

**DOUBLE USE COMPACT SPF 15 GOLD DELUXE EDITION CLAIRE 1-2-3- octinoxate, titanium dioxide, zinc oxide powder**

**DOUBLE USE COMPACT SPF 15 GOLD DELUXE EDITION CLAIRE 4- octinoxate, titanium dioxide, zinc oxide powder**

**DOUBLE USE COMPACT SPF 15 GOLD DELUXE EDITION MEDIUM 5- octinoxate, titanium dioxide, zinc oxide powder**

**DOUBLE USE COMPACT SPF 15 GOLD DELUXE EDITION MEDIUM 6- octinoxate, titanium dioxide, zinc oxide powder**

**DOUBLE USE COMPACT SPF 15 GOLD DELUXE EDITION MEDIUM 7- octinoxate, titanium dioxide, zinc oxide 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.*

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### **L'BEL DIVINE Double Use Compact SPF 15 gold deluxe edition**

#### **Active ingredients Purpose**

Octinoxate 3.00% Sunscreen

Titanium Dioxide 6.24% Sunscreen

Zinc Oxide 4.90 % Sunscreen

Uses:

Helps prevent Sunburn

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

**Stop use and ask a doctor if** rash occurs.

**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 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.

#### **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, polymethylsiloxane, hdi/trimethylol hexyllactone crosspolymer, dimethicone, magnesium stearate, trimethylsiloxysilicate, isostearyl neopentanoate, hydrogen dimethicone, tocopheryl acetate, phenoxyethanol, alumina, triethoxycaprylylsilane, fragrance, caprylyl glycol, ceramide np, chlorphenesin, butylphenyl methylpropional, hydroxycitronellal, citronellol, geraniol, limonene, alpha-isomethyl ionone, **May contain:** Iron oxides, titanium dioxide

L'BEL

Divine

Polvos Compactos doble uso FPS 15 edicion de lujo dorado

Double use compact SPF 15 gold deluxe edition

Tone: Claire 1-2-3

Net. Wt. 0.35 oz (10g)



**ARTE REFERENCIAL  
NO REPRODUCIR**  
SOLICITAR ARTE EN ILLUSTRATOR A COMPRAS



Arte - Caja		
Arte N°: CJ-48351-B	Nombre del Producto: POLVOS DOBLE USO FPS 15 edición de lujo Dorado x 10 g	
Plano: DS4033A	Fecha: 18/02/20	Destino: Puerto Rico; USA

L'BEL

Divine

Polvos Compactos doble uso FPS 15 edicion de lujo dorado

Double use compact SPF 15 gold deluxe edition

Tone: Claire 4

Net. Wt. 0.35 oz (10g)



**ARTE REFERENCIAL  
NO REPRODUCIR**  
SOLICITAR ARTE EN ILLUSTRATOR A COMPRAS



**Drug Facts**

**Active ingredients**

Octinoxate 3.00%, Titanium dioxide 6.24%, Zinc oxide 4.90%

**Purpose**

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, polymethylsilsesquioxane, hdiltrimethylol hexyllactone crosspolymer, dimethicone, magnesium stearate, trimethylsilylsilicate, isostearyl neopentanoate, hydrogen dimethicone, tocopheryl acetate, phenoxyethanol, alumina, triethoxycaprylylsilane, fragrance, caprylyl glycol, ceramide np, chlorphenesin, butylphenyl methylpropional, hydroxycitronellal, citronellol, geraniol, limonene, alpha-isomethyl ionone. **May Contain:** Iron oxides, titanium dioxide.

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

**TOPE: CLAIR 4**

**L'BEL  
DIVINE**

Polvos compactos doble uso FPS 15 edición de lujo dorado  
Double use compact SPF 15 gold deluxe edition

Net Wt. 0.35 oz. e (10 g)

Arte - Caja		
Arte N°: CJ-48351-B	Nombre del Producto: POLVOS DOBLE USO FPS 15 edición de lujo Dorado x 10 g	
Plano: DS4033A	Fecha: 18/02/20	Destino: Puerto Rico; USA

L'BEL

Divine

Polvos Compactos doble uso FPS 15 edición de lujo dorado

Double use compact SPF 15 gold deluxe edition

Tone: Medium 5

Net. Wt. 0.35 oz (10g)



**ARTE REFERENCIAL  
NO REPRODUCIR**  
SOLICITAR ARTE EN ILLUSTRATOR A COMPRAS



Arte - Caja		
Arte N°: CJ-48351-B	Nombre del Producto: POLVOS DOBLE USO FPS 15 edición de lujo Dorado x 10 g	
Plano: DS4033A	Fecha: 18/02/20	Destino: Puerto Rico; USA

L'BEL

Divine

Polvos Compactos doble uso FPS 15 edición de lujo dorado

Double use compact SPF 15 gold deluxe edition

Tone: Medium 6

Net. Wt. 0.35 oz (10g)



**ARTE REFERENCIAL  
NO REPRODUCIR**  
SOLICITAR ARTE EN ILLUSTRATOR A COMPRAS



Arte - Caja		
Arte N°: CJ-48351-B	Nombre del Producto: POLVOS DOBLE USO FPS 15 edición de lujo Dorado x 10 g	
Plano: DS4033A	Fecha: 18/02/20	Destino: Puerto Rico; USA

L'BEL

Divine

Polvos Compactos doble uso FPS 15 edición de lujo dorado

Double use compact SPF 15 gold deluxe edition

Tone: Medium 7

Net. Wt. 0.35 oz (10g)



**ARTE REFERENCIAL  
NO REPRODUCIR**  
SOLICITAR ARTE EN ILLUSTRATOR A COMPRAS



Arte - Caja		
Arte N°: CJ-48351-B	Nombre del Producto: POLVOS DOBLE USO FPS 15 edición de lujo Dorado x 10 g	
Plano: DS4033A	Fecha: 18/02/20	Destino: Puerto Rico; USA

## DOUBLE USE COMPACT SPF 15 GOLD DELUXE EDITION CLAIRE 1-2-3

octinoxate, titanium dioxide, zinc oxide powder

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-275
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	4.9 g in 100 g
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	6.24 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
CHLORPHENESIN (UNII: I670DAL4SZ)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
CERAMIDE NP (UNII: 4370DF050B)	
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	
GERANIOL (UNII: L837108USY)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
POLYMETHYLSILSESQUOXANE (11 MICRONS) (UNII: Z570VEV8XK)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)	
MICA (UNII: V8A1AW0880)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
HYDROGEN DIMETHICONE (13 CST) (UNII: 4QGR4P2YOI)	
ALUMINUM OXIDE (UNII: LM26O6933)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-275-01	10 g in 1 BOTTLE; Type 0: Not a Combination Product	11/12/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	11/12/2020	

## DOUBLE USE COMPACT SPF 15 GOLD DELUXE EDITION CLAIRE 4

octinoxate, titanium dioxide, zinc oxide powder

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-276
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	4.9 g in 100 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	6.24 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
CHLORPHENESIN (UNII: I670DAL4SZ)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
CERAMIDE NP (UNII: 4370DF050B)	
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	
GERANIOL (UNII: L837108USY)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
POLYMETHYLSILSESQUIOXANE (11 MICRONS) (UNII: Z570VEV8XK)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)	
MICA (UNII: V8A1AW0880)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
HYDROGEN DIMETHICONE (13 CST) (UNII: 4QGR4P2YOI)	
ALUMINUM OXIDE (UNII: LM26O6933)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-276-01	10 g in 1 BOTTLE; Type 0: Not a Combination Product	11/12/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	11/12/2020	

## DOUBLE USE COMPACT SPF 15 GOLD DELUXE EDITION MEDIUM 5

octinoxate, titanium dioxide, zinc oxide powder

### Product Information



<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:14783-277
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	4.9 g in 100 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	6.24 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
CHLORPHENESIN (UNII: I670DAL4SZ)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
CERAMIDE NP (UNII: 4370DF050B)	
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	
GERANIOL (UNII: L837108USY)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
ISO STEARYL NEOPENTANOATE (UNII: 411THY156Q)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
POLYMETHYLSILSESQUOXANE (11 MICRONS) (UNII: Z570VEV8XK)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)	
MICA (UNII: V8A1AW0880)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
HYDROGEN DIMETHICONE (13 CST) (UNII: 4QGR4P2YOI)	
ALUMINUM OXIDE (UNII: LM26O6933)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-277-01	10 g in 1 BOTTLE; Type 0: Not a Combination Product	11/12/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	11/12/2020	

# DOUBLE USE COMPACT SPF 15 GOLD DELUXE EDITION MEDIUM 6

octinoxate, titanium dioxide, zinc oxide powder

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-278
Route of Administration	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	4.9 g in 100 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	6.24 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
CHLORPHENESIN (UNII: I670DAL4SZ)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
CERAMIDE NP (UNII: 4370DF050B)	
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	
GERANIOL (UNII: L837108USY)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)	
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	
PHENOXYETHANOL (UNII: HE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
POLYMETHYLSILSESQUOXANE (11 MICRONS) (UNII: Z570VEV8XK)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)	
MICA (UNII: V8A1AW0880)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
HYDROGEN DIMETHICONE (13 CST) (UNII: 4QGR4P2YOI)	
ALUMINUM OXIDE (UNII: LM26O6933)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-278-01	10 g in 1 BOTTLE; Type 0: Not a Combination Product	11/12/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	11/12/2020	

## DOUBLE USE COMPACT SPF 15 GOLD DELUXE EDITION MEDIUM 7

octinoxate, titanium dioxide, zinc oxide powder

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-279
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	4.9 g in 100 g
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	6.24 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
CHLORPHENESIN (UNII: I670DAL4SZ)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
CERAMIDE NP (UNII: 4370DF050B)	
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	
GERANIOL (UNII: L837108USY)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
ISO STEARYL NEOPENTANOATE (UNII: 411THY156Q)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
POLYMETHYLSILSESQUOXANE (11 MICRONS) (UNII: Z570VEV8XK)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)	
MICA (UNII: V8A1AW0880)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
HYDROGEN DIMETHICONE (13 CST) (UNII: 4QGR4P2YOI)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-279-01	10 g in 1 BOTTLE; Type 0: Not a Combination Product	11/12/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	11/12/2020	

**Labeler** - Ventura International LTD (603192787)

## Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	manufacture(14783-275, 14783-276, 14783-277, 14783-278, 14783-279)

Revised: 12/2020

Ventura International LTD