

LBEL DIVINE LIP GLOSS SPF 15- octinoxate and oxybenzone lotion
Ventura International Ltd. (San Juan, P.R)

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.

DIVINE LIP GLOSS

Active Ingredients

Octinoxate 7.5%, Oxybenzone 3.0%.

Purpose

Sunscreen.

Uses

Helps prevent sunburn.

Warnings

Stop use if skin rash occurs.

Inactive Ingredients

Hydrogenated polyisobutene, diisopropyl dimer dilinoleate, isostearyl neopentanoate, cera alba (beeswax), silica dimethyl silylate, parfum (fragrance), parfum (fragrance), glycerin, prunus amygdalus dulcis oil (prunus amygdalus dulcis (sweet almond) oil), tocopheryl acetate, cocos nucifera oil (cocos nucifera (coconut) oil), aloe barbadensis leaf extract, hydrogenated vegetable oil, propylparaben, methylparaben, sodium saccharin, bht, citrus limon peel cera (citrus limon (lemon) peel wax), citrus limon peel oil (citrus limon (lemon) peel oil), citrus aurantium dulcis peel oil (citrus aurantium dulcis (orange) peel oil), citrus aurantium dulcis peel cera (citrus aurantium dulcis (orange) peel wax). **May Contain:** CI 77019 (mica), CI 15850 (red 7 lake), CI 77891 (titanium dioxide), CI 77491, CI 77492, CI 77499 (iron oxides), CI 19140 (yellow 5 lake), CI 16035 (red 40 lake), CI 42090 (blue 1 lake), CI 75470 (carmine), talc, palmitic acid.

USA: Dist. by Ventura International Ltd. San Francisco, CA 94111.

PRINCIPAL DISPLAY PANEL - 12 ml Bottle Carton

DIVINE LIP GLOSS

Lip gloss SPF 15

12 ml e (.40 fl.oz.)

L'BEL

methylparaben, sodium saccharin, bht, citrus limon peel cera (citrus limon (lemon) peel wax), citrus limon peel oil (citrus limon (lemon) peel oil), citrus aurantium dulcis peel oil (citrus aurantium dulcis (orange) peel oil), citrus aurantium dulcis peel cera (citrus aurantium dulcis (orange) peel wax), May Contain: CI 77019 (mica), CI 15850 (red 7 lake), CI 77891 (titanium dioxide), CI 77491, CI 77492, CI 77499 (iron oxides), CI 19140 (yellow 5 lake), CI 16035 (red 40 lake), CI 42090 (blue 1 lake), CI 75470 (carmine), talc, palmitic acid.

USA: Dist. by Ventura International Ltd. San Francisco, CA 94111. Made in Colombia. PUERTO RICO: Dist. by Ventura Corporation, Ltd., San Juan, Puerto Rico 00926. Made in Colombia. www.lbel.com

DIVINE LIP GLOSS

Lip gloss SPF 15
Brillo labial FPS 15
12 ml e (40 fl.oz.)

L'BEL



Active Ingredients: Octinoxate 7.5%, Oxybenzone 3.0%.
Purpose: Sunscreen.
Uses: Helps prevent sunburn.
Warnings: Stop use if skin rash occurs.
Inactive Ingredients: Hydrogenated polyisobutene, diisopropyl dimer dilinoleate, isostearyl neopentanoate, cera alba (beeswax), silica dimethyl silylate, parfum (fragrance), parfum (fragrance), glycerin, prunus amygdalus dulcis oil (prunus amygdalus dulcis (sweet almond) oil), tocopheryl acetate, cocos nucifera oil (cocos nucifera (coconut) oil), aloe barbadensis leaf extract, hydrogenated vegetable oil, propylparaben.

LBEL DIVINE LIP GLOSS SPF 15

octinoxate and oxybenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-121
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.075 mL in 1 mL
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.03 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
diisopropyl dilinoleate (UNII: 5323S7S2LR)	
isostearyl neopentanoate (UNII: 411THY156Q)	
yellow wax (UNII: 2ZA36H0S2V)	
silica dimethyl silylate (UNII: EU2PSP0G0W)	
glycerin (UNII: PDC6A3C0OX)	
almond oil (UNII: 66YXD4DKO9)	
alpha-tocopherol acetate (UNII: 9E8X80D2L0)	
coconut oil (UNII: Q9L0O73W7L)	
aloe vera leaf (UNII: ZY81Z83H0X)	
propylparaben (UNII: Z8IX2SC1OH)	
methylparaben (UNII: A218C7HI9T)	

saccharin sodium (UNII: SB8ZUX40TY)
butylated hydroxytoluene (UNII: 1P9D0Z171K)
lemon peel wax (UNII: 20G0UPO0TI)
lemon oil (UNII: I9GRO824LL)
orange oil (UNII: AKN3KSD11B)
orange peel wax (UNII: 0U715N387C)
mica (UNII: V8A1AW0880)
D&C red no. 7 (UNII: ECW0LZ41X8)
titanium dioxide (UNII: 15FIX9V2JP)
ferric oxide red (UNII: 1K09F3G675)
ferric oxide yellow (UNII: EX438O2MRT)
ferrosoferric oxide (UNII: XM0M87F357)
FD&C yellow no. 5 (UNII: I753WB2F1M)
FD&C red no. 40 (UNII: WZB9127XOA)
FD&C blue no. 1 (UNII: H3R47K3TBD)
aluminum oxide (UNII: LM26O6933)
cochineal (UNII: TZ8Z31B35M)
talc (UNII: 7SEV7J4RIU)
palmitic acid (UNII: 2V16EO95H1)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-121-01	12 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	11/14/2011	

Labeler - Ventura International Ltd. (San Juan, P.R) (603192787)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star, S. A.(Colombia)		880160197	MANUFACTURE(14783-121)

Establishment

Name	Address	ID/FEI	Business Operations
Yobel Supply Chain Management (Peru)		934116930	MANUFACTURE(14783-121)

Revised: 11/2011

Ventura International Ltd. (San Juan, P.R)