

**LBEL EFFET PARFAIT LONG LASTING COMPACT SPF 15 CLAIRE 1/BEIGE- titanium dioxide and zinc oxide powder**  
**LBEL EFFET PARFAIT LONG LASTING COMPACT SPF 15 CLAIRE 2/BEIGE- titanium dioxide and zinc oxide powder**  
**LBEL EFFET PARFAIT LONG LASTING COMPACT SPF 15 CLAIRE 3/BEIGE- titanium dioxide and zinc oxide powder**  
**LBEL EFFET PARFAIT LONG LASTING COMPACT SPF 15 CLAIRE 4/BEIGE- titanium dioxide and zinc oxide powder**  
**LBEL EFFET PARFAIT LONG LASTING COMPACT SPF 15 MEDIUM 5/BEIGE- titanium dioxide and zinc oxide powder**  
**LBEL EFFET PARFAIT LONG LASTING COMPACT SPF 15 MEDIUM 6/BEIGE- titanium dioxide and zinc oxide powder**  
**LBEL EFFET PARFAIT LONG LASTING COMPACT SPF 15 MEDIUM 7/BEIGE- titanium dioxide and zinc oxide powder**  
**LBEL EFFET PARFAIT LONG LASTING COMPACT SPF 15 OBSCURE 8/BEIGE- titanium dioxide and zinc oxide powder**  
**LBEL EFFET PARFAIT LONG LASTING COMPACT SPF 15 OBSCURE 9/BEIGE- titanium dioxide and zinc oxide powder**  
**Ventura Corporation LTD**

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

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## **L'BEL EFFET PARFAIT LONG LASTING COMPACT POWDER SPF 15**

### ***Drug Facts***

<b><i>Active Ingredients</i></b>	<b><i>Purpose</i></b>
TITANIUM DIOXIDE 5.75 %	Sunscreen
ZINC OXIDE 4.90 %	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. 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**

MICA, DIMETHICONE, POLYMETHYLSILSESQUIOXANE, ZINC STEARATE, HDI/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER, TRIMETHYLSILOXYSILICATE, CAPRYLIC/CAPRIC TRIGLYCERIDE, PERFLUOROOCTYL TRIETHOXYSILANE, TOCOPHERYL ACETATE, HYDROGEN DIMETHICONE, PHENOXYETHANOL, CETYL PEG/PPG-10/1 DIMETHICONE, POLYGLYCERYL-4 ISOSTEARATE, ALUMINA, HEXYL LAURATE, FRAGRANCE, CAPRYLYL GLYCOL, CRITHMUM MARITIMUM EXTRACT, TRIETHOXYCAPRYLYLSILANE, CHLORPHENESIN, CERAMIDE 3, BUTYLPHENYL METHYLPROPIONAL, HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXALDEHYDE, HYDROXYCITRONELLAL, CITRONELLOL, GERANIOL, d-LIMONENE, ALPHA-ISOMETHYL IONONE. **MAY CONTAIN:** IRON OXIDES, TITANIUM DIOXIDE.

Dist. by Ventura Corp, Ltd., San Juan, Puerto Rico 00926.

**PRINCIPAL DISPLAY PANEL - 10 g Container Box - Claire 1/Beige**

L'BEL

EFFET PARFAIT

Long lasting compact powder SPF 15

Net wt. 0.35 oz. e (10 g)



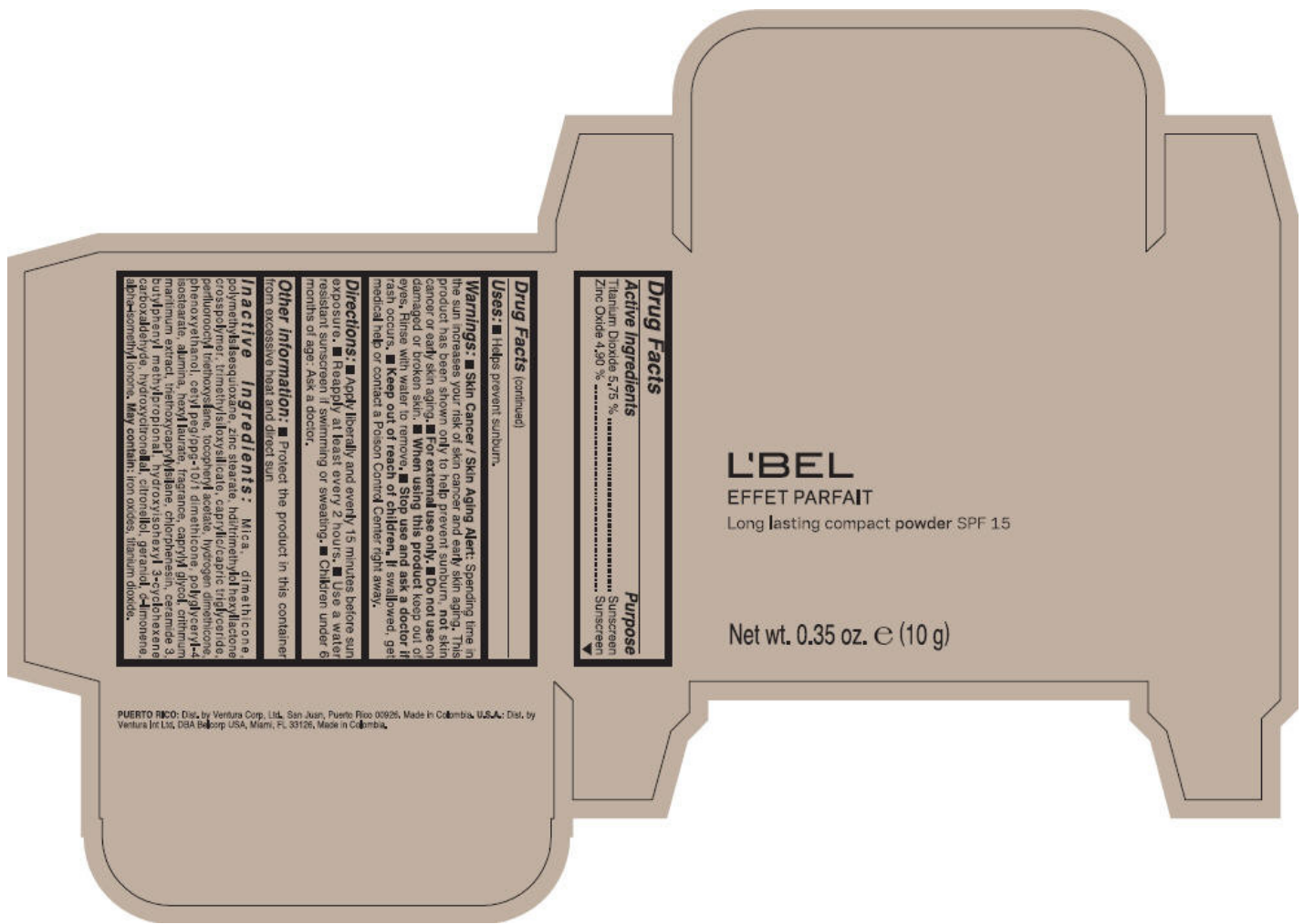












**PRINCIPAL DISPLAY PANEL - 10 g Container Box - Medium 7/Beige**

L'BEL

EFFET PARFAIT

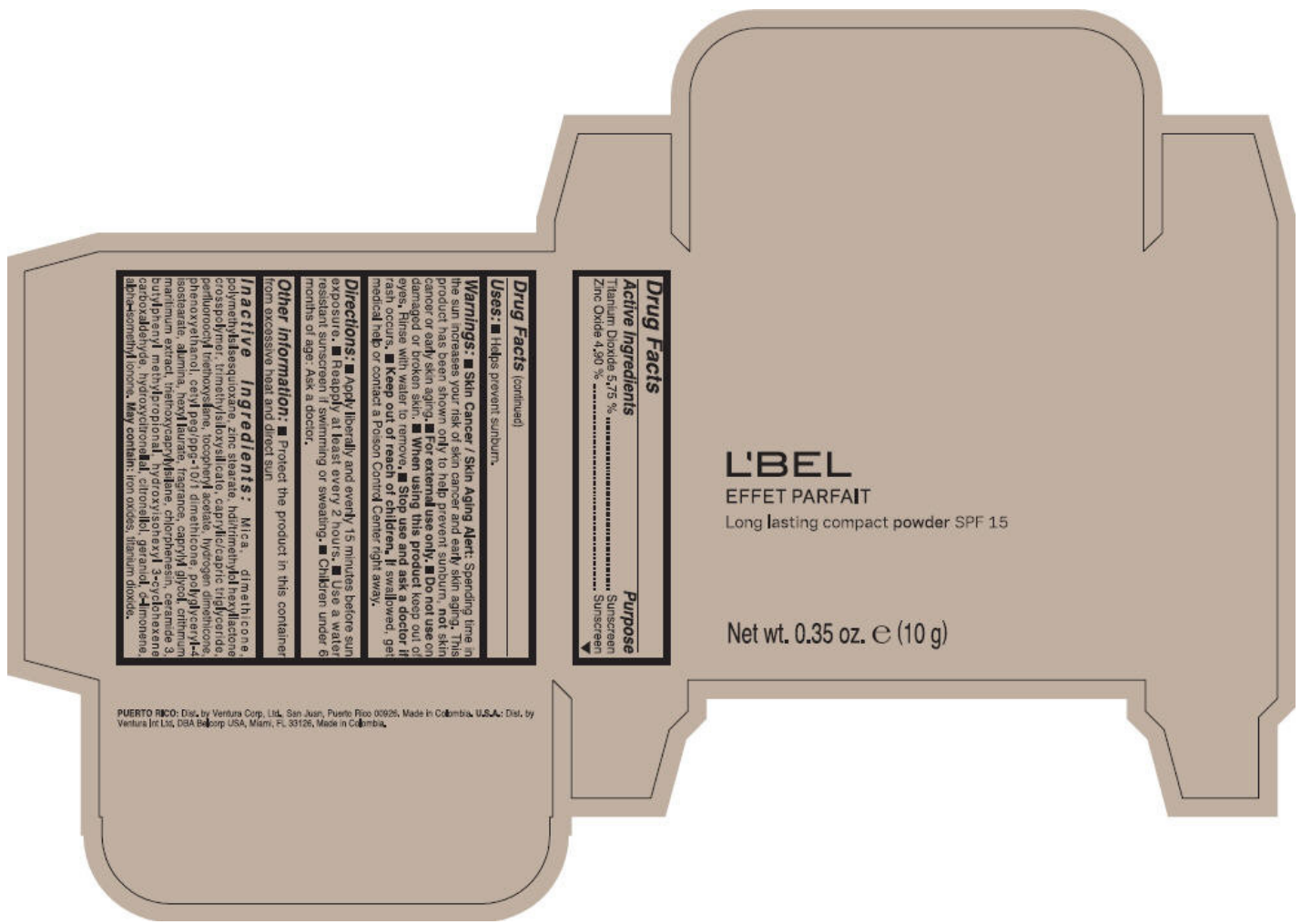
Long lasting compact powder SPF 15

Net wt. 0.35 oz. e (10 g)









## LBEL EFFET PARFAIT LONG LASTING COMPACT SPF 15 CLAIRE 1/BEIGE

titanium dioxide and zinc oxide powder

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:43596-0090
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Titanium Dioxide</b> (UNII: 15FIX9 V2JP) (Titanium Dioxide - UNII:15FIX9 V2JP)	Titanium Dioxide	0.0575 g in 1 g
<b>Zinc Oxide</b> (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.049 g in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>MICA</b> (UNII: V8A1AW0880)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>POLYMETHYLSILSESQUIOXANE (4.5 MICRONS)</b> (UNII: 59Z907ZB69)	
<b>ZINC STEARATE</b> (UNII: H92E6QA4FV)	
<b>HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER</b> (UNII: WB5K9Y35Y9)	

PUERTO RICO: Dis. by Ventura Corp. Ltd., San Juan, Puerto Rico 00926, Made in Columbia, U.S.A.; Dis. by Ventura Int Ltd, DBA B&B Corp USA, Miami, FL 33126, Made in Columbia.

MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
PERFLUORO OCTYL TRIETHOXY SILANE (UNII: 814P46684U)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
ALUMINUM OXIDE (UNII: LM26O6933)
HEXYL LAURATE (UNII: 4CG9F9W01Q)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
CHLORPHENESIN (UNII: I670DAL4SZ)
CERAMIDE NP (UNII: 4370DF050B)
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)
HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXYALDEHYDE (UNII: QUE43B9Z2Q)
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
GERANIOL (UNII: L837I08USY)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
FERRIC OXIDE RED (UNII: 1K09F3G675)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0090-2	1 in 1 BOX	08/18/2018	
1	NDC:43596-0090-1	12 g in 1 CONTAINER; Type 0: Not a Combination Product		
2	NDC:43596-0090-4	1 in 1 BOX	08/18/2018	
2	NDC:43596-0090-3	10 g in 1 CONTAINER; 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	08/18/2018	

## LBEL EFFET PARFAIT LONG LASTING COMPACT SPF 15 CLAIRE 2/BEIGE

titanium dioxide and zinc oxide powder

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0091
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.0575 g in 1 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.049 g in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
ZINC STEARATE (UNII: H92E6QA4FV)	
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PERFLUOROCTYL TRIETHOXY SILANE (UNII: 814P46684U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
ALUMINUM OXIDE (UNII: LM26O6933)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	
HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXYALDEHYDE (UNII: QUE43B9Z2Q)	
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
GERANIOL (UNII: L837108USY)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0091-2	1 in 1 BOX	08/18/2018	
1	NDC:43596-0091-1	12 g in 1 CONTAINER; Type 0: Not a Combination Product		
2	NDC:43596-0091-4	1 in 1 BOX	08/18/2018	
2	NDC:43596-0091-3	10 g in 1 CONTAINER; 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	08/18/2018	

**LBEL EFFET PARFAIT LONG LASTING COMPACT SPF 15 CLAIRE 3/BEIGE**

titanium dioxide and zinc oxide powder

**Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0092
Route of Administration	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>Titanium Dioxide</b> (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.0575 g in 1 g
<b>Zinc Oxide</b> (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.049 g in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>MICA</b> (UNII: V8A1AW0880)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>POLYMETHYLSILSESQUOXANE (4.5 MICRONS)</b> (UNII: 59Z907ZB69)	
<b>ZINC STEARATE</b> (UNII: H92E6QA4FV)	
<b>HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER</b> (UNII: WB5K9Y35Y9)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>PERFLUOROOCTYL TRIETHOXY SILANE</b> (UNII: 814P46684U)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>POLYGLYCERYL-4 ISOSTEARATE</b> (UNII: 820DPX33S7)	
<b>ALUMINUM OXIDE</b> (UNII: LM26O6933)	
<b>HEXYL LAURATE</b> (UNII: 4CG9F9W01Q)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)	
<b>CERAMIDE NP</b> (UNII: 4370DF050B)	
<b>BUTYLPHENYL METHYLPROPIONAL</b> (UNII: T7540GJV69)	
<b>HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXYALDEHYDE</b> (UNII: QUE43B9Z2Q)	
<b>HYDROXYCITRONELLAL</b> (UNII: 8SQ0VA4YUR)	
<b>.BETA.-CITRONELLOL, (R)-</b> (UNII: P01OUT964K)	
<b>GERANIOL</b> (UNII: L837108USY)	
<b>LIMONENE, (+)-</b> (UNII: GFD7C86Q1W)	
<b>ISOMETHYL-.ALPHA.-IONONE</b> (UNII: 9XP4LC555B)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0092-2	1 in 1 BOX	08/18/2018	
1	NDC:43596-0092-1	12 g in 1 CONTAINER; Type 0: Not a Combination Product		
2	NDC:43596-0092-4	1 in 1 BOX	08/18/2018	
2	NDC:43596-0092-3	10 g in 1 CONTAINER; 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	08/18/2018	

**LBEL EFFET PARFAIT LONG LASTING COMPACT SPF 15 CLAIRE 4/BEIGE**

titanium dioxide and zinc oxide powder

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:43596-0093
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Titanium Dioxide</b> (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.0575 g in 1 g
<b>Zinc Oxide</b> (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.049 g in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>MICA</b> (UNII: V8A1AW0880)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>POLYMETHYLSILSESQUIOXANE (4.5 MICRONS)</b> (UNII: 59Z907ZB69)	
<b>ZINC STEARATE</b> (UNII: H92E6QA4FV)	
<b>HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER</b> (UNII: WB5K9Y35Y9)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>PERFLUOROOCTYL TRIETHOXY SILANE</b> (UNII: 814P46684U)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>POLYGLYCERYL-4 ISOSTEARATE</b> (UNII: 820DPX33S7)	
<b>ALUMINUM OXIDE</b> (UNII: LM26O6933)	
<b>HEXYL LAURATE</b> (UNII: 4CG9F9W01Q)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)	
<b>CERAMIDE NP</b> (UNII: 4370DF050B)	
<b>BUTYLPHENYL METHYLPROPIONAL</b> (UNII: T7540GJV69)	
<b>HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXYALDEHYDE</b> (UNII: QUE43B9Z2Q)	
<b>HYDROXYCITRONELLAL</b> (UNII: 8SQ0VA4YUR)	
<b>.BETA.-CITRONELLOL, (R)-</b> (UNII: P01OUT964K)	
<b>GERANIOL</b> (UNII: L837108USY)	
<b>LIMONENE, (+)-</b> (UNII: GFD7C86Q1W)	
<b>ISOMETHYL-.ALPHA.-IONONE</b> (UNII: 9XP4LC555B)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0093-2	1 in 1 BOX	08/18/2018	
1	NDC:43596-0093-1	12 g in 1 CONTAINER; Type 0: Not a Combination Product		
2	NDC:43596-0093-4	1 in 1 BOX	08/18/2018	
2	NDC:43596-0093-3	10 g in 1 CONTAINER; 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	08/18/2018	

## LBEL EFFET PARFAIT LONG LASTING COMPACT SPF 15 MEDIUM 5/BEIGE

titanium dioxide and zinc oxide powder

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0094
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Titanium Dioxide</b> (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.0575 g in 1 g
<b>Zinc Oxide</b> (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.049 g in 1 g

### Inactive Ingredients

Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
ZINC STEARATE (UNII: H92E6QA4FV)	
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PERFLUOROOCTYL TRIETHOXY SILANE (UNII: 814P46684U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
ALUMINUM OXIDE (UNII: LM26O6933)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	
HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXYALDEHYDE (UNII: QUE43B9Z2Q)	
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
GERANIOL (UNII: L837108USY)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0094-2	1 in 1 BOX	08/18/2018	
1	NDC:43596-0094-1	12 g in 1 CONTAINER; Type 0: Not a Combination Product		
2	NDC:43596-0094-4	1 in 1 BOX	08/18/2018	
2	NDC:43596-0094-3	10 g in 1 CONTAINER; 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	08/18/2018	

## LBEL EFFET PARFAIT LONG LASTING COMPACT SPF 15 MEDIUM 6/BEIGE

titanium dioxide and zinc oxide powder

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0095
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.0575 g in 1 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.049 g in 1 g

### Inactive Ingredients

Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
ZINC STEARATE (UNII: H92E6QA4FV)	
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PERFLUOROOCTYL TRIETHOXY SILANE (UNII: 814P46684U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
ALUMINUM OXIDE (UNII: LM26O6933)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	
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HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)	
.BETA.-CITRONELLOL, (R)- (UNII: P010UT964K)	

GERANIOL (UNII: L837108USY)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0095-2	1 in 1 BOX	08/18/2018	
1	NDC:43596-0095-1	12 g in 1 CONTAINER; Type 0: Not a Combination Product		
2	NDC:43596-0095-4	1 in 1 BOX	08/18/2018	
2	NDC:43596-0095-3	10 g in 1 CONTAINER; 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	08/18/2018	

## LBEL EFFET PARFAIT LONG LASTING COMPACT SPF 15 MEDIUM 7/BEIGE

titanium dioxide and zinc oxide powder

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0096
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.0575 g in 1 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.049 g in 1 g

### Inactive Ingredients

Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
ZINC STEARATE (UNII: H92E6QA4FV)	
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PERFLUOROOCTYL TRIETHOXYSILANE (UNII: 814P46684U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
ALUMINUM OXIDE (UNII: LM26O6933)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	

TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
CHLORPHENESIN (UNII: I670DAL4SZ)
CERAMIDE NP (UNII: 4370DF050B)
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)
HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXYALDEHYDE (UNII: QUE43B9Z2Q)
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
GERANIOL (UNII: L837108USY)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
FERRIC OXIDE RED (UNII: 1K09F3G675)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0096-2	1 in 1 BOX	08/18/2018	
1	NDC:43596-0096-1	12 g in 1 CONTAINER; Type 0: Not a Combination Product		
2	NDC:43596-0096-4	1 in 1 BOX	08/18/2018	
2	NDC:43596-0096-3	10 g in 1 CONTAINER; 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	08/18/2018	

## LBEL EFFET PARFAIT LONG LASTING COMPACT SPF 15 OBSCURE 8/BEIGE

titanium dioxide and zinc oxide powder

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0097
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.0575 g in 1 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.049 g in 1 g

### Inactive Ingredients

Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
ZINC STEARATE (UNII: H92E6QA4FV)	

HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
PERFLUOROOCTYL TRIETHOXY SILANE (UNII: 814P46684U)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
ALUMINUM OXIDE (UNII: LM26O6933)
HEXYL LAURATE (UNII: 4CG9F9W01Q)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
CHLORPHENESIN (UNII: I670DAL4SZ)
CERAMIDE NP (UNII: 4370DF050B)
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)
HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXYALDEHYDE (UNII: QUE43B9Z2Q)
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
GERANIOL (UNII: L837108USY)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
FERRIC OXIDE RED (UNII: 1K09F3G675)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0097-2	1 in 1 BOX	08/18/2018	
1	NDC:43596-0097-1	12 g in 1 CONTAINER; Type 0: Not a Combination Product		
2	NDC:43596-0097-4	1 in 1 BOX	08/18/2018	
2	NDC:43596-0097-3	10 g in 1 CONTAINER; 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	08/18/2018	

**LBEL EFFET PARFAIT LONG LASTING COMPACT SPF 15 OBSCURE 9/BEIGE**  
titanium dioxide and zinc oxide powder

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0098
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.0575 g in 1 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.049 g in 1 g

## Inactive Ingredients

Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
ZINC STEARATE (UNII: H92E6QA4FV)	
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PERFLUORO OCTYL TRIETHOXY SILANE (UNII: 814P46684U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
ALUMINUM OXIDE (UNII: LM26O6933)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CERAMIDE NP (UNII: 4370DF050B)	
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	
HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXYALDEHYDE (UNII: QUE43B9Z2Q)	
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
GERANIOL (UNII: L837108USY)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0098-2	1 in 1 BOX	08/18/2018	
1	NDC:43596-0098-1	12 g in 1 CONTAINER; Type 0: Not a Combination Product		
2	NDC:43596-0098-4	1 in 1 BOX	08/18/2018	
2	NDC:43596-0098-3	10 g in 1 CONTAINER; 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	08/18/2018	

**Labeler** - Ventura Corporation LTD (602751344)

## Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(43596-0090, 43596-0091, 43596-0092, 43596-0093, 43596-0094, 43596-0095, 43596-0096, 43596-0097, 43596-0098)

