LBEL PARIS REGRESSION JOUR- octinoxate, octisalate, and oxybenzone cream
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.

L'BEL
PARIS
REGRESSION
JOUR

Drug Facts

Active Ingredients

Octinoxate (7.5 %), Octisalate (4 %), Oxybenzone (4 %)

Purpose

Sunscreen

Uses

- helps prevent sunburn
- higher SPF gives more sunburn protection
- provides moderate protection against sunburn

Warnings

- **For external use only.**

When using this product

- keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if

- rash and irritation develops and lasts.

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

Directions

- apply smoothly every morning before sun exposure and as needed.
- apply after cleansing and toning on face and neck.
- children under 6 months of age: ask a doctor.

Other information

- Moderate sun protection product.
- Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risk of skin cancer, and other harmful effects of the sun.

Inactive ingredients

Aqua (water), glycine soja (soybean) protein, c12-15 alkyl benzoate, pisum sativum (pea) extract, cyclohexasiloxane, dimethicone, mannitol, cetearyl alcohol, glyceryl stearate, hdi/ trimethylol hexyllactone crosspolymer, phenoxyethanol, sodium acrylate/ acryloyldimethyltaurate/ dimethylacrylamide crosspolymer, c20-22 alkyl phosphate, hydroxyethyl acrylate/ sodium acryloyldymethyl taurate copolymer, c20-22 alcohols, triethanolamine, isohexadecane, methylparaben, c14-22 alcohols, cetearyl glucoside, hydrolyzed adansonia digitata extract, butylparaben, cyclopentasiloxane, chlorphenesin, propylparaben, xanthan gum, disodium edta, acrylates/c10-30 alkyl acrylate crosspolymer, parfum (fragance), sorbic acid, polysorbate 60, cyclodextrin, c12-20 alkyl glucoside, faex extract (yeast extract), hydrolyzed algin, ethylparaben, chlorella vulgaris extract, maris aqua (sea water), isobutylparaben, silica, disodium succinate, ci42090 (blue 1).

US: Distributed by Ventura International, Ltd. San Francisco, CA 94111

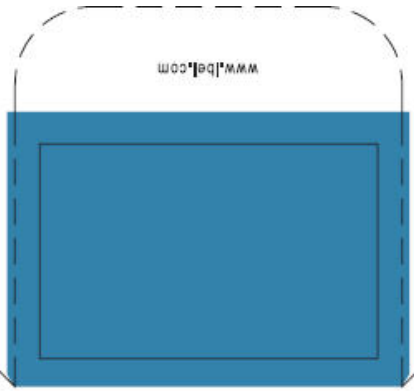
PRINCIPAL DISPLAY PANEL - 50 ml Carton

L'BEL
PARIS

REGRESSION
JOUR

protective complex against
the first signs of age
with spf 15 facial day lotion
normal to combination skin

50 ml e (1.6 fl.oz.)



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L'BEL
PARIS

REGRESSION JOUR

complexe protecteur contre
les premiers signes de l'âge
spf 15 lotion de jour
pour le visage
peau normale à mixte

protective complex against
the first signs of age
with spf 15 facial day lotion
normal to combination skin

complejo protector contra
los primeros signos de la edad
fps 15 loción facial de día
cutis normal a mixto

50 ml e (1.6 fl.oz.)

US: Distributed by Ventura International, Ltd.
San Francisco, CA 94111.
P.R.: Distributed by Ventura Corporation, Ltd.
San Juan, Puerto Rico 00926.

MADE IN FRANCE

LBEL PARIS REGRESSION JOUR

octinoxate, octisalate, and oxybenzone cream

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:14783-055
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	3.75 g in 50 g
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	2 g in 50 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	2 g in 50 g

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
soybean (UNII: L7HT8F1ZOD)	
c12-15 alkyl benzoate (UNII: A9EJ3J61HQ)	
snow pea (UNII: 84SKC33B1I)	
cyclomethicone 6 (UNII: XHK3U310BA)	
dimethicone (UNII: 92RU3N3Y1O)	
mannitol (UNII: 3OWL53L36A)	
cetostearyl alcohol (UNII: 2DMT128M1S)	
glyceryl monostearate (UNII: 230OU9XXE4)	
phenoxyethanol (UNII: HIE492ZZ3T)	
trolamine (UNII: 9O3K93S3TK)	
isohexadecane (UNII: 918X1OUF1E)	
methylparaben (UNII: A2I8C7HI9T)	
butylparaben (UNII: 3QPI1U3FV8)	
cyclomethicone 5 (UNII: 0THT5PCI0R)	
chlorphenesin (UNII: I670DAL4SZ)	
propylparaben (UNII: Z8IX2SC1OH)	
xanthan gum (UNII: TTV12P4NEE)	
edetate disodium (UNII: 7FLD91C86K)	
sorbic acid (UNII: X045WJ989B)	
polysorbate 60 (UNII: CAL22UVI4M)	
yeast (UNII: 3NY3SM6B8U)	
ethylparaben (UNII: 14255EXE39)	
isobutylparaben (UNII: 0QQJ25X58G)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
sodium succinate anhydrous (UNII: V8ZGC8ISR3)	
FD&C blue no. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:14783-055-61	1 in 1 BOX		
1	NDC:14783-055-66	50 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	08/15/2010	

LBEL PARIS REGRESSION JOUR

octinoxate, octisalate, and oxybenzone cream

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:14783-045
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.375 g in 5 g
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	0.2 g in 5 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.2 g in 5 g

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
soybean (UNII: L7HT8F1ZOD)	
c12-15 alkyl benzoate (UNII: A9EJ3J61HQ)	
snow pea (UNII: 84SKC33B1I)	
cyclomethicone 6 (UNII: XHK3U310BA)	
dimethicone (UNII: 92RU3N3Y1O)	
mannitol (UNII: 3OWL53L36A)	
cetostearyl alcohol (UNII: 2DMT128M1S)	
glyceryl monostearate (UNII: 230OU9XXE4)	
phenoxyethanol (UNII: HIE492ZZ3T)	
trolamine (UNII: 9O3K93S3TK)	
isohexadecane (UNII: 918X1OUF1E)	
methylparaben (UNII: A2I8C7HI9T)	
butylparaben (UNII: 3QPI1U3FV8)	
cyclomethicone 5 (UNII: 0THT5PCI0R)	
chlorphenesin (UNII: I670DAL4SZ)	
propylparaben (UNII: Z8IX2SC1OH)	
xanthan gum (UNII: TTV12P4NEE)	
edetate disodium (UNII: 7FLD91C86K)	
sorbic acid (UNII: X045WJ989B)	
polysorbate 60 (UNII: CAL22UVI4M)	

yeast (UNII: 3NY3SM6B8U)	
ethylparaben (UNII: 14255EXE39)	
isobutylparaben (UNII: 0QQJ25X58G)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
sodium succinate anhydrous (UNII: V8ZGC8ISR3)	
FD&C blue no. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-045-51	1 in 1 BOX		
1	NDC:14783-045-52	5 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	08/15/2010	

LBEL PARIS REGRESSION JOUR

octinoxate, octisalate, and oxybenzone cream

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:14783-035
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.75 g in 1 g
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	0.04 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	2 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
soybean (UNII: L7HT8F1ZOD)	
c12-15 alkyl benzoate (UNII: A9EJ3J61HQ)	
snow pea (UNII: 84SKC33B1I)	
cyclomethicone 6 (UNII: XHK3U310BA)	
dimethicone (UNII: 92RU3N3Y1O)	
mannitol (UNII: 3OWL53L36A)	
cetostearyl alcohol (UNII: 2DMT128M1S)	
glyceryl monostearate (UNII: 230OU9XXE4)	
phenoxyethanol (UNII: HIE492ZZ3T)	
trolamine (UNII: 9O3K93S3TK)	

isohexadecane (UNII: 918X1OUF1E)	
methylparaben (UNII: A2I8C7HI9T)	
butylparaben (UNII: 3QPI1U3FV8)	
cyclomethicone 5 (UNII: 0THT5PCI0R)	
chlorphenesin (UNII: I670DAL4SZ)	
propylparaben (UNII: Z8IX2SC1OH)	
xanthan gum (UNII: TTV12P4NEE)	
edetate disodium (UNII: 7FLD91C86K)	
sorbic acid (UNII: X045WJ989B)	
polysorbate 60 (UNII: CAL22UVI4M)	
yeast (UNII: 3NY3SM6B8U)	
ethylparaben (UNII: 14255EXE39)	
isobutylparaben (UNII: 0QQJ25X58G)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
sodium succinate anhydrous (UNII: V8ZGC8ISR3)	
FD&C blue no. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-035-41	1 in 1 BOX		
1	NDC:14783-035-42	1 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	08/15/2010	

Labeler - Ventura International LTD (603192787)

Revised: 8/2010 Ventura International LTD