyl alcohol, cetearyl glucoside, polyglyceryl-2 dipolyhydroxystearate, isobutylparaben, propylparaben, glycosphingolipids, maltodextrin, zea mays starch( zea mays (corn) starch), sodium hyaluronate, CI 15850 (red 7 lake), CI 45410 (red 27 lake), CI 77491 (iron oxides), CI 77492 (iron oxides), CI 77499 (iron oxides), CI 77019 (mica), CI 19140 (yellow 5 lake), CI 77891 (titanium dioxide ), CI 15850 (red 6 lake), isononyl isononanoate, talc, isopropyl myristate, CI 42090 (blue 1 lake), CI 75470 (carmine), isopropyl titanium triisostearate, triethoxycaprylylsilane, stearalkonium hectorite, C9-15 fluoroalcohol phosphate, polyhydroxystearic acid, propylene carbonate.

**PRINCIPAL DISPLAY PANEL - 4 g Carton - Rojo Amor**

**ēsika**  
**Maximum Color**  
**Lipstick SPF 18**

**4 g e (.14 oz.)**



**Active Ingredients:** Octinoxate 7.30 %, Oxybenzone 1.65 %.

**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 of natural lip line.  
**Inactive Ingredients:** Diisopropyl dimer dilinoleate, ethylhexyl palmitate, ozokerite, copernicia cerifera cera (copernicia cerifera (carnauba) wax), polyethylene, butyrospermum parkii butter (butyrospermum parkii (shea) butter), silica, octyldodecanol, aqua (water), phenoxyethanol, microcrystalline cera (microcrystalline wax), petrolatum, phospholipids, methylparaben, parium (fragrance), bht, cholesterol, butylparaben, ethylparaben, candellilla cera (euphorbia cerifera (candellilla) wax), cera alba (beeswax), cetearyl alcohol, cetearyl glucoside, polyglyceryl-2 dipolyhydroxystearate, isobutylparaben, propylparaben, glycosphingolipids, maltodextrin, zea

mays starch (zea mays (corn) starch), sodium hyaluronate. **May Contain:** CI 15850 (red 7 lake), CI 45410 (red 27 lake), CI 77491 (iron oxides), CI 77492 (iron oxides), CI 77499 (iron oxides), CI 77019 (mica), CI 19140 (yellow 5 lake), CI 77891 (titanium dioxide), CI 15850 (red 6 lake), isononyl isononanoate, talc, isopropyl myristate, CI 42090 (blue 1 lake), CI 75470 (carmine), isopropyl titanium triisostearate, triethoxycaprylsilane, stearylkonium hectorite, c9-15 fluoroalcohol phosphate, polyhydroxystearic acid, propylene carbonate.

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

ESIKA

Maximum Color  
Lipstick SPF 18

4 g e (.14 oz.)



**PRINCIPAL DISPLAY PANEL - 4 g Carton - Naranja Vivaz**

**ēsika**

**Maximum Color**

**Lipstick SPF 18**

**4 g e (.14 oz.)**

**Active Ingredients:** Octinoxate 7.30 %, Oxybenzone 1.65 %.

**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 of natural lip line.

**Inactive Ingredients:** Diisopropyl dimer dilinoleate, ethylhexyl palmitate, ozokerite, copernicia cerifera cera (copernicia cerifera (carnauba) wax), polyethylene, butyrospermum parkii butter (butyrospermum parkii (shea) butter), silica, octyldodecanol, aqua (water), phenoxyethanol, microcrystalline cera (microcrystalline wax), petrolatum, phospholipids, methylparaben, parium (fragrance), bht, cholesterol, butylparaben, ethylparaben, candellilla cera (euphorbia cerifera (candellilla) wax), cera alba (beeswax), cetearyl alcohol, cetearyl glucoside, polyglyceryl-2 dipolyhydroxystearate, isobutylparaben, propylparaben, glycosphingolipids, maltodextrin, zea

mays starch (zea mays (corn) starch), sodium hyaluronate. **May Contain:** CI 15850 (red 7 lake), CI 45410 (red 27 lake), CI 77491 (iron oxides), CI 77492 (iron oxides), CI 77499 (iron oxides), CI 77019 (mica), CI 19140 (yellow 5 lake), CI 77891 (titanium dioxide), CI 15850 (red 6 lake), isononyl isononanoate, talc, isopropyl myristate, CI 42090 (blue 1 lake), CI 75470 (carmine), isopropyl titanium trisostearate, triethoxycaprylsilane, stearylkonium hectorite, c9-15 fluoroalcohol phosphate, polyhydroxystearic acid, propylene carbonate.

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Maximum Color  
Lipstick SPF 18

4 g e (.14 oz.)



**PRINCIPAL DISPLAY PANEL - 4 g Carton - Rojo Cherry**

**ēsika**

**Maximum Color**

**Lipstick SPF 18**

**4 g e (.14 oz.)**

**Active Ingredients:** Octinoxate 7.30 %, Oxybenzone 1.65 %.

**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 of natural lip line.

**Inactive Ingredients:** Diisopropyl dimer dilinoleate, ethylhexyl palmitate, ozokerite, copernicia cerifera cera (copernicia cerifera (carnauba) wax), polyethylene, butyrospermum parkii butter (butyrospermum parkii (shea) butter), silica, octyldodecanol, aqua (water), phenoxyethanol, microcrystalline cera (microcrystalline wax), petrolatum, phospholipids, methylparaben, parium (fragrance), bht, cholesterol, butylparaben, ethylparaben, candellilla cera (euphorbia cerifera (candellilla) wax), cera alba (beeswax), cetearyl alcohol, cetearyl glucoside, polyglyceryl-2 dipolyhydroxystearate, isobutylparaben, propylparaben, glycosphingolipids, maltodextrin, zea

mays starch (zea mays (corn) starch), sodium hyaluronate. **May Contain:** CI 15850 (red 7 lake), CI 45410 (red 27 lake), CI 77491 (iron oxides), CI 77492 (iron oxides), CI 77499 (iron oxides), CI 77019 (mica), CI 19140 (yellow 5 lake), CI 77891 (titanium dioxide), CI 15850 (red 6 lake), isononyl isononanoate, talc, isopropyl myristate, CI 42090 (blue 1 lake), CI 75470 (carmine), isopropyl titanium trisostearate, triethoxycaprylsilane, stearylkonium hectorite, c9-15 fluoroalcohol phosphate, polyhydroxystearic acid, propylene carbonate.

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Maximum Color  
Lipstick SPF 18

4 g e (.14 oz.)



**PRINCIPAL DISPLAY PANEL - 4 g Carton - Fucsia Fancy**

**ēsika**

**Maximum Color**

**Lipstick SPF 18**

**4 g e (.14 oz.)**



**Active Ingredients:** Octinoxate 7.30 %, Oxybenzone 1.65 %.

**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 of natural lip line.

**Inactive Ingredients:** Diisopropyl dimer dilinoleate, ethylhexyl palmitate, ozokerite, copernicia cerifera cera (copernicia cerifera (carnauba) wax), polyethylene, butyrospermum parkii butter (butyrospermum parkii (shea) butter), silica, octyldodecanol, aqua (water), phenoxyethanol, microcrystalline cera (microcrystalline wax), petrolatum, phospholipids, methylparaben, parium (fragrance), bht, cholesterol, butylparaben, ethylparaben, candellilla cera (euphorbia cerifera (candellilla) wax), cera alba (beeswax), cetearyl alcohol, cetearyl glucoside, polyglyceryl-2 dipolyhydroxystearate, isobutylparaben, propylparaben, glycosphingolipids, maltodextrin, zea

mays starch (zea mays (corn) starch), sodium hyaluronate. **May Contain:** CI 15850 (red 7 lake), CI 45410 (red 27 lake), CI 77491 (iron oxides), CI 77492 (iron oxides), CI 77499 (iron oxides), CI 77019 (mica), CI 19140 (yellow 5 lake), CI 77891 (titanium dioxide), CI 15850 (red 6 lake), isononyl isononanoate, talc, isopropyl myristate, CI 42090 (blue 1 lake), CI 75470 (carmine), isopropyl titanium trisostearate, triethoxycaprylsilane, stearylkonium hectorite, c9-15 fluoroalcohol phosphate, polyhydroxystearic acid, propylene carbonate.

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4 g e (.14 oz.)



**PRINCIPAL DISPLAY PANEL - 4 g Carton - Magenta Atrevida**

**ēsika**

**Maximum Color**

**Lipstick SPF 18**

**4 g e (.14 oz.)**

**Active Ingredients:** Octinoxate 7.30 %, Oxybenzone 1.65 %.

**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 of natural lip line.

**Inactive Ingredients:** Diisopropyl dimer dilinoleate, ethylhexyl palmitate, ozokerite, copernicia cerifera cera (copernicia cerifera (carnauba) wax), polyethylene, butyrospermum parkii butter (butyrospermum parkii (shea) butter), silica, octyldodecanol, aqua (water), phenoxyethanol, microcrystalline cera (microcrystalline wax), petrolatum, phospholipids, methylparaben, parium (fragrance), bht, cholesterol, butylparaben, ethylparaben, candellilla cera (euphorbia cerifera (candellilla) wax), cera alba (beeswax), cetearyl alcohol, cetearyl glucoside, polyglyceryl-2 dipolyhydroxystearate, isobutylparaben, propylparaben, glycosphingolipids, maltodextrin, zea

mays starch (zea mays (corn) starch), sodium hyaluronate. **May Contain:** CI 15850 (red 7 lake), CI 45410 (red 27 lake), CI 77491 (iron oxides), CI 77492 (iron oxides), CI 77499 (iron oxides), CI 77019 (mica), CI 19140 (yellow 5 lake), CI 77891 (titanium dioxide), CI 15850 (red 6 lake), isononyl isononanoate, talc, isopropyl myristate, CI 42090 (blue 1 lake), CI 75470 (carmine), isopropyl titanium trisostearate, triethoxycaprylsilane, stearylkonium hectorite, c9-15 fluoroalcohol phosphate, polyhydroxystearic acid, propylene carbonate.

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Maximum Color  
Lipstick SPF 18

4 g e (.14 oz.)



**PRINCIPAL DISPLAY PANEL - 4 g Carton - Vino Glamour**

**ēsika**

**Maximum Color**

**Lipstick SPF 18**

**4 g e (.14 oz.)**

**Active Ingredients:** Octinoxate 7.30 %, Oxybenzone 1.65 %.

**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 of natural lip line.

**Inactive Ingredients:** Diisopropyl dimer dilinoleate, ethylhexyl palmitate, ozokerite, copernicia cerifera cera (copernicia cerifera (carnauba) wax), polyethylene, butyrospermum parkii butter (butyrospermum parkii (shea) butter), silica, octyldodecanol, aqua (water), phenoxyethanol, microcrystalline cera (microcrystalline wax), petrolatum, phospholipids, methylparaben, parium (fragrance), bht, cholesterol, butylparaben, ethylparaben, candellilla cera (euphorbia cerifera (candellilla) wax), cera alba (beeswax), cetearyl alcohol, cetearyl glucoside, polyglyceryl-2 dipolyhydroxystearate, isobutylparaben, propylparaben, glycosphingolipids, maltodextrin, zea

mays starch (zea mays (corn) starch), sodium hyaluronate. **May Contain:** CI 15850 (red 7 lake), CI 45410 (red 27 lake), CI 77491 (iron oxides), CI 77492 (iron oxides), CI 77499 (iron oxides), CI 77019 (mica), CI 19140 (yellow 5 lake), CI 77891 (titanium dioxide), CI 15850 (red 6 lake), isononyl isononanoate, talc, isopropyl myristate, CI 42090 (blue 1 lake), CI 75470 (carmine), isopropyl titanium trisostearate, triethoxycaprylsilane, stearylkonium hectorite, c9-15 fluoroalcohol phosphate, polyhydroxystearic acid, propylene carbonate.

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Lipstick SPF 18

4 g e (.14 oz.)



**PRINCIPAL DISPLAY PANEL - 4 g Carton - Rosa Divina**

**ēsika**

**Maximum Color**

**Lipstick SPF 18**

**4 g e (.14 oz.)**

**Active Ingredients:** Octinoxate 7.30 %, Oxybenzone 1.65 %.

**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 of natural lip line.

**Inactive Ingredients:** Diisopropyl dimer dilinoleate, ethylhexyl palmitate, ozokerite, copernicia cerifera cera (copernicia cerifera (carnauba) wax), polyethylene, butyrospermum parkii butter (butyrospermum parkii (shea) butter), silica, octyldodecanol, aqua (water), phenoxyethanol, microcrystalline cera (microcrystalline wax), petrolatum, phospholipids, methylparaben, parium (fragrance), bht, cholesterol, butylparaben, ethylparaben, candellilla cera (euphorbia cerifera (candellilla) wax), cera alba (beeswax), cetearyl alcohol, cetearyl glucoside, polyglyceryl-2 dipolyhydroxystearate, isobutylparaben, propylparaben, glycosphingolipids, maltodextrin, zea

mays starch (zea mays (corn) starch), sodium hyaluronate. **May Contain:** CI 15850 (red 7 lake), CI 45410 (red 27 lake), CI 77491 (iron oxides), CI 77492 (iron oxides), CI 77499 (iron oxides), CI 77019 (mica), CI 19140 (yellow 5 lake), CI 77891 (titanium dioxide), CI 15850 (red 6 lake), isononyl isononanoate, talc, isopropyl myristate, CI 42090 (blue 1 lake), CI 75470 (carmine), isopropyl titanium trisostearate, triethoxycaprylsilane, stearylkonium hectorite, c9-15 fluoroalcohol phosphate, polyhydroxystearic acid, propylene carbonate.

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Maximum Color  
Lipstick SPF 18

4 g e (.14 oz.)



**PRINCIPAL DISPLAY PANEL - 4 g Carton - Coral Shine**

**ēsika**

**Maximum Color**

**Lipstick SPF 18**

**4 g e (.14 oz.)**



**Active Ingredients:** Octinoxate 7.30 %, Oxybenzone 1.65 %.

**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 of natural lip line.

**Inactive Ingredients:** Diisopropyl dimer dilinoleate, ethylhexyl palmitate, ozokerite, copernicia cerifera cera (copernicia cerifera (carnauba) wax), polyethylene, butyrospermum parkii butter (butyrospermum parkii (shea) butter), silica, octyldodecanol, aqua (water), phenoxyethanol, microcrystalline cera (microcrystalline wax), petrolatum, phospholipids, methylparaben, parium (fragrance), bht, cholesterol, butylparaben, ethylparaben, candellilla cera (euphorbia cerifera (candellilla) wax), cera alba (beeswax), cetearyl alcohol, cetearyl glucoside, polyglyceryl-2 dipolyhydroxystearate, isobutylparaben, propylparaben, glycosphingolipids, maltodextrin, zea

mays starch (zea mays (corn) starch), sodium hyaluronate. **May Contain:** CI 15850 (red 7 lake), CI 45410 (red 27 lake), CI 77491 (iron oxides), CI 77492 (iron oxides), CI 77499 (iron oxides), CI 77019 (mica), CI 19140 (yellow 5 lake), CI 77891 (titanium dioxide), CI 15850 (red 6 lake), isononyl isononanoate, talc, isopropyl myristate, CI 42090 (blue 1 lake), CI 75470 (carmine), isopropyl titanium triisostearate, triethoxycaprylsilane, stearylkonium hectorite, c9-15 fluoroalcohol phosphate, polyhydroxystearic acid, propylene carbonate.

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Maximum Color  
Lipstick SPF 18

4 g e (.14 oz.)



**PRINCIPAL DISPLAY PANEL - 4 g Carton - Mocca Misterio**

**ēsika**

**Maximum Color**

**Lipstick SPF 18**

**4 g e (.14 oz.)**

**Active Ingredients:** Octinoxate 7.30 %, Oxybenzone 1.65 %.

**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 of natural lip line.

**Inactive Ingredients:** Diisopropyl dimer dilinoleate, ethylhexyl palmitate, ozokerite, copernicia cerifera cera (copernicia cerifera (carnauba) wax), polyethylene, butyrospermum parkii butter (butyrospermum parkii (shea) butter), silica, octyldodecanol, aqua (water), phenoxyethanol, microcrystalline cera (microcrystalline wax), petrolatum, phospholipids, methylparaben, parium (fragrance), bht, cholesterol, butylparaben, ethylparaben, candellilla cera (euphorbia cerifera (candellilla) wax), cera alba (beeswax), cetearyl alcohol, cetearyl glucoside, polyglyceryl-2 dipolyhydroxystearate, isobutylparaben, propylparaben, glycosphingolipids, maltodextrin, zea

mays starch (zea mays (corn) starch), sodium hyaluronate. **May Contain:** CI 15850 (red 7 lake), CI 45410 (red 27 lake), CI 77491 (iron oxides), CI 77492 (iron oxides), CI 77499 (iron oxides), CI 77019 (mica), CI 19140 (yellow 5 lake), CI 77891 (titanium dioxide), CI 15850 (red 6 lake), isononyl isononanoate, talc, isopropyl myristate, CI 42090 (blue 1 lake), CI 75470 (carmine), isopropyl titanium triisostearate, triethoxycaprylsilane, stearylkonium hectorite, c9-15 fluoroalcohol phosphate, polyhydroxystearic acid, propylene carbonate.

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ESIKA

Maximum Color  
Lipstick SPF 18

4 g e (.14 oz.)



**PRINCIPAL DISPLAY PANEL - 4 g Carton - Marron Calido**

**ēsika**

**Maximum Color**

**Lipstick SPF 18**

**4 g e (.14 oz.)**

**Active Ingredients:** Octinoxate 7.30 %, Oxybenzone 1.65 %.

**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 of natural lip line.

**Inactive Ingredients:** Diisopropyl dimer dilinoleate, ethylhexyl palmitate, ozokerite, copernicia cerifera cera (copernicia cerifera (carnauba) wax), polyethylene, butyrospermum parkii butter (butyrospermum parkii (shea) butter), silica, octyldodecanol, aqua (water), phenoxyethanol, microcrystalline cera (microcrystalline wax), petrolatum, phospholipids, methylparaben, parium (fragrance), bht, cholesterol, butylparaben, ethylparaben, candellilla cera (euphorbia cerifera (candellilla) wax), cera alba (beeswax), cetearyl alcohol, cetearyl glucoside, polyglyceryl-2 dipolyhydroxystearate, isobutylparaben, propylparaben, glycosphingolipids, maltodextrin, zea

mays starch (zea mays (corn) starch), sodium hyaluronate. **May Contain:** CI 15850 (red 7 lake), CI 45410 (red 27 lake), CI 77491 (iron oxides), CI 77492 (iron oxides), CI 77499 (iron oxides), CI 77019 (mica), CI 19140 (yellow 5 lake), CI 77891 (titanium dioxide), CI 15850 (red 6 lake), isononyl isononanoate, talc, isopropyl myristate, CI 42090 (blue 1 lake), CI 75470 (carmine), isopropyl titanium trisostearate, triethoxycaprylsilane, stearylkonium hectorite, c9-15 fluoroalcohol phosphate, polyhydroxystearic acid, propylene carbonate.

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ESIKA

Maximum Color  
Lipstick SPF 18

4 g e (.14 oz.)

# ESIKA MAXIMUM COLOR SPF 18

octinoxate and oxybenzone lipstick

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:13537-343
<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	0.073 g in 1 g
<b>Oxybenzone</b> (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.0165 g in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>ethylhexyl palmitate</b> (UNII: 2865993309)	
<b>carnauba wax</b> (UNII: R12CBM0EIZ)	
<b>shea butter</b> (UNII: K49155WL9Y)	
<b>silicon dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>octyldodecanol</b> (UNII: 461N1O614Y)	
<b>water</b> (UNII: 059QF0KO0R)	
<b>phenoxyethanol</b> (UNII: HIE492ZZ3T)	
<b>microcrystalline wax</b> (UNII: XOF597Q3KY)	
<b>petrolatum</b> (UNII: 4T6H12BN9U)	
<b>methylparaben</b> (UNII: A218C7HI9T)	
<b>butylated hydroxytoluene</b> (UNII: 1P9D0Z171K)	
<b>cholesterol</b> (UNII: 97C5T2UQ7J)	
<b>butylparaben</b> (UNII: 3QPII1U3FV8)	
<b>ethylparaben</b> (UNII: 14255EXE39)	
<b>candelilla wax</b> (UNII: WL0328HX19)	
<b>yellow wax</b> (UNII: 2ZA36H0S2V)	
<b>cetostearyl alcohol</b> (UNII: 2DMT128M1S)	
<b>cetearyl glucoside</b> (UNII: 09FUA47KNA)	
<b>isobutylparaben</b> (UNII: 0QQJ25X58G)	
<b>propylparaben</b> (UNII: Z8IX2SC1OH)	
<b>maltodextrin</b> (UNII: 7CVR7L4A2D)	
<b>starch, corn</b> (UNII: O8232NY3SJ)	
<b>hyaluronate sodium</b> (UNII: YSE9PPT4TH)	
<b>d&amp;c red no. 7</b> (UNII: ECW0LZ41X8)	
<b>d&amp;c red no. 28</b> (UNII: 767IP0Y5NH)	
<b>aluminum oxide</b> (UNII: LM26O6933)	
<b>ferric oxide red</b> (UNII: 1K09F3G675)	
<b>ferric oxide yellow</b> (UNII: EX438O2MRT)	
<b>ferrosoferric oxide</b> (UNII: XM0M87F357)	
<b>mica</b> (UNII: V8A1AW0880)	

fd&c yellow no. 5 (UNII: I753WB2F1M)	
titanium dioxide (UNII: 15FIX9V2JP)	
d&c red no. 6 (UNII: 481744A14O)	
isononyl isononanoate (UNII: S4V5BS6GCX)	
talc (UNII: 7SEV7J4RIU)	
isopropyl myristate (UNII: 0RE8K4LNJS)	
fd&c blue no. 1 (UNII: H3R47K3TBD)	
cochineal (UNII: TZ8Z31B35M)	
triethoxycaprylsilane (UNII: LDC331P08E)	
propylene carbonate (UNII: 8D08K3S51E)	

### Product Characteristics

Color	RED (Rojo Amor)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-343-02	1 in 1 BOX		
1	NDC:13537-343-01	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	

## ESIKA MAXIMUM COLOR SPF 18

octinoxate and oxybenzone lipstick

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-344
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.073 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.0165 g in 1 g

### Inactive Ingredients

Ingredient Name	Strength
ethylhexyl palmitate (UNII: 2865993309)	

<b>carnauba wax</b> (UNII: R12CBM0EIZ)	
<b>shea butter</b> (UNII: K49155WL9Y)	
<b>silicon dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>octyldodecanol</b> (UNII: 461N1O614Y)	
<b>water</b> (UNII: 059QF0KO0R)	
<b>phenoxyethanol</b> (UNII: HIE492ZZ3T)	
<b>microcrystalline wax</b> (UNII: XOF597Q3KY)	
<b>petrolatum</b> (UNII: 4T6H12BN9U)	
<b>methylparaben</b> (UNII: A2I8C7HI9T)	
<b>butylated hydroxytoluene</b> (UNII: 1P9D0Z171K)	
<b>cholesterol</b> (UNII: 97C5T2UQ7J)	
<b>butylparaben</b> (UNII: 3QPH1U3FV8)	
<b>ethylparaben</b> (UNII: 14255EXE39)	
<b>candelilla wax</b> (UNII: WL0328HX19)	
<b>yellow wax</b> (UNII: 2ZA36H0S2V)	
<b>cetostearyl alcohol</b> (UNII: 2DMT128M1S)	
<b>cetearyl glucoside</b> (UNII: 09FUA47KNA)	
<b>isobutylparaben</b> (UNII: 0QQJ25X58G)	
<b>propylparaben</b> (UNII: Z8IX2SC1OH)	
<b>maltodextrin</b> (UNII: 7CVR7L4A2D)	
<b>starch, corn</b> (UNII: O8232NY3SJ)	
<b>hyaluronate sodium</b> (UNII: YSE9PPT4TH)	
<b>d&amp;c red no. 7</b> (UNII: ECW0LZ41X8)	
<b>d&amp;c red no. 28</b> (UNII: 767IP0Y5NH)	
<b>aluminum oxide</b> (UNII: LMI26O6933)	
<b>ferric oxide red</b> (UNII: 1K09F3G675)	
<b>ferric oxide yellow</b> (UNII: EX438O2MRT)	
<b>ferrosoferric oxide</b> (UNII: XM0M87F357)	
<b>mica</b> (UNII: V8A1AW0880)	
<b>fd&amp;c yellow no. 5</b> (UNII: I753WB2F1M)	
<b>titanium dioxide</b> (UNII: 15FIX9V2JP)	
<b>d&amp;c red no. 6</b> (UNII: 481744AI4O)	
<b>isononyl isononanoate</b> (UNII: S4V5BS6GCX)	
<b>talc</b> (UNII: 7SEV7J4RIU)	
<b>isopropyl myristate</b> (UNII: 0RE8K4LNJS)	
<b>fd&amp;c blue no. 1</b> (UNII: H3R47K3TBD)	
<b>cochineal</b> (UNII: TZ8Z31B35M)	
<b>triethoxycaprylylsilane</b> (UNII: LDC331P08E)	
<b>propylene carbonate</b> (UNII: 8D08K3S51E)	

### Product Characteristics

<b>Color</b>	ORANGE (Naranja Vivaz)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging



#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-344-02	1 in 1 BOX		
1	NDC:13537-344-01	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	

## ESIKA MAXIMUM COLOR SPF 18

octinoxate and oxybenzone lipstick

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-345
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.073 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.0165 g in 1 g

### Inactive Ingredients

Ingredient Name	Strength
ethylhexyl palmitate (UNII: 2865993309)	
carnauba wax (UNII: R12CBM0EIZ)	
shea butter (UNII: K49155WL9Y)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
octyldodecanol (UNII: 461N1O614Y)	
water (UNII: 059QF0KO0R)	
phenoxyethanol (UNII: HIE492ZZ3T)	
microcrystalline wax (UNII: XOF597Q3KY)	
petrolatum (UNII: 4T6H12BN9U)	
methylparaben (UNII: A218C7HI9T)	
butylated hydroxytoluene (UNII: 1P9D0Z171K)	
cholesterol (UNII: 97C5T2UQ7J)	
butylparaben (UNII: 3QPIU3FV8)	
ethylparaben (UNII: 14255EXE39)	
candelilla wax (UNII: WL0328HX19)	
yellow wax (UNII: 2ZA36H0S2V)	
cetostearyl alcohol (UNII: 2DMT128M1S)	
cetearyl glucoside (UNII: 09FUA47KNA)	
isobutylparaben (UNII: 0QQJ25X58G)	
propylparaben (UNII: Z8IX2SC1OH)	
maltodextrin (UNII: 7CVR7L4A2D)	

starch, corn (UNII: O8232NY3SJ)
hyaluronate sodium (UNII: YSE9PPT4TH)
d&c red no. 7 (UNII: ECW0LZ41X8)
d&c red no. 28 (UNII: 767IP0Y5NH)
aluminum oxide (UNII: LM26O6933)
ferric oxide red (UNII: 1K09F3G675)
ferric oxide yellow (UNII: EX438O2MRT)
ferrosoferric oxide (UNII: XM0M87F357)
mica (UNII: V8A1AW0880)
fd&c yellow no. 5 (UNII: I753WB2F1M)
titanium dioxide (UNII: 15FIX9V2JP)
d&c red no. 6 (UNII: 481744AI4O)
isononyl isononanoate (UNII: S4V5BS6GCX)
talc (UNII: 7SEV7J4RIU)
isopropyl myristate (UNII: 0RE8K4LNJS)
fd&c blue no. 1 (UNII: H3R47K3TBD)
cochineal (UNII: TZ8Z31B35M)
triethoxycaprylylsilane (UNII: LDC331P08E)
propylene carbonate (UNII: 8D08K3S51E)

**Product Characteristics**

Color	RED (Rojo Cherry)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-345-02	1 in 1 BOX		
1	NDC:13537-345-01	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	

**ESIKA MAXIMUM COLOR SPF 18**

octinoxate and oxybenzone lipstick

**Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-346
Route of Administration	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	0.073 g in 1 g
<b>Oxybenzone</b> (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.0165 g in 1 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>ethylhexyl palmitate</b> (UNII: 2865993309)	
<b>carnauba wax</b> (UNII: R12CBM0EIZ)	
<b>shea butter</b> (UNII: K49155WL9Y)	
<b>silicon dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>octyldodecanol</b> (UNII: 461N1O614Y)	
<b>water</b> (UNII: 059QF0K00R)	
<b>phenoxyethanol</b> (UNII: HIE492ZZ3T)	
<b>microcrystalline wax</b> (UNII: XOF597Q3KY)	
<b>petrolatum</b> (UNII: 4T6H12BN9U)	
<b>methylparaben</b> (UNII: A218C7H9T)	
<b>butylated hydroxytoluene</b> (UNII: 1P9D0Z171K)	
<b>cholesterol</b> (UNII: 97C5T2UQ7J)	
<b>butylparaben</b> (UNII: 3QPHU3FV8)	
<b>ethylparaben</b> (UNII: 14255EXE39)	
<b>candelilla wax</b> (UNII: WL0328HX19)	
<b>yellow wax</b> (UNII: 2ZA36H0S2V)	
<b>cetostearyl alcohol</b> (UNII: 2DMT128M1S)	
<b>cetearyl glucoside</b> (UNII: 09FUA47KNA)	
<b>isobutylparaben</b> (UNII: 0QQJ25X58G)	
<b>propylparaben</b> (UNII: Z8IX2SC1OH)	
<b>maltodextrin</b> (UNII: 7CVR7L4A2D)	
<b>starch, corn</b> (UNII: O8232NY3SJ)	
<b>hyaluronate sodium</b> (UNII: YSE9PPT4TH)	
<b>d&amp;c red no. 7</b> (UNII: ECW0LZ41X8)	
<b>d&amp;c red no. 28</b> (UNII: 767IP0Y5NH)	
<b>aluminum oxide</b> (UNII: LM26O6933)	
<b>ferric oxide red</b> (UNII: 1K09F3G675)	
<b>ferric oxide yellow</b> (UNII: EX438O2MRT)	
<b>ferrosoferric oxide</b> (UNII: XM0M87F357)	
<b>mica</b> (UNII: V8A1AW0880)	
<b>fd&amp;c yellow no. 5</b> (UNII: I753WB2F1M)	
<b>titanium dioxide</b> (UNII: 15FIX9V2JP)	
<b>d&amp;c red no. 6</b> (UNII: 481744AI4O)	
<b>isononyl isononanoate</b> (UNII: S4V5BS6GCX)	
<b>talc</b> (UNII: 7SEV7J4RIU)	
<b>isopropyl myristate</b> (UNII: 0RE8K4LNJS)	
<b>fd&amp;c blue no. 1</b> (UNII: H3R47K3TBD)	
<b>cochineal</b> (UNII: TZ8Z31B35M)	
<b>triethoxycaprylylsilane</b> (UNII: LDC331P08E)	
<b>propylene carbonate</b> (UNII: 8D08K3S51E)	

## Product Characteristics

<b>Color</b>	PINK (Fuchsia Fancy)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-346-02	1 in 1 BOX		
1	NDC:13537-346-01	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	

## ESIKA MAXIMUM COLOR SPF 18

octinoxate and oxybenzone lipstick

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:13537-347
<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	0.073 g in 1 g
<b>Oxybenzone</b> (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.0165 g in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>ethylhexyl palmitate</b> (UNII: 2865993309)	
<b>carnauba wax</b> (UNII: R12CBM0EIZ)	
<b>shea butter</b> (UNII: K49155WL9Y)	
<b>silicon dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>octyldodecanol</b> (UNII: 461N1O614Y)	
<b>water</b> (UNII: 059QF0K00R)	
<b>phenoxyethanol</b> (UNII: HIE492ZZ3T)	
<b>microcrystalline wax</b> (UNII: XOF597Q3KY)	
<b>petrolatum</b> (UNII: 4T6H12BN9U)	
<b>methylparaben</b> (UNII: A218C7H19T)	
<b>butylated hydroxytoluene</b> (UNII: 1P9D0Z171K)	
<b>cholesterol</b> (UNII: 97C5T2UQ7J)	

<b>butylparaben</b> (UNII: 3QP1U3FV8)
<b>ethylparaben</b> (UNII: 14255EXE39)
<b>candelilla wax</b> (UNII: WL0328HX19)
<b>yellow wax</b> (UNII: 2ZA36H0S2V)
<b>cetostearyl alcohol</b> (UNII: 2DMT128M1S)
<b>cetearyl glucoside</b> (UNII: 09FUA47KNA)
<b>isobutylparaben</b> (UNII: 0QQJ25X58G)
<b>propylparaben</b> (UNII: Z8IX2SC1OH)
<b>maltodextrin</b> (UNII: 7CVR7L4A2D)
<b>starch, corn</b> (UNII: O8232NY3SJ)
<b>hyaluronate sodium</b> (UNII: YSE9PPT4TH)
<b>d&amp;c red no. 7</b> (UNII: ECW0LZ41X8)
<b>d&amp;c red no. 28</b> (UNII: 767IP0Y5NH)
<b>aluminum oxide</b> (UNII: LMI26O6933)
<b>ferric oxide red</b> (UNII: 1K09F3G675)
<b>ferric oxide yellow</b> (UNII: EX438O2MRT)
<b>ferrosoferric oxide</b> (UNII: XM0M87F357)
<b>mica</b> (UNII: V8A1AW0880)
<b>fd&amp;c yellow no. 5</b> (UNII: I753WB2F1M)
<b>titanium dioxide</b> (UNII: 15FIX9V2JP)
<b>d&amp;c red no. 6</b> (UNII: 481744AI4O)
<b>isononyl isononanoate</b> (UNII: S4V5BS6GCX)
<b>talc</b> (UNII: 7SEV7J4RIU)
<b>isopropyl myristate</b> (UNII: 0RE8K4LNJS)
<b>fd&amp;c blue no. 1</b> (UNII: H3R47K3TBD)
<b>cochineal</b> (UNII: TZ8Z31B35M)
<b>triethoxycaprylylsilane</b> (UNII: LDC331P08E)
<b>propylene carbonate</b> (UNII: 8D08K3S51E)

### Product Characteristics

<b>Color</b>	PURPLE (Magenta Atrevida)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-347-02	1 in 1 BOX		
1	NDC:13537-347-01	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	

# ESIKA MAXIMUM COLOR SPF 18

octinoxate and oxybenzone lipstick

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:13537-348
<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	0.073 g in 1 g
<b>Oxybenzone</b> (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.0165 g in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>ethylhexyl palmitate</b> (UNII: 2865993309)	
<b>carnauba wax</b> (UNII: R12CBM0EIZ)	
<b>shea butter</b> (UNII: K49155WL9Y)	
<b>silicon dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>octyldodecanol</b> (UNII: 461N1O614Y)	
<b>water</b> (UNII: 059QF0K00R)	
<b>phenoxyethanol</b> (UNII: HIE492ZZ3T)	
<b>microcrystalline wax</b> (UNII: XOF597Q3KY)	
<b>petrolatum</b> (UNII: 4T6H12BN9U)	
<b>methylparaben</b> (UNII: A218C7H9T)	
<b>butylated hydroxytoluene</b> (UNII: 1P9D0Z171K)	
<b>cholesterol</b> (UNII: 97C5T2UQ7J)	
<b>butylparaben</b> (UNII: 3QP1U3FV8)	
<b>ethylparaben</b> (UNII: 14255EXE39)	
<b>candelilla wax</b> (UNII: WL0328HX19)	
<b>yellow wax</b> (UNII: 2ZA36H0S2V)	
<b>cetostearyl alcohol</b> (UNII: 2DMT128M1S)	
<b>cetearyl glucoside</b> (UNII: 09FUA47KNA)	
<b>isobutylparaben</b> (UNII: 0QQJ25X58G)	
<b>propylparaben</b> (UNII: Z8IX2SC1OH)	
<b>maltodextrin</b> (UNII: 7CVR7L4A2D)	
<b>starch, corn</b> (UNII: O8232NY3SJ)	
<b>hyaluronate sodium</b> (UNII: YSE9PPT4TH)	
<b>d&amp;c red no. 7</b> (UNII: ECW0LZ41X8)	
<b>d&amp;c red no. 28</b> (UNII: 767IP0Y5NH)	
<b>aluminum oxide</b> (UNII: LM26O6933)	
<b>ferric oxide red</b> (UNII: 1K09F3G675)	
<b>ferric oxide yellow</b> (UNII: EX438O2MRT)	
<b>ferrosoferric oxide</b> (UNII: XM0M87F357)	
<b>mica</b> (UNII: V8A1AW0880)	
<b>fd&amp;c yellow no. 5</b> (UNII: I753WB2F1M)	
<b>titanium dioxide</b> (UNII: 15FIX9V2JP)	

d&c red no. 6 (UNII: 481744AI4O)	
isononyl isononanoate (UNII: S4V5BS6GCX)	
talc (UNII: 7SEV7J4RIU)	
isopropyl myristate (UNII: 0RE8K4LNJS)	
fd&c blue no. 1 (UNII: H3R47K3TBD)	
cochineal (UNII: TZ8Z31B35M)	
triethoxycaprylylsilane (UNII: LDC331P08E)	
propylene carbonate (UNII: 8D08K3S51E)	

### Product Characteristics

Color	RED (Vino Glamour)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-348-02	1 in 1 BOX		
1	NDC:13537-348-01	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	

## ESIKA MAXIMUM COLOR SPF 18

octinoxate and oxybenzone lipstick

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-349
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.073 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.0165 g in 1 g

### Inactive Ingredients

Ingredient Name	Strength
ethylhexyl palmitate (UNII: 2865993309)	
carnauba wax (UNII: R12CBM0EIZ)	
shea butter (UNII: K49155WL9Y)	

silicon dioxide (UNII: ETJ7Z6XBU4)	
octyldodecanol (UNII: 461N1O614Y)	
water (UNII: 059QF0KO0R)	
phenoxyethanol (UNII: HIE492ZZ3T)	
microcrystalline wax (UNII: XOF597Q3KY)	
petrolatum (UNII: 4T6H12BN9U)	
methylparaben (UNII: A2I8C7HI9T)	
butylated hydroxytoluene (UNII: 1P9D0Z171K)	
cholesterol (UNII: 97C5T2UQ7J)	
butylparaben (UNII: 3QPII1U3FV8)	
ethylparaben (UNII: 14255EXE39)	
candelilla wax (UNII: WL0328HX19)	
yellow wax (UNII: 2ZA36H0S2V)	
cetostearyl alcohol (UNII: 2DMT128M1S)	
cetearyl glucoside (UNII: 09FUA47KNA)	
isobutylparaben (UNII: 0QQJ25X58G)	
propylparaben (UNII: Z8IX2SC10H)	
maltodextrin (UNII: 7CVR7L4A2D)	
starch, corn (UNII: O8232NY3SJ)	
hyaluronate sodium (UNII: YSE9PPT4TH)	
d&c red no. 7 (UNII: ECW0LZ41X8)	
d&c red no. 28 (UNII: 767IP0Y5NH)	
aluminum oxide (UNII: LMI26O6933)	
ferric oxide red (UNII: 1K09F3G675)	
ferric oxide yellow (UNII: EX438O2MRT)	
ferrosoferric oxide (UNII: XM0M87F357)	
mica (UNII: V8A1AW0880)	
fd&c yellow no. 5 (UNII: I753WB2F1M)	
titanium dioxide (UNII: 15FIX9V2JP)	
d&c red no. 6 (UNII: 481744AI4O)	
isononyl isononanoate (UNII: S4V5BS6GCX)	
talc (UNII: 7SEV7J4RIU)	
isopropyl myristate (UNII: 0RE8K4LNJS)	
fd&c blue no. 1 (UNII: H3R47K3TBD)	
cochineal (UNII: TZ8Z31B35M)	
triethoxycaprylylsilane (UNII: LDC331P08E)	
propylene carbonate (UNII: 8D08K3S51E)	

### Product Characteristics

Color	RED (Rosa Divina)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-349-02	1 in 1 BOX		



1	NDC:13537-349-01	4 g in 1 TUBE		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
OTC MONOGRAPH NOT FINAL	part352	05/17/2011		

## ESIKA MAXIMUM COLOR SPF 18

octinoxate and oxybenzone lipstick

<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:13537-350
<b>Route of Administration</b>	TOPICAL		

<b>Active Ingredient/Active Moiety</b>		
<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>Octinoxate</b> (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.073 g in 1 g
<b>Oxybenzone</b> (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.0165 g in 1 g

<b>Inactive Ingredients</b>	
<b>Ingredient Name</b>	<b>Strength</b>
<b>ethylhexyl palmitate</b> (UNII: 2865993309)	
<b>carnauba wax</b> (UNII: R12CBM0EIZ)	
<b>shea butter</b> (UNII: K49155WL9Y)	
<b>silicon dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>octyldodecanol</b> (UNII: 461N10614Y)	
<b>water</b> (UNII: 059QF0KO0R)	
<b>phenoxyethanol</b> (UNII: HIE492ZZ3T)	
<b>microcrystalline wax</b> (UNII: XOF597Q3KY)	
<b>petrolatum</b> (UNII: 4T6H12BN9U)	
<b>methylparaben</b> (UNII: A218C7HI9T)	
<b>butylated hydroxytoluene</b> (UNII: 1P9D0Z171K)	
<b>cholesterol</b> (UNII: 97C5T2UQ7J)	
<b>butylparaben</b> (UNII: 3QPH1U3FV8)	
<b>ethylparaben</b> (UNII: 14255EXE39)	
<b>candelilla wax</b> (UNII: WL0328HX19)	
<b>yellow wax</b> (UNII: 2ZA36H0S2V)	
<b>cetostearyl alcohol</b> (UNII: 2DMT128M1S)	
<b>cetearyl glucoside</b> (UNII: 09FUA47KNA)	
<b>isobutylparaben</b> (UNII: 0QQJ25X58G)	
<b>propylparaben</b> (UNII: Z8IX2SC1OH)	
<b>maltodextrin</b> (UNII: 7CVR7L4A2D)	
<b>starch, corn</b> (UNII: O8232NY3SJ)	
<b>hyaluronate sodium</b> (UNII: YSE9PPT4TH)	

d&c red no. 7 (UNII: ECW0LZ41X8)	
d&c red no. 28 (UNII: 767IP0Y5NH)	
aluminum oxide (UNII: LM26O6933)	
ferric oxide red (UNII: 1K09F3G675)	
ferric oxide yellow (UNII: EX438O2MRT)	
ferrosoferric oxide (UNII: XM0M87F357)	
mica (UNII: V8A1AW0880)	
fd&c yellow no. 5 (UNII: I753WB2F1M)	
titanium dioxide (UNII: 15FIX9V2JP)	
d&c red no. 6 (UNII: 481744AI4O)	
isononyl isononanoate (UNII: S4V5BS6GCX)	
talc (UNII: 7SEV7J4RIU)	
isopropyl myristate (UNII: 0RE8K4LNJS)	
fd&c blue no. 1 (UNII: H3R47K3TBD)	
cochineal (UNII: TZ8Z31B35M)	
triethoxycaprylylsilane (UNII: LDC331P08E)	
propylene carbonate (UNII: 8D08K3S51E)	

### Product Characteristics

Color	RED (Coral Shine)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-350-02	1 in 1 BOX		
1	NDC:13537-350-01	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	

## ESIKA MAXIMUM COLOR SPF 18

octinoxate and oxybenzone lipstick

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-351
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>Octinoxate</b> (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.073 g in 1 g
<b>Oxybenzone</b> (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.0165 g in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>ethylhexyl palmitate</b> (UNII: 2865993309)	
<b>carnauba wax</b> (UNII: R12CBM0EIZ)	
<b>shea butter</b> (UNII: K49155WL9Y)	
<b>silicon dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>octyldodecanol</b> (UNII: 461N10614Y)	
<b>water</b> (UNII: 059QF0KO0R)	
<b>phenoxyethanol</b> (UNII: HIE492ZZ3T)	
<b>microcrystalline wax</b> (UNII: XOF597Q3KY)	
<b>petrolatum</b> (UNII: 4T6H12BN9U)	
<b>methylparaben</b> (UNII: A2I8C7HI9T)	
<b>butylated hydroxytoluene</b> (UNII: 1P9D0Z171K)	
<b>cholesterol</b> (UNII: 97C5T2UQ7J)	
<b>butylparaben</b> (UNII: 3QPII1U3FV8)	
<b>ethylparaben</b> (UNII: 14255EXE39)	
<b>candelilla wax</b> (UNII: WL0328HX19)	
<b>yellow wax</b> (UNII: 2ZA36H0S2V)	
<b>cetostearyl alcohol</b> (UNII: 2DMT128M1S)	
<b>cetearyl glucoside</b> (UNII: 09FUA47KNA)	
<b>isobutylparaben</b> (UNII: 0QQJ25X58G)	
<b>propylparaben</b> (UNII: Z8IX2SC10H)	
<b>maltodextrin</b> (UNII: 7CVR7L4A2D)	
<b>starch, corn</b> (UNII: O8232NY3SJ)	
<b>hyaluronate sodium</b> (UNII: YSE9PPT4TH)	
<b>d&amp;c red no. 7</b> (UNII: ECW0LZ41X8)	
<b>d&amp;c red no. 28</b> (UNII: 767IP0Y5NH)	
<b>aluminum oxide</b> (UNII: LMI26O6933)	
<b>ferric oxide red</b> (UNII: 1K09F3G675)	
<b>ferric oxide yellow</b> (UNII: EX438O2MRT)	
<b>ferrosoferric oxide</b> (UNII: XM0M87F357)	
<b>mica</b> (UNII: V8A1AW0880)	
<b>fd&amp;c yellow no. 5</b> (UNII: I753WB2F1M)	
<b>titanium dioxide</b> (UNII: 15FIX9V2JP)	
<b>d&amp;c red no. 6</b> (UNII: 481744AI4O)	
<b>isononyl isononanoate</b> (UNII: S4V5BS6GCX)	
<b>talc</b> (UNII: 7SEV7J4RIU)	
<b>isopropyl myristate</b> (UNII: 0RE8K4LNJS)	
<b>fd&amp;c blue no. 1</b> (UNII: H3R47K3TBD)	
<b>cochineal</b> (UNII: TZ8Z31B35M)	
<b>triethoxycaprylylsilane</b> (UNII: LDC331P08E)	
<b>propylene carbonate</b> (UNII: 8D08K3S51E)	

### Product Characteristics

<b>Color</b>	BROWN (Mocca Misterio)	<b>Score</b>	
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<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			
<b>Packaging</b>			
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>
1	NDC:13537-351-02	1 in 1 BOX	
1	NDC:13537-351-01	4 g in 1 TUBE	
<b>Marketing Information</b>			
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC MONOGRAPH NOT FINAL	part352	05/17/2011	

## ESIKA MAXIMUM COLOR SPF 18

octinoxate and oxybenzone lipstick

<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:13537-352
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
	Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.073 g in 1 g
	Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.0165 g in 1 g
<b>Inactive Ingredients</b>			
	<b>Ingredient Name</b>	<b>Strength</b>	
	ethylhexyl palmitate (UNII: 2865993309)		
	carnauba wax (UNII: R12CBM0EIZ)		
	shea butter (UNII: K49155WL9Y)		
	silicon dioxide (UNII: ETJ7Z6XBU4)		
	octyldodecanol (UNII: 461N1O614Y)		
	water (UNII: 059QF0KO0R)		
	phenoxyethanol (UNII: HIE492ZZ3T)		
	microcrystalline wax (UNII: XOF597Q3KY)		
	petrolatum (UNII: 4T6H12BN9U)		
	methylparaben (UNII: A2I8C7HI9T)		
	butylated hydroxytoluene (UNII: 1P9D0Z171K)		
	cholesterol (UNII: 97C5T2UQ7J)		
	butylparaben (UNII: 3QPH1U3FV8)		
	ethylparaben (UNII: 14255EXE39)		
	candelilla wax (UNII: WL0328HX19)		

yellow wax (UNII: 2ZA36H0S2V)
cetostearyl alcohol (UNII: 2DMT128M1S)
cetearyl glucoside (UNII: 09FUA47KNA)
isobutylparaben (UNII: 0QQJ25X58G)
propylparaben (UNII: Z8IX2SC1OH)
maltodextrin (UNII: 7CVR7L4A2D)
starch, corn (UNII: O8232NY3SJ)
hyaluronate sodium (UNII: YSE9PPT4TH)
d&c red no. 7 (UNII: ECW0LZ41X8)
d&c red no. 28 (UNII: 767IP0Y5NH)
aluminum oxide (UNII: LM26O6933)
ferric oxide red (UNII: 1K09F3G675)
ferric oxide yellow (UNII: EX438O2MRT)
ferrosoferric oxide (UNII: XM0M87F357)
mica (UNII: V8A1AW0880)
fd&c yellow no. 5 (UNII: I753WB2F1M)
titanium dioxide (UNII: 15FIX9V2JP)
d&c red no. 6 (UNII: 481744AI4O)
isononyl isononanoate (UNII: S4V5BS6GCX)
talc (UNII: 7SEV7J4RIU)
isopropyl myristate (UNII: 0RE8K4LNJS)
fd&c blue no. 1 (UNII: H3R47K3TBD)
cochineal (UNII: TZ8Z31B35M)
triethoxycaprylylsilane (UNII: LDC331P08E)
propylene carbonate (UNII: 8D08K3S51E)

### Product Characteristics

Color	BROWN (Marron Calido)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-352-02	1 in 1 BOX		
1	NDC:13537-352-01	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**

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

Revised: 5/2011

Ventura Corporation (San Juan, P.R)