

LBEL CLARIFIQUE DERMO RADIANCE MAINS SPF 15- 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
CLARIFIQUE
DERMO RADIANCE
MAINS SPF 15**

Drug Facts

Active Ingredients

Octinoxate (7.5 %), Octisalate (5 %), Oxybenzone (6 %)

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 twice a day before sun exposure and as needed.
- Reapply as needed or after towel drying, swimming or sweating.
- Moderate sun protection product.
- Children under 6 months of age: ask a doctor.

Other information

- 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), cyclohexasiloxane, c12-15 alkyl benzoate, cetearyl alcohol, ethylhexyl stearate, cyclopentasiloxane, citrus unshui peel extract, propylene glycol, triethanolamine, glycerin, dicetyl phosphate, ceteth-10 phosphate, sodium lactate, tocopheryl acetate, phenoxyethanol, diazolidinyl urea, parfum (fragrance), glycolic acid, methylparaben, sucrose, urea, sodium citrate, propylparaben, malic acid, tartaric acid, camellia sinensis leaf extract.

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

PRINCIPAL DISPLAY PANEL - 100 g Tube Carton

L'BEL

CLARIFIQUE

DERMO RADIANCE

MAINS SPF 15

clarifying and illuminating
treatment hand cream spf 15

100 g e (3.5 oz.)

www.lbel.com

L'BEL

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CLARIFIQUE
DERMO RADIANCE
MAINS SPF 15

traitement éclaircissant et
illuminant pour les mains
en crème spf 15

clarifying and illuminating
treatment hand cream spf 15

tratamiento aclarador e
iluminador para manos
en crema spf 15

100 g e (3.5 oz.)

www.belcorp.biz



CO: Fabricado y distribuido por BEL STAR S.A., Tocancipá, Colombia, N.S. Hecho en Colombia. **PE:** Fabricado por BEL STAR S.A., Tocancipá, Colombia. Importado por COTCO S.A., Apartado Postal 18-0687, R.U.C. 20100123783 N.S. Hecho en Colombia. **US:** Distributed by Ventura International Ltd., San Francisco, CA 94111, PA. Distributed by Ventura Corporation, Ltd., San Juan, Puerto Rico 00956. Made in Colombia. **VE:** Fabricado por BEL STAR S.A., Colombia. Imp y Dist por Grupo Transol C.A., Caracas, Venezuela. Reg. en el MPPS bajo el # CPE# R.U.C. 1-0332575-0. **HECHO EN COLOMBIA.**

LBEL CLARIFIQUE DERMO RADIANCE MAINS SPF 15

octinoxate, octisalate, and oxybenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-077
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	7.5 g in 100 g
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	5 g in 100 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	6 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
cyclomethicone 6 (UNII: XHK3U310BA)	
c12-15 alkyl benzoate (UNII: A9EJ3J61HQ)	
cetostearyl alcohol (UNII: 2DMT128M1S)	
cyclomethicone 5 (UNII: 0THT5PCI0R)	
tangerine (UNII: KHBE3096OO)	
propylene glycol (UNII: 6DC9Q167V3)	
trolamine (UNII: 9O3K93S3TK)	
glycerin (UNII: PDC6A3C0OX)	
dihexadecyl phosphate (UNII: 2V6E5WN99N)	
phosphate ion (UNII: NK08V8K8HR)	
sodium lactate (UNII: TU7HW0W0QT)	
phenoxyethanol (UNII: HIE492ZZ3T)	
diazolidinyl urea (UNII: H5RIZ3MPW4)	
glycolic acid (UNII: 0WT12SX38S)	
methylparaben (UNII: A2I8C7HI9T)	
sucrose (UNII: C151H8M554)	
urea (UNII: 8W8T17847W)	
sodium citrate (UNII: 1Q73Q2JULR)	
propylparaben (UNII: Z8IX2SC1OH)	
malic acid (UNII: 817L1N4CKP)	
tartaric acid (UNII: W4888I119H)	
green tea leaf (UNII: W2ZU1RY8B0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-077-61	1 in 1 BOX		
1	NDC:14783-077-62	100 g in 1 TUBE		

Marketing Information

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

