

EFFET PARFAIT NATURAL FINISH MOISTURIZING FOUNDATION SPF 25- octinoxate and titanium dioxide lotion
VENTURA INTERNATIONAL LTD

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

**EFFET
PARFAIT
natural finish
moisturizing
foundation
SPF 25**

Drug Facts

<i>Active Ingredient</i>	<i>Purpose</i>
Octinoxate 6.5%,	Sunscreen
Titanium Dioxide 1.6%	Sunscreen

Uses

- Helps prevent sunburn
- Higher SPF gives more sunburn protection
- Provides moderate protection against sunburn

Warnings

For external use only

When using this product

- Keep out of eyes. Rinse with water to remove

Stop use and ask a doctor if

- Rash or irritation develops and lasts

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply generously and evenly before sun exposure and as needed

Other information

- Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreen may reduce the risk of skin aging, skin cancer, and other harmful effects of the sun.

Inactive ingredients

Aqua(water),Cyclopentasiloxane, Cyclohexasiloxane, Propylene Glycol Dicaprylate/dicaprate, Peg/ppg-18/18 Dimethicone, Trimethylsiloxysilicate , Dimethicone/vinyl Dimethicone Crosspolymer,

Xylitylglucoside, Octyldodecanol, Polymethyl methacrylate, Oleth-5, Anhydroxylitol, Glycerin, Linoleic Acid, Peg/ppg-19/19 Dimethicone, Cera Microcristallina (microcrystalline wax), C12-15 Alkyl Benzoate, Xylitol, Diazolidinyl Urea, Alumina, Petrolatum, Tocopheryl Acetate, Triethoxycaprylylsilane, Phospholipids, Ribes Nigrum Seed Oil (ribes nigrum (black currant) seed oil), Silica, Methylparaben, Propylparaben, Copernicia Cerifera Cera (copernicia cerifera (carnauba) wax), Parfum (fragrance), Tribehenin, Cholesterol, Methicone, BHT, Menthoxypropanediol, Cetearyl Alcohol, Cera Alba (beeswax), Candelilla Cera (euphorbia cerifera (candelilla) wax), Polyglyceryl-2 dipolyhydroxystearate, Cetearyl Glucoside, Glycosphingolipids, Ceramide 2, Linolenic Acid, Decyl Glucoside, Peg-10 Rapeseed Sterol, Palmitoyl Oligopeptide. May Contain:CI 77891 (Titanium Dioxide), CI 77491, CI 77492, CI 77499 (Iron Oxides)

PRINCIPAL DISPLAY PANEL - 30 ml Bottle Carton

EFFET
PARFAIT

natural finish
moisturizing
foundation

SPF 25

30 ml e (1 fl.oz.)

L'BEL

Drug Facts

Active Ingredients

Octinoxate 6.5% sunscreen
Titanium Dioxide 1.6% sunscreen

Uses

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- Higher SPF gives more sunburn protection
- Provides moderate protection against sunburn

Warnings

For external use only.

When using this product

- Keep out of eyes. Rinse with water to remove
- Stop use and ask a doctor if
- Rash or irritation develops and lasts.

Drug Facts (continued)

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions ■ Apply generously and evenly before sun exposure and as needed

Other information ■ Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreen may reduce the risk of skin aging, skin cancer, and other harmful effects of the sun.

Inactive ingredients

Aqua (water), Cyclopentasiloxane, Cyclohexastoxane, Propylene Glycol Dicaprylate/dicaprate, Peg/ppg-18/18 Dimethicone, Trimethylsilyloxyethylate, Dimethicone/vinyl Dimethicone Crosspolymer, Xylitylglucoside, Octyltodecanol, Polymethyl methacrylate, Oleth-5, Anhydroxylicol, Glycerin, Linoleic Acid, ▼

Drug Facts (continued)

Peg/ppg-18/18 Dimethicone, Cera Microcristalina (microcrystalline wax), C12-15 Alkyl Benzooate, Xylitol, Diazolidinyl Urea, Alumina, Petrolatum, Tocopheryl Acetate, Triethoxycaprylsilane, Phospholipids, Ribes Nigrum Seed Oil (ribes nigrum (black currant) seed oil), Silica, Methylparaben, Propylparaben, Copernicia Cerifera Cera (copernicia cerifera (carnauba) wax), Parfum (fragrance), Tribehenin, Cetelesterol, Melthicone, BHT, Menthoxypropandiol, Cetearyl Alcohol, Cera Alba (beeswax), Candelilla Cera (euphorbia corifera (candelilla) wax), Polyglyceryl-2 dipolyhydroxystearate, Cetearyl Glucoside, Glycosphingolipids, Ceramide 2, Lindelic Acid, Decyl Glucoside, Peg-10 Rapeseed Sterol, Palmitoyl Oligopeptide. May Contain: CI 77891 (Titanium Dioxide), CI 77492, CI 77493, CI 77499 (Iron Oxides).



EFFET PARFAIT

natural finish
moisturizing
foundation
SPF 25

base de maquillaje
hidratante de
acabado natural
para rostro
FPS 25

30 ml e (1 fl.oz.)

L'BEL

USA: Dist. by Ventura International Ltd, San Francisco, CA 94111, Made in Colombia. **PUERTO RICO:** Dist. by Ventura Corporation, Ltd., San Juan, Puerto Rico 00926, Made in Colombia. www.lbel.com

EFFET PARFAIT NATURAL FINISH MOISTURIZING FOUNDATION SPF 25

octinoxate and titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-170
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.065 mL in 1 mL
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.016 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
Cyclomethicone 5 (UNII: 0THT5PCI0R)	
Cyclomethicone 6 (UNII: XHK3U310BA)	
Propylene Glycol Dicaprylate/Dicaprate (UNII: O4446S9CRA)	
Octyldodecanol (UNII: 461N1O614Y)	
Oleth-5 (UNII: 1GH33785AY)	
Glycerin (UNII: PDC6A3C0OX)	
Linoleic Acid (UNII: 9KJL21T0QJ)	
C12-15 Alkyl Benzoate (UNII: A9EJ3J61HQ)	
Xylitol (UNII: VCQ006KQ1E)	
Diazolidinyl Urea (UNII: H5RIZ3MPW4)	
Aluminum Oxide (UNII: LMI26O6933)	
Petrolatum (UNII: 4T6H12BN9U)	
Alpha-Tocopherol Acetate (UNII: 9E8X80D2L0)	
Octyltriethoxysilane (UNII: LDC331P08E)	
Ribes Nigrum Seed (UNII: EHO0V3IRF5)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Methylparaben (UNII: A2I8C7HI9T)	
Propylparaben (UNII: Z8IX2SC1OH)	
Carnauba Wax (UNII: R12CBM0EIZ)	
Tribehenin (UNII: 8OC9U7TQZ0)	
Cholesterol (UNII: 97C5T2UQ7J)	
Butylated Hydroxytoluene (UNII: 1P9D0Z171K)	
Propanediol (UNII: 5965N8W85T)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
Yellow Wax (UNII: 2ZA36H0S2V)	
Candelilla Wax (UNII: WL0328HX19)	
Cetearyl Glucoside (UNII: 09FUA47KNA)	
Linolenic Acid (UNII: 0RBV727H71)	
Ferric Oxide Red (UNII: 1K09F3G675)	
Ferric Oxide Yellow (UNII: EX438O2MRT)	
Ferrosoferric Oxide (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-170-21	1 in 1 CARTON		
1		40.5 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/16/2010	

EFFET PARFAIT NATURAL FINISH MOISTURIZING FOUNDATION SPF 25

octinoxate and titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-160
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.065 mL in 1 mL
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.016 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
Cyclomethicone 5 (UNII: 0THT5PCI0R)	
Cyclomethicone 6 (UNII: XHK3U310BA)	
Propylene Glycol Dicaprylate/Dicaprate (UNII: O4446S9CRA)	
Octyldodecanol (UNII: 461N1O614Y)	
Oleth-5 (UNII: 1GH33785AY)	
Glycerin (UNII: PDC6A3C0OX)	
Linoleic Acid (UNII: 9KJL21T0QJ)	
C12-15 Alkyl Benzoate (UNII: A9EJ3J61HQ)	
Xylitol (UNII: VCQ006KQ1E)	
Diazolidinyl Urea (UNII: H5RIZ3MPW4)	
Aluminum Oxide (UNII: LMI26O6933)	
Petrolatum (UNII: 4T6H12BN9U)	
Alpha-Tocopherol Acetate (UNII: 9E8X80D2L0)	
Octyltriethoxysilane (UNII: LDC331P08E)	
Ribes Nigrum Seed (UNII: EHO0V3IRF5)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Methylparaben (UNII: A2I8C7HI9T)	

Propylparaben (UNII: Z8IX2SC1OH)
Carnauba Wax (UNII: R12CBM0EIZ)
Tribehenin (UNII: 8OC9U7TQZ0)
Cholesterol (UNII: 97C5T2UQ7J)
Butylated Hydroxytoluene (UNII: 1P9D0Z171K)
Propanediol (UNII: 5965N8W85T)
Cetostearyl Alcohol (UNII: 2DMT128M1S)
Yellow Wax (UNII: 2ZA36H0S2V)
Candelilla Wax (UNII: WL0328HX19)
Cetearyl Glucoside (UNII: 09FUA47KNA)
Linolenic Acid (UNII: 0RBV727H71)
Ferric Oxide Red (UNII: 1K09F3G675)
Ferric Oxide Yellow (UNII: EX438O2MRT)
Ferrosoferric Oxide (UNII: XM0M87F357)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-160-21	1 in 1 CARTON		
1		30 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/16/2010	

EFFET PARFAIT NATURAL FINISH MOISTURIZING FOUNDATION SPF 25
 octinoxate and titanium dioxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-150
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.065 mL in 1 mL
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.016 mL in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
Cyclomethicone 5 (UNII: 0THT5PCI0R)	
Cyclomethicone 6 (UNII: XHK3U310BA)	
Propylene Glycol Dicaprylate/Dicaprate (UNII: O4446S9CRA)	

Octyldodecanol (UNII: 461N1O614Y)	
Oleth-5 (UNII: 1GH33785AY)	
Glycerin (UNII: PDC6A3C0OX)	
Linoleic Acid (UNII: 9KJL21T0QJ)	
C12-15 Alkyl Benzoate (UNII: A9EJ3J61HQ)	
Xylitol (UNII: VCQ006KQ1E)	
Diazolidinyl Urea (UNII: H5RIZ3MPW4)	
Aluminum Oxide (UNII: LMI26O6933)	
Petrolatum (UNII: 4T6H12BN9U)	
Alpha-Tocopherol Acetate (UNII: 9E8X80D2L0)	
Octyltriethoxysilane (UNII: LDC331P08E)	
Ribes Nigrum Seed (UNII: EHO0V3IRF5)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Methylparaben (UNII: A2B8C7HI9T)	
Propylparaben (UNII: Z8IX2SC1OH)	
Carnauba Wax (UNII: R12CBM0EIZ)	
Tribehenin (UNII: 8OC9U7TQZ0)	
Cholesterol (UNII: 97C5T2UQ7J)	
Butylated Hydroxytoluene (UNII: 1P9D0Z171K)	
Propanediol (UNII: 5965N8W85T)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
Yellow Wax (UNII: 2ZA36H0S2V)	
Candelilla Wax (UNII: WL0328HX19)	
Cetearyl Glucoside (UNII: 09FUA47KNA)	
Linolenic Acid (UNII: 0RBV727H71)	
Ferric Oxide Red (UNII: 1K09F3G675)	
Ferric Oxide Yellow (UNII: EX438O2MRT)	
Ferrosoferric Oxide (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-150-21	1 in 1 CARTON		
1		4.5 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/16/2010	

EFFET PARFAIT NATURAL FINISH MOISTURIZING FOUNDATION SPF 25

octinoxate and titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-140
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.065 mL in 1 mL
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.016 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
Cyclomethicone 5 (UNII: 0THT5PCI0R)	
Cyclomethicone 6 (UNII: XHK3U310BA)	
Propylene Glycol Dicaprylate/Dicaprate (UNII: O4446S9CRA)	
Octyldodecanol (UNII: 461N1O614Y)	
Oleth-5 (UNII: 1GH33785AY)	
Glycerin (UNII: PDC6A3C0OX)	
Linoleic Acid (UNII: 9KJL21T0QJ)	
C12-15 Alkyl Benzoate (UNII: A9EJ3J61HQ)	
Xylitol (UNII: VCQ006KQ1E)	
Diazolidinyl Urea (UNII: H5RIZ3MPW4)	
Aluminum Oxide (UNII: LMI26O6933)	
Petrolatum (UNII: 4T6H12BN9U)	
Alpha-Tocopherol Acetate (UNII: 9E8X80D2L0)	
Octyltriethoxysilane (UNII: LDC331P08E)	
Ribes Nigrum Seed (UNII: EHO0V3IRF5)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Methylparaben (UNII: A2I8C7HI9T)	
Propylparaben (UNII: Z8IX2SC1OH)	
Carnauba Wax (UNII: R12CBM0EIZ)	
Tribehenin (UNII: 8OC9U7TQZ0)	
Cholesterol (UNII: 97C5T2UQ7J)	
Butylated Hydroxytoluene (UNII: 1P9D0Z171K)	
Propanediol (UNII: 5965N8W85T)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
Yellow Wax (UNII: 2ZA36H0S2V)	
Candelilla Wax (UNII: WL0328HX19)	
Cetearyl Glucoside (UNII: 09FUA47KNA)	
Linolenic Acid (UNII: 0RBV727H71)	
Ferric Oxide Red (UNII: 1K09F3G675)	
Ferric Oxide Yellow (UNII: EX438O2MRT)	
Ferrosoferric Oxide (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-140-21	1 in 1 CARTON		
1		3 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/16/2010	

Labeler - VENTURA INTERNATIONAL LTD (603192787)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star, S.A.		880160197	MANUFACTURE

Revised: 9/2010

VENTURA INTERNATIONAL LTD