

LBEL EFFET PARFAIT LOOSE EXTRA-FINE PORTABLE SPF 15 FM PORCELAINÉ-BEIGE- octinoxate, titanium dioxide, and oxybenzone powder

LBEL EFFET PARFAIT LOOSE EXTRA-FINE PORTABLE SPF 15 FM TRANSLUCIDE-BEIGE- octinoxate, titanium dioxide, and oxybenzone powder

LBEL EFFET PARFAIT LOOSE EXTRA-FINE PORTABLE SPF 15 FM SANTÉ- BEIGE- octinoxate, titanium dioxide, and oxybenzone powder

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.

L'BEL EFFET PARFAIT Loose extra-fine portable powder SPF 15 FM

Drug Facts

Active Ingredients	Purpose
TITANIUM DIOXIDE 3.54 %	Sunscreen
OCTINOXATE 3.00 %	Sunscreen
OXYBENZONE 3.00 %	Sunscreen

Uses

- Helps prevent sunburn

Warnings

- Skin Cancer / Skin Aging Alert; Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging.
- For external use only.
- Do not use on damage or broken skin.
- When using this product keep out of eyes. Rinse with water to remove.
- Stop use and ask a doctor if rash occurs.

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

Directions

- Apply liberally and evenly 15 minutes before sun exposure.
- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating.
- Children under 6 months of age: Ask a doctor.

Other information

- Protect the product in this container from excessive heat and direct sun.

Inactive ingredients

TALC, ZEA MAYS (CORN) STARCH, SILICA, CALCIUM CARBONATE, KAOLIN, ZINC STEARATE, OCTYLDODECANOL, ISOSTEARYL NEOPENTANOATE, GLYCERYL CAPRYLATE, METHYL METHACRYLATE CROSSPOLYMER, MAGNESIUM MYRISTATE,

PHENOXYETHANOL, SODIUM POTASSIUM ALUMINUM SILICATE, HYDROGEN DIMETHICONE, TOCOPHERYL ACETATE, ALUMINA, CAPRYLYL GLYCOL, CHLORPHENESIN, MICROCRYSTALLINE WAX, PETROLATUM, PHOSPHOLIPIDS, CHOLESTEROL, EUPHORBIA CERIFERA (CANDELILLA) WAX, BEESWAX, CETEARYL ALCOHOL, CETEARYL GLUCOSIDE, COPERNICIA CERIFERA (CARNAUBA) WAX, POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE, GLYCOSPHINGOLIPIDS.

MAY CONTAIN:

IRON OXIDES, TITANIUM DIOXIDE

Dist. by Ventura Int Ltd. DBA Belcorp USA, Miami, FL 33126

PRINCIPAL DISPLAY PANEL - 12 g Case Box - PORCELAINE - BEIGE

L'BEL

EFFET PARFAIT

loose extra-fine portable

powder SPF 15 FM

Net Wt. 0.42 oz. e (12 g)

L'BEL

EFFET PARFAIT

Loose extra-fine portable
powder SPF 15 FM

Net Wt. 0.42 oz e (12 g)

Drug Facts

Active Ingredients	Purpose
Octinoxate 3%	Sunscreen
Oxybenzone 3%.....	Sunscreen
Titanium dioxide 3.54%	Sunscreen

Uses ■ Helps prevent sunburn.

Warnings ■ Skin Cancer / Skin Aging

Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, **not** skin cancer or early skin aging. ■ **For external use only.** ■ **Do not use** on damaged or broken skin. ■ **When using this product** keep out of eyes. Rinse with water to remove. ■ **Stop use and ask a doctor** if rash occurs. ■ **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Directions ■ Apply liberally and evenly 15 minutes before sun exposure. ■ Use a water resistant sunscreen if swimming or sweating. ■ Reapply at least every 2 hours ■ Children under 6 months of age: Ask a doctor

Drug Facts (continued)

Other Information

■ Protect the product in this container from excessive heat and direct sun.

Inactive Ingredients

Talc, zeo mays (corn) starch, silica, calcium carbonate, kaolin, zinc stearate, octyldodecanol, isostearyl neopentanoate, glyceryl caprylate, methyl methacrylate crosspolymer, magnesium myristate, phenoxyethanol, sodium potassium aluminum silicate, hydrogen dimethicone, tocopheryl acetate, alumina, caprylyl glycol, chlorphenesin, microcrystalline wax, petrolatum, phospholipids, cholesterol, beeswax, cetearyl alcohol, cetearyl glucoside, copernicia cerifera (carnauba) wax, euphorbia cerifera (candelilla) wax, polyglyceryl-2 dipolyhydroxystearate, glycosphingolipids. **May contain:** iron oxides, titanium dioxide.

PUERTO RICO: Dist. by Ventura Corp. Ltd., San Juan, Puerto Rico 00926. **U.S.A.:** Dist. by Ventura Int. Ltd. DBA Belcorp USA, Miami, FL 33126.
Made in Colombia.



PRINCIPAL DISPLAY PANEL - 12 g Case Box - TRANSLUCIDE- BEIGE

L'BEL

EFFET PARFAIT

loose extra-fine portable
powder SPF 15 FM

Net Wt. 0.42 oz. e (12 g)

L'BEL

EFFET PARFAIT

Loose extra-fine portable
powder SPF 15 FM

Net Wt. 0.42 oz e (12 g)

Drug Facts

Active Ingredients	Purpose
Octinoxate 3%	Sunscreen
Oxybenzone 3%.....	Sunscreen
Titanium dioxide 3.54%	Sunscreen

Uses ■ Helps prevent sunburn.

Warnings ■ Skin Cancer / Skin Aging

Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, **not** skin cancer or early skin aging. ■ **For external use only.** ■ **Do not use** on damaged or broken skin. ■ **When using this product** keep out of eyes. Rinse with water to remove. ■ **Stop use and ask a doctor** if rash occurs. ■ **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Directions ■ Apply liberally and evenly 15 minutes before sun exposure. ■ Use a water resistant sunscreen if swimming or sweating. ■ Reapply at least every 2 hours ■ Children under 6 months of age: Ask a doctor

Drug Facts (continued)

Other Information

■ Protect the product in this container from excessive heat and direct sun.

Inactive Ingredients

Talc, zeo mays (corn) starch, silica, calcium carbonate, kaolin, zinc stearate, octyldodecanol, isostearyl neopentanoate, glyceryl caprylate, methyl methacrylate crosspolymer, magnesium myristate, phenoxyethanol, sodium potassium aluminum silicate, hydrogen dimethicone, tocopheryl acetate, alumina, caprylyl glycol, chlorphenesin, microcrystalline wax, petrolatum, phospholipids, cholesterol, beeswax, cetearyl alcohol, cetearyl glucoside, copernicia cerifera (carnauba) wax, euphorbia cerifera (candelilla) wax, polyglyceryl-2 dipolyhydroxystearate, glycosphingolipids. **May contain:** iron oxides, titanium dioxide.

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Made in Colombia.



PRINCIPAL DISPLAY PANEL - 12 g Case Box - SANTE- BEIGE

L'BEL

EFFET PARFAIT

loose extra-fine portable
powder SPF 15 FM

Net Wt. 0.42 oz. e (12 g)

L'BEL

EFFET PARFAIT

Loose extra-fine portable
powder SPF 15 FM

Net Wt. 0.42 oz e (12 g)

Drug Facts

Active Ingredients	Purpose
Octinoxate 3%	Sunscreen
Oxybenzone 3%.....	Sunscreen
Titanium dioxide 3.54%	Sunscreen

Uses ■ Helps prevent sunburn.

Warnings ■ Skin Cancer / Skin Aging

Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, **not** skin cancer or early skin aging. ■ **For external use only.** ■ **Do not use** on damaged or broken skin. ■ **When using this product** keep out of eyes. Rinse with water to remove. ■ **Stop use and ask a doctor** if rash occurs. ■ **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Directions ■ Apply liberally and evenly 15 minutes before sun exposure. ■ Use a water resistant sunscreen if swimming or sweating. ■ Reapply at least every 2 hours ■ Children under 6 months of age: Ask a doctor

Drug Facts (continued)

Other Information

■ Protect the product in this container from excessive heat and direct sun.

Inactive Ingredients

Talc, zeo mays (corn) starch, silica, calcium carbonate, kaolin, zinc stearate, octyldodecanol, isostearyl neopentanoate, glyceryl caprylate, methyl methacrylate crosspolymer, magnesium myristate, phenoxyethanol, sodium potassium aluminum silicate, hydrogen dimethicone, tocopheryl acetate, alumina, caprylyl glycol, chlorphenesin, microcrystalline wax, petrolatum, phospholipids, cholesterol, beeswax, cetearyl alcohol, cetearyl glucoside, copernicia cerifera (carnauba) wax, euphorbia cerifera (candelilla) wax, polyglyceryl-2 dipolyhydroxystearate, glycosphingolipids. **May contain:** iron oxides, titanium dioxide.

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Made in Colombia.



LBEL EFFET PARFAIT LOOSE EXTRA-FINE PORTABLE SPF 15 FM PORCELAINES- BEIGE

octinoxate, titanium dioxide, and oxybenzone powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-721
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.03 g in 1 g
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.0354 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.03 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
TALC (UNII: 7SEV7J4R1U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
KAOLIN (UNII: 24H4NWX5CO)	
ZINC STEARATE (UNII: H92E6QA4FV)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	
GLYCERYL MONOCAPRYLATE (UNII: TM2TZD4G4A)	
MAGNESIUM MYRISTATE (UNII: Z1917F0578)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALUMINUM OXIDE (UNII: LM26O6933)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PETROLATUM (UNII: 4T6H12BN9U)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
CANDELILLA WAX (UNII: WL0328HX19)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	

POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229 XJ4V12)

FERRIC OXIDE RED (UNII: 1K09F3G675)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-721-02	1 in 1 BOX	12/22/2015	
1	NDC:14783-721-01	12 g in 1 CASE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	12/22/2015	

LBEL EFFET PARFAIT LOOSE EXTRA-FINE PORTABLE SPF 15 FM TRANSLUCIDE- BEIGE

octinoxate, titanium dioxide, and oxybenzone powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-722
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.03 g in 1 g
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.0354 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.03 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
TALC (UNII: 7SEV7J4R1U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
KAOLIN (UNII: 24H4NWX5CO)	
ZINC STEARATE (UNII: H92E6QA4FV)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	
GLYCERYL MONOCAPRYLATE (UNII: TM2TZD4G4A)	
MAGNESIUM MYRISTATE (UNII: Z1917F0578)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALUMINUM OXIDE (UNII: LM26O6933)	

CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CHLORPHENESIN (UNII: I670DAL4SZ)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
PETROLATUM (UNII: 4T6H12BN9U)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
CHOLESTEROL (UNII: 97C5T2UQ7J)
CANDELILLA WAX (UNII: WL0328HX19)
YELLOW WAX (UNII: 2ZA36H0S2V)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)
CARNAUBA WAX (UNII: R12CBM0EIZ)
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)
FERRIC OXIDE RED (UNII: 1K09F3G675)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-722-02	1 in 1 BOX	12/22/2015	
1	NDC:14783-722-01	12 g in 1 CASE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	12/22/2015	

LBEL EFFET PARFAIT LOOSE EXTRA-FINE PORTABLE SPF 15 FM SANTE-BEIGE

octinoxate, titanium dioxide, and oxybenzone powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-723
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.03 g in 1 g
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.0354 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.03 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
TALC (UNII: 7SEV7J4R1U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

CALCIUM CARBONATE (UNII: H0G9379FGK)
KAOLIN (UNII: 24H4NWX5CO)
ZINC STEARATE (UNII: H92E6QA4FV)
OCTYLDODECANOL (UNII: 461N1O614Y)
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)
GLYCERYL MONOCAPRYLATE (UNII: TM2TZD4G4A)
MAGNESIUM MYRISTATE (UNII: Z1917F0578)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
ALUMINUM OXIDE (UNII: LM26O6933)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CHLORPHENESIN (UNII: I670DAL4SZ)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
PETROLATUM (UNII: 4T6H12BN9U)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
CHOLESTEROL (UNII: 97C5T2UQ7J)
CANDELILLA WAX (UNII: WL0328HX19)
YELLOW WAX (UNII: 2ZA36H0S2V)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)
CARNAUBA WAX (UNII: R12CBM0EIZ)
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)
FERRIC OXIDE RED (UNII: 1K09F3G675)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-723-02	1 in 1 BOX	12/22/2015	
1	NDC:14783-723-01	12 g in 1 CASE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	12/22/2015	

Labeler - Ventura International LTD (603192787)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(14783-721, 14783-722, 14783-723)