

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

Bel Star S.A. (Colombia)

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 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, polymethylsilsesquioxane, hdi/trimethylol hexyllactone crosspolymer, dimethicone, magnesium stearate, trimethylsiloxysilicate, isostearyl

neopentanoate, hydrogen dimethicone, tocopheryl acetate, phenoxyethanol, alumina, triethoxycaprylylsilane, fragrance, caprylyl glycol, ceramide np, chlorphenesin, linalool, 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)



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)



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)



Drug Facts

Active Ingredients

Octinoxate 3.00 %, Titanium dioxide 6.24 %, Zinc oxide 4.50 %

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, hdI/trimethylol hexylactone crosspolymer, dimethicone, magnesium stearate, trimethylsilyloxyethyl acetate, isostearyl neopentanoate, hydrogen dimethicone, tocopheryl acetate, phenoxethanol, alumina, triethoxypropylsilane, fragrance, caprylyl glycol, ceramide np, chlorphenesin, linoleol, hydroxytoluenal, citronellol, geraniol, limonene, alpha-isomethyl ionone, **May Contain:** Iron oxides, titanium dioxide.

U.S.A.: Dist. by Ventura Int. Ltd. DBA Securo USA, Miami, FL 33155. PUERTO RICO: Dist. by Ventura Corp. Ltd. San Juan, Puerto Rico 00938. Made in Colombia

Tone: Medium 5

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 (10g)

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)



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)



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:14141-201
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)	

LINALOOL, (+/-)- (UNII: D81QY6I88E)
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)
FERROSOFERRIC 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: LMI26O6933)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14141-201-01	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:14141-202
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)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
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)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
POLYMETHYLSILSESQUIOXANE (11 MICRONS) (UNII: Z570VEV8XK)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
MAGNESIUM STEARATE (UNII: 70097M6I3O)	
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)	
MICA (UNII: V8A1AW0880)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
HYDROGEN DIMETHICONE (13 CST) (UNII: 4QGR4P2YOI)	
ALUMINUM OXIDE (UNII: LMI26O6933)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14141-202-01	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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14141-203
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)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
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: LMI26O6933)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14141-203-01	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:14141-204
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)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
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: LMI26O6933)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14141-204-01	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:14141-205
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)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
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)	
FERROSO FERRIC 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: LMI26O6933)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14141-205-01	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 - Bel Star S.A. (Colombia) (880160197)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	manufacture(14141-201, 14141-202, 14141-203, 14141-204, 14141-205)

Revised: 6/2022

Bel Star S.A. (Colombia)