

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)

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

Product Labeling Claire 1-2-3



Product Labeling Claire 4



Product Labeling Medium 5



Product Labeling Medium 6



Product Labeling Medium 7



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)
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: 70097M6130)
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 Drug	M020	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)	
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:14141-202-01	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 Drug	M020	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: 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:14141-203-01	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 Drug	M020	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
	NDC 14141-204	10 mL (1 BOTTLE) Type 0, Net Content		

1	NDC:14141-204-01	10 g in 1 BOTTLE; Type U: Not a Combination Product	11/12/2020
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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	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
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: 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)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	

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 Drug	M020	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: 6/2025

Bel Star S.A. (Colombia)