

ESIKA ULTRA SOFTENING SPF 15- 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.

Esika Ultra-Softening Lipstick FPS 15

Active Ingredients

Octinoxate 6.5%, Oxybenzone 1.82%

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

Ricinus communis seed oil (ricinus communis (castor) seed oil), ethylhexyl palmitate, caprylic/capric triglyceride, polyethylene, candelilla cera (euphorbia cerifera (candelilla) wax), butyrospermum parkii (butyrospermum parkii (shea butter)), cera alba (beeswax), silica dimethyl silylate, glycerin, octyldodecanol, parfum (fragrance), glyceryl isostearate, isostearyl alcohol, sodium saccharin, propylparaben, cera microcristallina (microcrystalline wax), beta-sitosterol, petrolatum, bht, phospholipids, cholesterol, cetearyl alcohol, cetearyl glucoside, copernicia cerifera cera (copernicia cerifera (carnauba) wax), polyglyceryl-2 dipolyhydroxystearate, glycosphingolipids, CI 77742 (manganese violet), CI 77491 (iron oxides), CI 77499 (iron oxides), CI 77492 (iron oxides), CI 77891 (titanium dioxide), CI 45410 (red 27 lake), CI 15850 (red 7 lake), CI 45380 (red 21 lake), CI 19140 (yellow 5 lake), CI 77019 (mica), CI 73360 (red 30 lake), talc, CI 42090 (blue 1 lake), CI 75470 (carmine)

PRINCIPAL DISPLAY PANEL - 4 g Carton - ROJO PROVOCACION

ēsika

**Ultra-Softening
Lipstick SPF 15**

4 g e (.14 oz.)

Active Ingredients: Octinoxate 6.5%, Oxybenzone 1.82%.

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: Ricinus communis seed oil (ricinus communis (castor) seed oil), ethylhexyl palmitate, caprylic/capric triglyceride, polyethylene, candelilla cera (euphorbia cerifera (candelilla) wax), butyrospermum parkii (butyrospermum parkii (shea butter)), cera alba (beeswax), silica dimethyl silylate, glycerin, octylododecanol, parfum (fragrance), glyceryl isostearate, isostearyl

alcohol, sodium saccharin, propylparaben, cera microcristallina (microcrystalline wax), beta-sitosterol, petrolatum, bht, phospholipids, cholesterol, cetearyl alcohol, cetearyl glucoside, copernicia cerifera cera (copernicia cerifera (carnauba) wax), polyglyceryl-2 dipolyhydroxystearate, glycosphingolipids, CI 77742 (manganese violet), CI 77491 (iron oxides), CI 77499 (iron oxides), CI 77492 (iron oxides), CI 77891 (titanium dioxide), CI 45410 (red 27 lake), CI 15850 (red 7 lake), CI 45380 (red 21 lake), CI 19140 (yellow 5 lake), CI 77019 (mica), CI 73360 (red 30 lake), talc, CI 42090 (blue 1 lake), CI 75470 (carmine).

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

ESIKA

Ultra-Softening
Lipstick SPF 15

4 g e (.14 oz.)



PRINCIPAL DISPLAY PANEL - 4 g Carton - ROJO VIVAZ

Ēsika

**Ultra-Softening
Lipstick SPF 15**

4 g e (.14 oz.)

Active Ingredients: Octinoxate 6.5%, Oxybenzone 1.82%.

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: Ricinus communis seed oil (ricinus communis (castor) seed oil), ethylhexyl palmitate, caprylic/capric triglyceride, polyethylene, candelilla cera (euphorbia cerifera (candelilla) wax), butyrospermum parkii (butyrospermum parkii (shea butter)), cera alba (beeswax), silica dimethyl silylate, glycerin, octylododecanol, parfum (fragrance), glyceryl isostearate, isostearyl


alcohol, sodium saccharin, propylparaben, cera microcristallina (microcrystalline wax), beta-sitosterol, petrolatum, bht, phospholipids, cholesterol, cetearyl alcohol, cetearyl glucoside, copernicia cerifera cera (copernicia cerifera (carnauba) wax), polyglyceryl-2 dipolyhydroxystearate, glycosphingolipids, CI 77742 (manganese violet), CI 77491 (iron oxides), CI 77499 (iron oxides), CI 77492 (iron oxides), CI 77891 (titanium dioxide), CI 45410 (red 27 lake), CI 15850 (red 7 lake), CI 45380 (red 21 lake), CI 19140 (yellow 5 lake), CI 77019 (mica), CI 73360 (red 30 lake), talc, CI 42090 (blue 1 lake), CI 75470 (carmine).

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Ultra-Softening
Lipstick SPF 15

4 g e (.14 oz.)



PRINCIPAL DISPLAY PANEL - 4 g Carton - FUCSIA FANTASIA

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**Ultra-Softening
Lipstick SPF 15**

4 g e (.14 oz.)

Active Ingredients: Octinoxate 6.5%, Oxybenzone 1.82%.

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: Ricinus communis seed oil (ricinus communis (castor) seed oil), ethylhexyl palmitate, caprylic/capric triglyceride, polyethylene, candelilla cera (euphorbia cerifera (candelilla) wax), butyrospermum parkii (butyrospermum parkii (shea butter)), cera alba (beeswax), silica dimethyl silylate, glycerin, octylododecanol, parfum (fragrance), glyceryl isostearate, isostearyl


alcohol, sodium saccharin, propylparaben, cera microcristallina (microcrystalline wax), beta-sitosterol, petrolatum, bht, phospholipids, cholesterol, cetearyl alcohol, cetearyl glucoside, copernicia cerifera cera (copernicia cerifera (carnauba) wax), polyglyceryl-2 dipolyhydroxystearate, glycosphingolipids, CI 77742 (manganese violet), CI 77491 (iron oxides), CI 77499 (iron oxides), CI 77492 (iron oxides), CI 77891 (titanium dioxide), CI 45410 (red 27 lake), CI 15850 (red 7 lake), CI 45380 (red 21 lake), CI 19140 (yellow 5 lake), CI 77019 (mica), CI 73360 (red 30 lake), talc, CI 42090 (blue 1 lake), CI 75470 (carmine).

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Ultra-Softening
Lipstick SPF 15

4 g e (.14 oz.)



PRINCIPAL DISPLAY PANEL - 4 g Carton - FUCSIA SEDUCTOR

ēsika

**Ultra-Softening
Lipstick SPF 15**

4 g e (.14 oz.)

Active Ingredients: Octinoxate 6.5%, Oxybenzone 1.82%.

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: Ricinus communis seed oil (ricinus communis (castor) seed oil), ethylhexyl palmitate, caprylic/capric triglyceride, polyethylene, candelilla cera (euphorbia cerifera (candelilla) wax), butyrospermum parkii (butyrospermum parkii (shea butter)), cera alba (beeswax), silica dimethyl silylate, glycerin, octyldodecanol, parfüm (fragrance), glyceryl isostearate, isostearyl


alcohol, sodium saccharin, propylparaben, cera microcristallina (microcrystalline wax), beta-sitosterol, petrolatum, bht, phospholipids, cholesterol, cetearyl alcohol, cetearyl glucoside, copernicia cerifera cera (copernicia cerifera (carnauba) wax), polyglyceryl-2 dipolyhydroxystearate, glycosphingolipids, CI 77742 (manganese violet), CI 77491 (iron oxides), CI 77499 (iron oxides), CI 77492 (iron oxides), CI 77891 (titanium dioxide), CI 45410 (red 27 lake), CI 15850 (red 7 lake), CI 45380 (red 21 lake), CI 19140 (yellow 5 lake), CI 77019 (mica), CI 73360 (red 30 lake), talc, CI 42090 (blue 1 lake), CI 75470 (carmine).

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Ultra-Softening
Lipstick SPF 15

4 g e (.14 oz.)



PRINCIPAL DISPLAY PANEL - 4 g Carton - ROSA INTRIGA

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**Ultra-Softening
Lipstick SPF 15**

4 g e (.14 oz.)

Active Ingredients: Octinoxate 6.5%, Oxybenzone 1.82%.

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: Ricinus communis seed oil (ricinus communis (castor) seed oil), ethylhexyl palmitate, caprylic/capric triglyceride, polyethylene, candelilla cera (euphorbia cerifera (candelilla) wax), butyrospermum parkii (butyrospermum parkii (shea butter)), cera alba (beeswax), silica dimethyl silylate, glycerin, octyldodecanol, parfüm (fragrance), glyceryl isostearate, isostearyl


alcohol, sodium saccharin, propylparaben, cera microcristallina (microcrystalline wax), beta-sitosterol, petrolatum, bht, phospholipids, cholesterol, cetearyl alcohol, cetearyl glucoside, copernicia cerifera cera (copernicia cerifera (carnauba) wax), polyglyceryl-2 dipolyhydroxystearate, glycosphingolipids, CI 77742 (manganese violet), CI 77491 (iron oxides), CI 77499 (iron oxides), CI 77492 (iron oxides), CI 77891 (titanium dioxide), CI 45410 (red 27 lake), CI 15850 (red 7 lake), CI 45380 (red 21 lake), CI 19140 (yellow 5 lake), CI 77019 (mica), CI 73360 (red 30 lake), talc, CI 42090 (blue 1 lake), CI 75470 (carmine).

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Ultra-Softening
Lipstick SPF 15

4 g e (.14 oz.)



PRINCIPAL DISPLAY PANEL - 4 g Carton - MORADO OBSESION

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**Ultra-Softening
Lipstick SPF 15**

4 g e (.14 oz.)

Active Ingredients: Octinoxate 6.5%, Oxybenzone 1.82%.

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: Ricinus communis seed oil (ricinus communis (castor) seed oil), ethylhexyl palmitate, caprylic/capric triglyceride, polyethylene, candelilla cera (euphorbia cerifera (candelilla) wax), butyrospermum parkii (butyrospermum parkii (shea butter)), cera alba (beeswax), silica dimethyl silylate, glycerin, octyldodecanol, parfüm (fragrance), glyceryl isostearate, isostearyl


alcohol, sodium saccharin, propylparaben, cera microcristallina (microcrystalline wax), beta-sitosterol, petrolatum, bht, phospholipids, cholesterol, cetearyl alcohol, cetearyl glucoside, copernicia cerifera cera (copernicia cerifera (carnauba) wax), polyglyceryl-2 dipolyhydroxystearate, glycosphingolipids, CI 77742 (manganese violet), CI 77491 (iron oxides), CI 77499 (iron oxides), CI 77492 (iron oxides), CI 77891 (titanium dioxide), CI 45410 (red 27 lake), CI 15850 (red 7 lake), CI 45380 (red 21 lake), CI 19140 (yellow 5 lake), CI 77019 (mica), CI 73360 (red 30 lake), talc, CI 42090 (blue 1 lake), CI 75470 (carmine).

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Ultra-Softening
Lipstick SPF 15

4 g e (.14 oz.)



PRINCIPAL DISPLAY PANEL - 4 g Carton - ROSA COQUETA

ēsika

**Ultra-Softening
Lipstick SPF 15**

4 g e (.14 oz.)

Active Ingredients: Octinoxate 6.5%, Oxybenzone 1.82%.

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: Ricinus communis seed oil (ricinus communis (castor) seed oil), ethylhexyl palmitate, caprylic/capric triglyceride, polyethylene, candelilla cera (euphorbia cerifera (candelilla) wax), butyrospermum parkii (butyrospermum parkii (shea butter)), cera alba (beeswax), silica dimethyl silylate, glycerin, octyldodecanol, parfüm (fragrance), glyceryl isostearate, isostearyl


alcohol, sodium saccharin, propylparaben, cera microcristallina (microcrystalline wax), beta-sitosterol, petrolatum, bht, phospholipids, cholesterol, cetearyl alcohol, cetearyl glucoside, copernicia cerifera cera (copernicia cerifera (carnauba) wax), polyglyceryl-2 dipolyhydroxystearate, glycosphingolipids, CI 77742 (manganese violet), CI 77491 (iron oxides), CI 77499 (iron oxides), CI 77492 (iron oxides), CI 77891 (titanium dioxide), CI 45410 (red 27 lake), CI 15850 (red 7 lake), CI 45380 (red 21 lake), CI 19140 (yellow 5 lake), CI 77019 (mica), CI 73360 (red 30 lake), talc, CI 42090 (blue 1 lake), CI 75470 (carmine).

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Ultra-Softening
Lipstick SPF 15

4 g e (.14 oz.)



PRINCIPAL DISPLAY PANEL - 4 g Carton - MALVA ILUSION

ēsika

**Ultra-Softening
Lipstick SPF 15**

4 g e (.14 oz.)

Active Ingredients: Octinoxate 6.5%, Oxybenzone 1.82%.

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: Ricinus communis seed oil (ricinus communis (castor) seed oil), ethylhexyl palmitate, caprylic/capric triglyceride, polyethylene, candelilla cera (euphorbia cerifera (candelilla) wax), butyrospermum parkii (butyrospermum parkii (shea butter)), cera alba (beeswax), silica dimethyl silylate, glycerin, octylododecanol, parfüm (fragrance), glyceryl isostearate, isostearyl


alcohol, sodium saccharin, propylparaben, cera microcristallina (microcrystalline wax), beta-sitosterol, petrolatum, bht, phospholipids, cholesterol, cetearyl alcohol, cetearyl glucoside, copernicia cerifera cera (copernicia cerifera (carnauba) wax), polyglyceryl-2 dipolyhydroxystearate, glycosphingolipids, CI 77742 (manganese violet), CI 77491 (iron oxides), CI 77499 (iron oxides), CI 77492 (iron oxides), CI 77891 (titanium dioxide), CI 45410 (red 27 lake), CI 15850 (red 7 lake), CI 45380 (red 21 lake), CI 19140 (yellow 5 lake), CI 77019 (mica), CI 73360 (red 30 lake), talc, CI 42090 (blue 1 lake), CI 75470 (carmine).

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Ultra-Softening
Lipstick SPF 15

4 g e (.14 oz.)



PRINCIPAL DISPLAY PANEL - 4 g Carton - VINO SENSUAL

ēsika

**Ultra-Softening
Lipstick SPF 15**

4 g e (.14 oz.)

Active Ingredients: Octinoxate 6.5%, Oxybenzone 1.82%.

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: Ricinus communis seed oil (ricinus communis (castor) seed oil), ethylhexyl palmitate, caprylic/capric triglyceride, polyethylene, candelilla cera (euphorbia cerifera (candelilla) wax), butyrospermum parkii (butyrospermum parkii (shea butter)), cera alba (beeswax), silica dimethyl silylate, glycerin, octylododecanol, parfum (fragrance), glyceryl isostearate, isostearyl


alcohol, sodium saccharin, propylparaben, cera microcristallina (microcrystalline wax), beta-sitosterol, petrolatum, bht, phospholipids, cholesterol, cetearyl alcohol, cetearyl glucoside, copernicia cerifera cera (copernicia cerifera (carnauba) wax), polyglyceryl-2 dipolyhydroxystearate, glycosphingolipids, CI 77742 (manganese violet), CI 77491 (iron oxides), CI 77499 (iron oxides), CI 77492 (iron oxides), CI 77891 (titanium dioxide), CI 45410 (red 27 lake), CI 15850 (red 7 lake), CI 45380 (red 21 lake), CI 19140 (yellow 5 lake), CI 77019 (mica), CI 73360 (red 30 lake), talc, CI 42090 (blue 1 lake), CI 75470 (carmine).

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Ultra-Softening
Lipstick SPF 15

4 g e (.14 oz.)



PRINCIPAL DISPLAY PANEL - 4 g Carton - MARRON OTONO

ēsika

**Ultra-Softening
Lipstick SPF 15**

4 g e (.14 oz.)

Active Ingredients: Octinoxate 6.5%, Oxybenzone 1.82%.

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: Ricinus communis seed oil (ricinus communis (castor) seed oil), ethylhexyl palmitate, caprylic/capric triglyceride, polyethylene, candelilla cera (euphorbia cerifera (candelilla) wax), butyrospermum parkii (butyrospermum parkii (shea butter)), cera alba (beeswax), silica dimethyl silylate, glycerin, octylododecanol, parfüm (fragrance), glyceryl isostearate, isostearyl


alcohol, sodium saccharin, propylparaben, cera microcristallina (microcrystalline wax), beta-sitosterol, petrolatum, bht, phospholipids, cholesterol, cetearyl alcohol, cetearyl glucoside, copernicia cerifera cera (copernicia cerifera (carnauba) wax), polyglyceryl-2 dipolyhydroxystearate, glycosphingolipids, CI 77742 (manganese violet), CI 77491 (iron oxides), CI 77499 (iron oxides), CI 77492 (iron oxides), CI 77891 (titanium dioxide), CI 45410 (red 27 lake), CI 15850 (red 7 lake), CI 45380 (red 21 lake), CI 19140 (yellow 5 lake), CI 77019 (mica), CI 73360 (red 30 lake), talc, CI 42090 (blue 1 lake), CI 75470 (carmine).

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Ultra-Softening
Lipstick SPF 15

4 g e (.14 oz.)



PRINCIPAL DISPLAY PANEL - 4 g Carton - MARRON TENTACION

ēsika

**Ultra-Softening
Lipstick SPF 15**

4 g e (.14 oz.)

Active Ingredients: Octinoxate 6.5%, Oxybenzone 1.82%.

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: Ricinus communis seed oil (ricinus communis (castor) seed oil), ethylhexyl palmitate, caprylic/capric triglyceride, polyethylene, candelilla cera (euphorbia cerifera (candelilla) wax), butyrospermum parkii (butyrospermum parkii (shea butter)), cera alba (beeswax), silica dimethyl silylate, glycerin, octylododecanol, parfum (fragrance), glyceryl isostearate, isostearyl


alcohol, sodium saccharin, propylparaben, cera microcristallina (microcrystalline wax), beta-sitosterol, petrolatum, bht, phospholipids, cholesterol, cetearyl alcohol, cetearyl glucoside, copernicia cerifera cera (copernicia cerifera (carnauba) wax), polyglyceryl-2 dipolyhydroxystearate, glycosphingolipids, CI 77742 (manganese violet), CI 77491 (iron oxides), CI 77499 (iron oxides), CI 77492 (iron oxides), CI 77891 (titanium dioxide), CI 45410 (red 27 lake), CI 15850 (red 7 lake), CI 45380 (red 21 lake), CI 19140 (yellow 5 lake), CI 77019 (mica), CI 73360 (red 30 lake), talc, CI 42090 (blue 1 lake), CI 75470 (carmine).

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Ultra-Softening
Lipstick SPF 15

4 g e (.14 oz.)



PRINCIPAL DISPLAY PANEL - 4 g Carton - ROSADO MAGICO

ēsika

**Ultra-Softening
Lipstick SPF 15**

4 g e (.14 oz.)

Active Ingredients: Octinoxate 6.5%, Oxybenzone 1.82%.

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: Ricinus communis seed oil (ricinus communis (castor) seed oil), ethylhexyl palmitate, caprylic/capric triglyceride, polyethylene, candelilla cera (euphorbia cerifera (candelilla) wax), butyrospermum parkii (butyrospermum parkii (shea butter)), cera alba (beeswax), silica dimethyl silylate, glycerin, octylododecanol, parfüm (fragrance), glyceryl isostearate, isostearyl

alcohol, sodium saccharin, propylparaben, cera microcristallina (microcrystalline wax), beta-sitosterol, petrolatum, bht, phospholipids, cholesterol, cetearyl alcohol, cetearyl glucoside, copernicia cerifera cera (copernicia cerifera (carnauba) wax), polyglyceryl-2 dipolyhydroxystearate, glycosphingolipids, CI 77742 (manganese violet), CI 77491 (iron oxides), CI 77499 (iron oxides), CI 77492 (iron oxides), CI 77891 (titanium dioxide), CI 45410 (red 27 lake), CI 15850 (red 7 lake), CI 45380 (red 21 lake), CI 19140 (yellow 5 lake), CI 77019 (mica), CI 73360 (red 30 lake), talc, CI 42090 (blue 1 lake), CI 75470 (carmine).

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Ultra-Softening
Lipstick SPF 15

4 g e (.14 oz.)

ESIKA ULTRA SOFTENING SPF 15

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-049
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.065 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.0182 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
castor oil (UNII: D5340Y2I9G)	
ethylhexyl palmitate (UNII: 2865993309)	
medium-chain triglycerides (UNII: C9H2L21V7U)	
high density polyethylene (UNII: UG00KM4WR7)	
candelilla wax (UNII: WL0328HX19)	
shea butter (UNII: K49155WL9Y)	
yellow wax (UNII: 2ZA36H0S2V)	
glycerin (UNII: PDC6A3C0OX)	
octyldodecanol (UNII: 461N1O614Y)	
glyceryl isostearate (UNII: HYE7O27HAO)	
isostearyl alcohol (UNII: Q613OCQ44Y)	
saccharin sodium (UNII: SB8ZUX40TY)	
propylparaben (UNII: Z8IX2SC1OH)	
microcrystalline wax (UNII: XOF597Q3KY)	
.beta.-sitosterol (UNII: S347WMO6M4)	
petrolatum (UNII: 4T6H12BN9U)	
butylated hydroxytoluene (UNII: 1P9D0Z171K)	
cholesterol (UNII: 97C5T2UQ7J)	
cetostearyl alcohol (UNII: 2DMT128M1S)	
cetearyl glucoside (UNII: 09FUA47KNA)	
carnauba wax (UNII: R12CBM0EIZ)	
ferric oxide red (UNII: 1K09F3G675)	
ferrosoferric oxide (UNII: XM0M87F357)	
ferric oxide yellow (UNII: EX438O2MRT)	
titanium dioxide (UNII: 15FIX9V2JP)	
D&C red no. 27 (UNII: 2LRS185U6K)	
D&C red no. 7 (UNII: ECW0LZ41X8)	
D&C red no. 21 (UNII: 08744Z6JNY)	
FD&C yellow no. 5 (UNII: I753WB2F1M)	
D&C red no. 30 (UNII: 2S42T2808B)	

FD&C blue no. 1 (UNII: H3R47K3TBD)	
mica (UNII: V8A1AW0880)	
talc (UNII: 7SEV7J4RIU)	
cochineal (UNII: TZ8Z31B35M)	

Product Characteristics

Color	RED (ROJO PROVOCACION)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-049-02	1 in 1 BOX		
1	NDC:13537-049-01	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	09/23/2011	

ESIKA ULTRA SOFTENING SPF 15

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-050
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.065 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.0182 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
castor oil (UNII: D5340Y2I9G)	
ethylhexyl palmitate (UNII: 2865993309)	
medium-chain triglycerides (UNII: C9H2L21V7U)	
high density polyethylene (UNII: UG00KM4WR7)	
candelilla wax (UNII: WL0328HX19)	
shea butter (UNII: K49155WL9Y)	
yellow wax (UNII: 2ZA36H0S2V)	

glycerin (UNII: PDC6A3C0OX)
octyldodecanol (UNII: 461N1O614Y)
glyceryl isostearate (UNII: HYE7O27HAO)
isostearyl alcohol (UNII: Q613OCQ44Y)
saccharin sodium (UNII: SB8ZUX40TY)
propylparaben (UNII: Z8IX2SC1OH)
microcrystalline wax (UNII: XOF597Q3KY)
.beta.-sitosterol (UNII: S347WMO6M4)
petrolatum (UNII: 4T6H12BN9U)
butylated hydroxytoluene (UNII: 1P9D0Z171K)
cholesterol (UNII: 97C5T2UQ7J)
cetostearyl alcohol (UNII: 2DMT128M1S)
cetearyl glucoside (UNII: 09FUA47KNA)
carnauba wax (UNII: R12CBM0EIZ)
ferric oxide red (UNII: 1K09F3G675)
ferrosoferric oxide (UNII: XM0M87F357)
ferric oxide yellow (UNII: EX438O2MRT)
titanium dioxide (UNII: 15FIX9V2JP)
D&C red no. 27 (UNII: 2LRS185U6K)
D&C red no. 7 (UNII: ECW0LZ41X8)
D&C red no. 21 (UNII: 08744Z6JNY)
FD&C yellow no. 5 (UNII: I753WB2F1M)
D&C red no. 30 (UNII: 2S42T2808B)
FD&C blue no. 1 (UNII: H3R47K3TBD)
aluminum oxide (UNII: LM26O6933)
mica (UNII: V8A1AW0880)
talc (UNII: 7SEV7J4R1U)
cochineal (UNII: TZ8Z31B35M)

Product Characteristics

Color	RED (ROJO VIVAZ)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-050-02	1 in 1 BOX		
1	NDC:13537-050-01	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	09/23/2011	

ESIKA ULTRA SOFTENING SPF 15

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-051
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.065 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.0182 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
castor oil (UNII: D5340Y2I9G)	
ethylhexyl palmitate (UNII: 2865993309)	
medium-chain triglycerides (UNII: C9H2L21V7U)	
high density polyethylene (UNII: UG00KM4WR7)	
candelilla wax (UNII: WL0328HX19)	
shea butter (UNII: K49155WL9Y)	
yellow wax (UNII: 2ZA36H0S2V)	
glycerin (UNII: PDC6A3C0OX)	
octyldodecanol (UNII: 461N1O614Y)	
glyceryl isostearate (UNII: HYE7O27HAO)	
isostearyl alcohol (UNII: Q613OCQ44Y)	
saccharin sodium (UNII: SB8ZUX40TY)	
propylparaben (UNII: Z8IX2SC1OH)	
microcrystalline wax (UNII: XOF597Q3KY)	
.beta.-sitosterol (UNII: S347WMO6M4)	
petrolatum (UNII: 4T6H12BN9U)	
butylated hydroxytoluene (UNII: 1P9D0Z171K)	
cholesterol (UNII: 97C5T2UQ7J)	
cetostearyl alcohol (UNII: 2DMT128M1S)	
cetearyl glucoside (UNII: 09FUA47KNA)	
carnauba wax (UNII: R12CBM0EIZ)	
ferric oxide red (UNII: 1K09F3G675)	
ferrosoferric oxide (UNII: XM0M87F357)	
ferric oxide yellow (UNII: EX438O2MRT)	
titanium dioxide (UNII: 15FIX9V2JP)	
D&C red no. 27 (UNII: 2LRS185U6K)	
D&C red no. 7 (UNII: ECW0LZ41X8)	
D&C red no. 21 (UNII: 08744Z6JNY)	
FD&C yellow no. 5 (UNII: I753WB2F1M)	
D&C red no. 30 (UNII: 2S42T2808B)	
FD&C blue no. 1 (UNII: H3R47K3TBD)	
aluminum oxide (UNII: LMI26O6933)	

mica (UNII: V8A1AW0880)	
talc (UNII: 7SEV7J4R1U)	
cochineal (UNII: TZ8Z31B35M)	

Product Characteristics

Color	PURPLE (FUCSIA FANTASIA)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-051-02	1 in 1 BOX		
1	NDC:13537-051-01	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	09/23/2011	

ESIKA ULTRA SOFTENING SPF 15

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-052
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.065 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.0182 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
castor oil (UNII: D5340Y2I9G)	
ethylhexyl palmitate (UNII: 2865993309)	
medium-chain triglycerides (UNII: C9H2L21V7U)	
high density polyethylene (UNII: UG00KM4WR7)	
candelilla wax (UNII: WL0328HX19)	
shea butter (UNII: K49155WL9Y)	
yellow wax (UNII: 2ZA36H0S2V)	
glycerin (UNII: PDC6A3C0OX)	

octyldodecanol (UNII: 461N1O614Y)
glyceryl isostearate (UNII: HYE7O27HAO)
isostearyl alcohol (UNII: Q613OCQ44Y)
saccharin sodium (UNII: SB8ZUX40TY)
propylparaben (UNII: Z8IX2SC1OH)
microcrystalline wax (UNII: XOF597Q3KY)
.beta.-sitosterol (UNII: S347WMO6M4)
petrolatum (UNII: 4T6H12BN9U)
butylated hydroxytoluene (UNII: 1P9D0Z171K)
cholesterol (UNII: 97C5T2UQ7J)
cetostearyl alcohol (UNII: 2DMT128M1S)
cetearyl glucoside (UNII: 09FUA47KNA)
carnauba wax (UNII: R12CBM0EIZ)
ferric oxide red (UNII: 1K09F3G675)
ferrosoferric oxide (UNII: XM0M87F357)
ferric oxide yellow (UNII: EX438O2MRT)
titanium dioxide (UNII: 15FIX9V2JP)
D&C red no. 27 (UNII: 2LRS185U6K)
D&C red no. 7 (UNII: ECW0LZ41X8)
D&C red no. 21 (UNII: 08744Z6JNY)
FD&C yellow no. 5 (UNII: I753WB2F1M)
D&C red no. 30 (UNII: 2S42T2808B)
FD&C blue no. 1 (UNII: H3R47K3TBD)
aluminum oxide (UNII: LM26O6933)
mica (UNII: V8A1AW0880)
talc (UNII: 7SEV7J4RIU)
cochineal (UNII: TZ8Z31B35M)

Product Characteristics

Color	PURPLE (FUCSIA SEDUCTOR)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-052-02	1 in 1 BOX		
1	NDC:13537-052-01	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	09/23/2011	

ESIKA ULTRA SOFTENING SPF 15

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-053
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.065 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.0182 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
castor oil (UNII: D5340Y2I9G)	
ethylhexyl palmitate (UNII: 2865993309)	
medium-chain triglycerides (UNII: C9H2L21V7U)	
high density polyethylene (UNII: UG00KM4WR7)	
candelilla wax (UNII: WL0328HX19)	
shea butter (UNII: K49155WL9Y)	
yellow wax (UNII: 2ZA36H0S2V)	
glycerin (UNII: PDC6A3C0OX)	
octyldodecanol (UNII: 461N1O614Y)	
glyceryl isostearate (UNII: HYE7O27HAO)	
isostearyl alcohol (UNII: Q613OCQ44Y)	
saccharin sodium (UNII: SB8ZUX40TY)	
propylparaben (UNII: Z8IX2SC1OH)	
microcrystalline wax (UNII: XOF597Q3KY)	
.beta.-sitosterol (UNII: S347WMO6M4)	
petrolatum (UNII: 4T6H12BN9U)	
butylated hydroxytoluene (UNII: 1P9D0Z171K)	
cholesterol (UNII: 97C5T2UQ7J)	
cetostearyl alcohol (UNII: 2DMT128M1S)	
cetearyl glucoside (UNII: 09FUA47KNA)	
carnauba wax (UNII: R12CBM0EIZ)	
ferric oxide red (UNII: 1K09F3G675)	
ferrosoferric oxide (UNII: XM0M87F357)	
ferric oxide yellow (UNII: EX438O2MRT)	
titanium dioxide (UNII: 15FIX9V2JP)	
D&C red no. 27 (UNII: 2LRS185U6K)	
D&C red no. 7 (UNII: ECW0LZ41X8)	
D&C red no. 21 (UNII: 08744Z6JNY)	
FD&C yellow no. 5 (UNII: I753WB2F1M)	
D&C red no. 30 (UNII: 2S42T2808B)	
FD&C blue no. 1 (UNII: H3R47K3TBD)	
aluminum oxide (UNII: LM26O6933)	
mica (UNII: V8A1AW0880)	

talc (UNII: 7SEV7J4RIU)	
cochineal (UNII: TZ8Z31B35M)	

Product Characteristics

Color	RED (ROSA INTRIGA)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-053-02	1 in 1 BOX		
1	NDC:13537-053-01	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	09/23/2011	

ESIKA ULTRA SOFTENING SPF 15

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-054
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.065 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.0182 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
castor oil (UNII: D5340Y2I9G)	
ethylhexyl palmitate (UNII: 2865993309)	
medium-chain triglycerides (UNII: C9H2L21V7U)	
high density polyethylene (UNII: UG00KM4WR7)	
candelilla wax (UNII: WL0328HX19)	
shea butter (UNII: K49155WL9Y)	
yellow wax (UNII: 2ZA36H0S2V)	
glycerin (UNII: PDC6A3C0OX)	
octyldodecanol (UNII: 461N1O614Y)	

glyceryl isostearate (UNII: HYE7O27HAO)	
isostearyl alcohol (UNII: Q613OCQ44Y)	
saccharin sodium (UNII: SB8ZUX40TY)	
propylparaben (UNII: Z8IX2SC1OH)	
microcrystalline wax (UNII: XOF597Q3KY)	
.beta.-sitosterol (UNII: S347WMO6M4)	
petrolatum (UNII: 4T6H12BN9U)	
butylated hydroxytoluene (UNII: 1P9D0Z171K)	
cholesterol (UNII: 97C5T2UQ7J)	
cetostearyl alcohol (UNII: 2DMT128M1S)	
cetearyl glucoside (UNII: 09FUA47KNA)	
carnauba wax (UNII: R12CBM0EIZ)	
ferric oxide red (UNII: 1K09F3G675)	
ferrosoferric oxide (UNII: XM0M87F357)	
ferric oxide yellow (UNII: EX438O2MRT)	
titanium dioxide (UNII: 15FIX9V2JP)	
D&C red no. 27 (UNII: 2LRS185U6K)	
D&C red no. 7 (UNII: ECW0LZ41X8)	
D&C red no. 21 (UNII: 08744Z6JNY)	
FD&C yellow no. 5 (UNII: I753WB2F1M)	
D&C red no. 30 (UNII: 2S42T2808B)	
FD&C blue no. 1 (UNII: H3R47K3TBD)	
aluminum oxide (UNII: LMI26O6933)	
mica (UNII: V8A1AW0880)	
talc (UNII: 7SEV7J4R1U)	
cochineal (UNII: TZ8Z31B35M)	

Product Characteristics

Color	BROWN (MORADO OBSESION)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-054-02	1 in 1 BOX		
1	NDC:13537-054-01	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	09/23/2011	

ESIKA ULTRA SOFTENING SPF 15
 octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-055
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.065 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.0182 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
castor oil (UNII: D5340Y2I9G)	
ethylhexyl palmitate (UNII: 2865993309)	
medium-chain triglycerides (UNII: C9H2L21V7U)	
high density polyethylene (UNII: UG00KM4WR7)	
candelilla wax (UNII: WL0328HX19)	
shea butter (UNII: K49155WL9Y)	
yellow wax (UNII: 2ZA36H0S2V)	
glycerin (UNII: PDC6A3C0OX)	
octyldodecanol (UNII: 461N1O614Y)	
glyceryl isostearate (UNII: HYE7O27HAO)	
isostearyl alcohol (UNII: Q613OCQ44Y)	
saccharin sodium (UNII: SB8ZUX40TY)	
propylparaben (UNII: Z8IX2SC1OH)	
microcrystalline wax (UNII: XOF597Q3KY)	
.beta.-sitosterol (UNII: S347WMO6M4)	
petrolatum (UNII: 4T6H12BN9U)	
butylated hydroxytoluene (UNII: 1P9D0Z171K)	
cholesterol (UNII: 97C5T2UQ7J)	
cetostearyl alcohol (UNII: 2DMT128M1S)	
cetearyl glucoside (UNII: 09FUA47KNA)	
carnauba wax (UNII: R12CBM0EIZ)	
ferric oxide red (UNII: 1K09F3G675)	
ferrosoferric oxide (UNII: XM0M87F357)	
ferric oxide yellow (UNII: EX438O2MRT)	
titanium dioxide (UNII: 15FIX9V2JP)	
D&C red no. 27 (UNII: 2LRS185U6K)	
D&C red no. 7 (UNII: ECW0LZ41X8)	
D&C red no. 21 (UNII: 08744Z6JNY)	
FD&C yellow no. 5 (UNII: I753WB2F1M)	
D&C red no. 30 (UNII: 2S42T2808B)	
FD&C blue no. 1 (UNII: H3R47K3TBD)	
aluminum oxide (UNII: LM26O6933)	
mica (UNII: V8A1AW0880)	
talc (UNII: 7SEV7J4R1U)	
cochineal (UNII: TZ8Z31B35M)	

Product Characteristics

Color	RED (ROSA COQUETA)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-055-02	1 in 1 BOX		
1	NDC:13537-055-01	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	09/23/2011	

ESIKA ULTRA SOFTENING SPF 15

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-056
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.065 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.0182 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
castor oil (UNII: D5340Y2I9G)	
ethylhexyl palmitate (UNII: 2865993309)	
medium-chain triglycerides (UNII: C9H2L21V7U)	
high density polyethylene (UNII: UG00KM4WR7)	
candelilla wax (UNII: WL0328HX19)	
shea butter (UNII: K49155WL9Y)	
yellow wax (UNII: 2ZA36H0S2V)	
glycerin (UNII: PDC6A3C0OX)	
octyldodecanol (UNII: 461N1O614Y)	
glyceryl isostearate (UNII: HYE7O27HAO)	
isostearyl alcohol (UNII: Q613OCQ44Y)	

saccharin sodium (UNII: SB8ZUX40TY)
propylparaben (UNII: Z8IX2SC1OH)
microcrystalline wax (UNII: XOF597Q3KY)
.beta.-sitosterol (UNII: S347WMO6M4)
petrolatum (UNII: 4T6HI2BN9U)
butylated hydroxytoluene (UNII: 1P9D0Z171K)
cholesterol (UNII: 97C5T2UQ7J)
cetostearyl alcohol (UNII: 2DMT128M1S)
cetearyl glucoside (UNII: 09FUA47KNA)
carnauba wax (UNII: R12CBM0EIZ)
ferric oxide red (UNII: 1K09F3G675)
ferrosoferric oxide (UNII: XM0M87F357)
ferric oxide yellow (UNII: EX438O2MRT)
titanium dioxide (UNII: 15FIX9V2JP)
D&C red no. 27 (UNII: 2LRS185U6K)
D&C red no. 7 (UNII: ECW0LZ41X8)
D&C red no. 21 (UNII: 08744Z6JNY)
FD&C yellow no. 5 (UNII: I753WB2F1M)
D&C red no. 30 (UNII: 2S42T2808B)
FD&C blue no. 1 (UNII: H3R47K3TBD)
aluminum oxide (UNII: LM26O6933)
mica (UNII: V8A1AW0880)
talc (UNII: 7SEV7J4R1U)
cochineal (UNII: TZ8Z31B35M)

Product Characteristics

Color	PINK (MALVA ILUSION)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-056-02	1 in 1 BOX		
1	NDC:13537-056-01	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	09/23/2011	

ESIKA ULTRA SOFTENING SPF 15

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-057
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.065 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.0182 g in 1 g

Inactive Ingredients	
Ingredient Name	Strength
castor oil (UNII: D5340Y2I9G)	
ethylhexyl palmitate (UNII: 2865993309)	
medium-chain triglycerides (UNII: C9H2L21V7U)	
high density polyethylene (UNII: UG00KM4WR7)	
candelilla wax (UNII: WL0328HX19)	
shea butter (UNII: K49155WL9Y)	
yellow wax (UNII: 2ZA36H0S2V)	
glycerin (UNII: PDC6A3C0OX)	
octyldodecanol (UNII: 461N1O614Y)	
glyceryl isostearate (UNII: HYE7O27HAO)	
isostearyl alcohol (UNII: Q613OCQ44Y)	
saccharin sodium (UNII: SB8ZUX40TY)	
propylparaben (UNII: Z8IX2SC1OH)	
microcrystalline wax (UNII: XOF597Q3KY)	
.beta.-sitosterol (UNII: S347WMO6M4)	
petrolatum (UNII: 4T6H12BN9U)	
butylated hydroxytoluene (UNII: 1P9D0Z171K)	
cholesterol (UNII: 97C5T2UQ7J)	
cetostearyl alcohol (UNII: 2DMT128M1S)	
cetearyl glucoside (UNII: 09FUA47KNA)	
carnauba wax (UNII: R12CBM0EIZ)	
ferric oxide red (UNII: 1K09F3G675)	
ferrosoferric oxide (UNII: XM0M87F357)	
ferric oxide yellow (UNII: EX438O2MRT)	
titanium dioxide (UNII: 15FIX9V2JP)	
D&C red no. 27 (UNII: 2LRS185U6K)	
D&C red no. 7 (UNII: ECW0LZ41X8)	
D&C red no. 21 (UNII: 08744Z6JNY)	
FD&C yellow no. 5 (UNII: I753WB2F1M)	
D&C red no. 30 (UNII: 2S42T2808B)	
FD&C blue no. 1 (UNII: H3R47K3TBD)	
aluminum oxide (UNII: LM26O6933)	
mica (UNII: V8A1AW0880)	
talc (UNII: 7SEV7J4RIU)	
cochineal (UNII: TZ8Z31B35M)	

Product Characteristics

Color	RED (VINO SENSUAL)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-057-02	1 in 1 BOX		
1	NDC:13537-057-01	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	09/23/2011	

ESIKA ULTRA SOFTENING SPF 15

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-058
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.065 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.0182 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
castor oil (UNII: D5340Y2I9G)	
ethylhexyl palmitate (UNII: 2865993309)	
medium-chain triglycerides (UNII: C9H2L21V7U)	
high density polyethylene (UNII: UG00KM4WR7)	
candelilla wax (UNII: WL0328HX19)	
shea butter (UNII: K49155WL9Y)	
yellow wax (UNII: 2ZA36H0S2V)	
glycerin (UNII: PDC6A3C0OX)	
octyldodecanol (UNII: 461N1O614Y)	
glyceryl isostearate (UNII: HYE7O27HAO)	
isostearyl alcohol (UNII: Q613OCQ44Y)	
saccharin sodium (UNII: SB8ZUX40TY)	

propylparaben (UNII: Z8IX2SC10H)
microcrystalline wax (UNII: XOF597Q3KY)
.beta.-sitosterol (UNII: S347WMO6M4)
petrolatum (UNII: 4T6H12BN9U)
butylated hydroxytoluene (UNII: 1P9D0Z171K)
cholesterol (UNII: 97C5T2UQ7J)
cetostearyl alcohol (UNII: 2DMT128M1S)
cetearyl glucoside (UNII: 09FUA47KNA)
carnauba wax (UNII: R12CBM0EIZ)
ferric oxide red (UNII: 1K09F3G675)
ferrosoferric oxide (UNII: XM0M87F357)
ferric oxide yellow (UNII: EX438O2MRT)
titanium dioxide (UNII: 15FIX9V2JP)
D&C red no. 27 (UNII: 2LRS185U6K)
D&C red no. 7 (UNII: ECW0LZ41X8)
D&C red no. 21 (UNII: 08744Z6JNY)
FD&C yellow no. 5 (UNII: I753WB2F1M)
D&C red no. 30 (UNII: 2S42T2808B)
FD&C blue no. 1 (UNII: H3R47K3TBD)
aluminum oxide (UNII: LMI26O6933)
mica (UNII: V8A1AW0880)
talc (UNII: 7SEV7J4RIU)
cochineal (UNII: TZ8Z31B35M)

Product Characteristics

Color	BROWN (MARRON OTONO)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-058-02	1 in 1 BOX		
1	NDC:13537-058-01	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	09/23/2011	

ESIKA ULTRA SOFTENING SPF 15

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-059
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Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.065 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.0182 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
castor oil (UNII: D5340Y2I9G)	
ethylhexyl palmitate (UNII: 2865993309)	
medium-chain triglycerides (UNII: C9H2L21V7U)	
high density polyethylene (UNII: UG00KM4WR7)	
candelilla wax (UNII: WL0328HX19)	
shea butter (UNII: K49155WL9Y)	
yellow wax (UNII: 2ZA36H0S2V)	
glycerin (UNII: PDC6A3C0OX)	
octyldodecanol (UNII: 461N1O614Y)	
glyceryl isostearate (UNII: HYE7O27HAO)	
isostearyl alcohol (UNII: Q613OCQ44Y)	
saccharin sodium (UNII: SB8ZUX40TY)	
propylparaben (UNII: Z8IX2SC1OH)	
microcrystalline wax (UNII: XOF597Q3KY)	
.beta.-sitosterol (UNII: S347WMO6M4)	
petrolatum (UNII: 4T6H12BN9U)	
butylated hydroxytoluene (UNII: 1P9D0Z171K)	
cholesterol (UNII: 97C5T2UQ7J)	
cetostearyl alcohol (UNII: 2DMT128M1S)	
cetearyl glucoside (UNII: 09FUA47KNA)	
carnauba wax (UNII: R12CBM0EIZ)	
ferric oxide red (UNII: 1K09F3G675)	
ferrosoferric oxide (UNII: XM0M87F357)	
ferric oxide yellow (UNII: EX438O2MRT)	
titanium dioxide (UNII: 15FIX9V2JP)	
D&C red no. 27 (UNII: 2LRS185U6K)	
D&C red no. 7 (UNII: ECW0LZ41X8)	
D&C red no. 21 (UNII: 08744Z6JNY)	
FD&C yellow no. 5 (UNII: I753WB2F1M)	
D&C red no. 30 (UNII: 2S42T2808B)	
FD&C blue no. 1 (UNII: H3R47K3TBD)	
aluminum oxide (UNII: LMI26O6933)	
mica (UNII: V8A1AW0880)	
talc (UNII: 7SEV7J4RIU)	
cochineal (UNII: TZ8Z31B35M)	

Product Characteristics

Color	BROWN (MARRON TENTACION)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-059-02	1 in 1 BOX		
1	NDC:13537-059-01	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	09/23/2011	

ESIKA ULTRA SOFTENING SPF 15

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-060
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.065 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.0182 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
castor oil (UNII: D5340Y2I9G)	
ethylhexyl palmitate (UNII: 2865993309)	
medium-chain triglycerides (UNII: C9H2L21V7U)	
high density polyethylene (UNII: UG00KM4WR7)	
candelilla wax (UNII: WL0328HX19)	
shea butter (UNII: K49155WL9Y)	
yellow wax (UNII: 2ZA36H0S2V)	
glycerin (UNII: PDC6A3C0OX)	
octyldodecanol (UNII: 461N1O614Y)	
glyceryl isostearate (UNII: HYE7O27HAO)	
isostearyl alcohol (UNII: Q613OCQ44Y)	
saccharin sodium (UNII: SB8ZUX40TY)	
propylparaben (UNII: Z8IX2SC1OH)	
microcrystalline wax (UNII: XOF597Q3KY)	

.beta.-sitosterol (UNII: S347WMO6M4)
petrolatum (UNII: 4T6H12BN9U)
butylated hydroxytoluene (UNII: 1P9D0Z171K)
cholesterol (UNII: 97C5T2UQ7J)
cetostearyl alcohol (UNII: 2DMT128M1S)
cetearyl glucoside (UNII: 09FUA47KNA)
carnauba wax (UNII: R12CBM0EIZ)
ferric oxide red (UNII: 1K09F3G675)
ferrosoferric oxide (UNII: XM0M87F357)
ferric oxide yellow (UNII: EX438O2MRT)
titanium dioxide (UNII: 15FIX9V2JP)
D&C red no. 27 (UNII: 2LRS185U6K)
D&C red no. 7 (UNII: ECW0LZ41X8)
D&C red no. 21 (UNII: 08744Z6JNY)
FD&C yellow no. 5 (UNII: I753WB2F1M)
D&C red no. 30 (UNII: 2S42T2808B)
FD&C blue no. 1 (UNII: H3R47K3TBD)
aluminum oxide (UNII: LM26O6933)
mica (UNII: V8A1AW0880)
talc (UNII: 7SEV7J4RIU)
cochineal (UNII: TZ8Z31B35M)

Product Characteristics

Color	PINK (ROSADO MAGICO)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-060-02	1 in 1 BOX		
1	NDC:13537-060-01	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	09/23/2011	

Labeler - Ventura Corporation (San Juan, P.R) (602751344)

Establishment

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

