

**LBEL EFFET PARFAIT- octinoxate, oxybenzone, and titanium dioxide lipstick
Ventura International, Limited**

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.

**EFFET PARFAIT
lip moisturizer SPF 18**

Active Ingredients

Octinoxate 7 % , Oxybenzone 3%., Titanium dioxide 0.8%

Purpose

Sunscreen

Uses

Helps prevent sunburn

Warnings

Stop use if skin rash occurs

Inactive ingredients

Octyldodecanol, Caprylic/capric triglyceride, Candelilla Cera (euphorbia cerifera (candelilla) wax), Cera Alba (beeswax), Copernicia Cerifera Cera (copernicia cerifera (carnauba) wax), Butyrospermum parkii (butyrospermum parkii (shea butter)), Hydrogenated polyisobutene, Silica, Propylparaben, Cera Microcristallina (microcrystalline wax), Aqua (water), Tocopheryl Acetate, Petrolatum, Phospholipids, bht, Parfum (fragrance), Cholesterol, Extracto de crambe maritima, Cetearyl Alcohol, Cetearyl Glucoside, Polyglyceryl-2 Dipolyhydroxystearate, Glycosphingolipids, Maltodextrin, Zea Mays Starch(zea mays (corn) starch), Phenoxyethanol, Sodium Hyaluronate, Methylparaben, Butylparaben, Ethylparaben, Iisobutylparaben.

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

PRINCIPAL DISPLAY PANEL - 4 g Carton

EFFET PARFAIT
lip moisturizer SPF 18

4 g e (.14 oz.)

L'BEL

Cholesterol, Extracto de crambe maritima, Cetearyl Alcohol, Cetearyl Glucoside, Polyglyceryl-2 Dipolyhydroxystearate, Glycosphingolipids, Maltodextrin, Zea Mays Starch (zea mays (corn) starch), Phenoxyethanol, Sodium Hyaluronate, Methylparaben, Butylparaben, Ethylparaben, Isobutylparaben.

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

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hidratante para labios FPS 18

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-011
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.07 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.03 g in 1 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	0.008 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
OCTYLDODECANOL (UNII: 461N1O614Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CANDELLA WAX (UNII: WL0328HX19)	
YELLOW WAX (UNII: 2ZA36H0S2V)	

CARNAUBA WAX (UNII: R12CBM0EIZ)
SHEA BUTTER (UNII: K49155WL9Y)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
PROPYLPARABEN (UNII: Z8IX2SC1OH)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
WATER (UNII: 059QF0KO0R)
PETROLATUM (UNII: 4T6H12BN9U)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
CHOLESTEROL (UNII: 97C5T2UQ7J)
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)
MALTODEXTRIN (UNII: 7CVR7L4A2D)
STARCH, CORN (UNII: O8232NY3SJ)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
METHYLPARABEN (UNII: A2I8C7HI9T)
BUTYLPARABEN (UNII: 3QPII03FV8)
ETHYLPARABEN (UNII: 14255EXE39)
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-011-05	1 in 1 CARTON		
1	NDC:14783-011-04	4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	12/15/2010	

Labeler - Ventura International, Limited (603192787)

Establishment

Name	Address	ID/FEI	Business Operations
BelStar, S.A.		880160197	MANUFACTURE