LBEL HYDRA CALME- octinoxate, octisalate, and oxybenzone lotion
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
HYDRA CALME

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.
- use in the morning after cleansing and toning. Apply small amounts using the fingertips and spreading with upward, circular movements. Rub gently until absorbed completely.
- children under 6 months of age: ask a doctor.
- moderate sun protection product.

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), c12-15 alkyl benzoate, pisum sativum (pea) extract, cyclohexasiloxane, dimethicone, butylene glycol, cetearyl alcohol, erythritol, hdi/trimethylol hexyllactone crosspolymer, phenoxyethanol, sodium acrylate/acryloyldimethyltaurate/dimethylacrylamide crosspolymer, c20-22 alkyl phosphate, propyleneglycol, hydroxyethyl acrylate/sodium acryloyldymethyl taurate copolymer, glyceryl stearate, c20-22 alcohols, triethanolamine, isohexadecane, methylparaben, parfum (fragance), c14-22 alcohols, cetearyl glucoside, butylparaben, cyclopentasiloxane, chlorphenesin, propylparaben, xanthan gum, disodium edta, acrylates/c10-30 alkylacrilate crosspolymer, sorbic acid, polysorbate 60, c12-20 alkyl glucoside, glycerin, hydrolized algin, ethylparaben, chlorella vulgaris extract, maris aqua (sea water), isobutylparaben, silica, homarine hcl, rubus chamaemorus fruit extract.

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

PRINCIPAL DISPLAY PANEL - 30 ml Carton

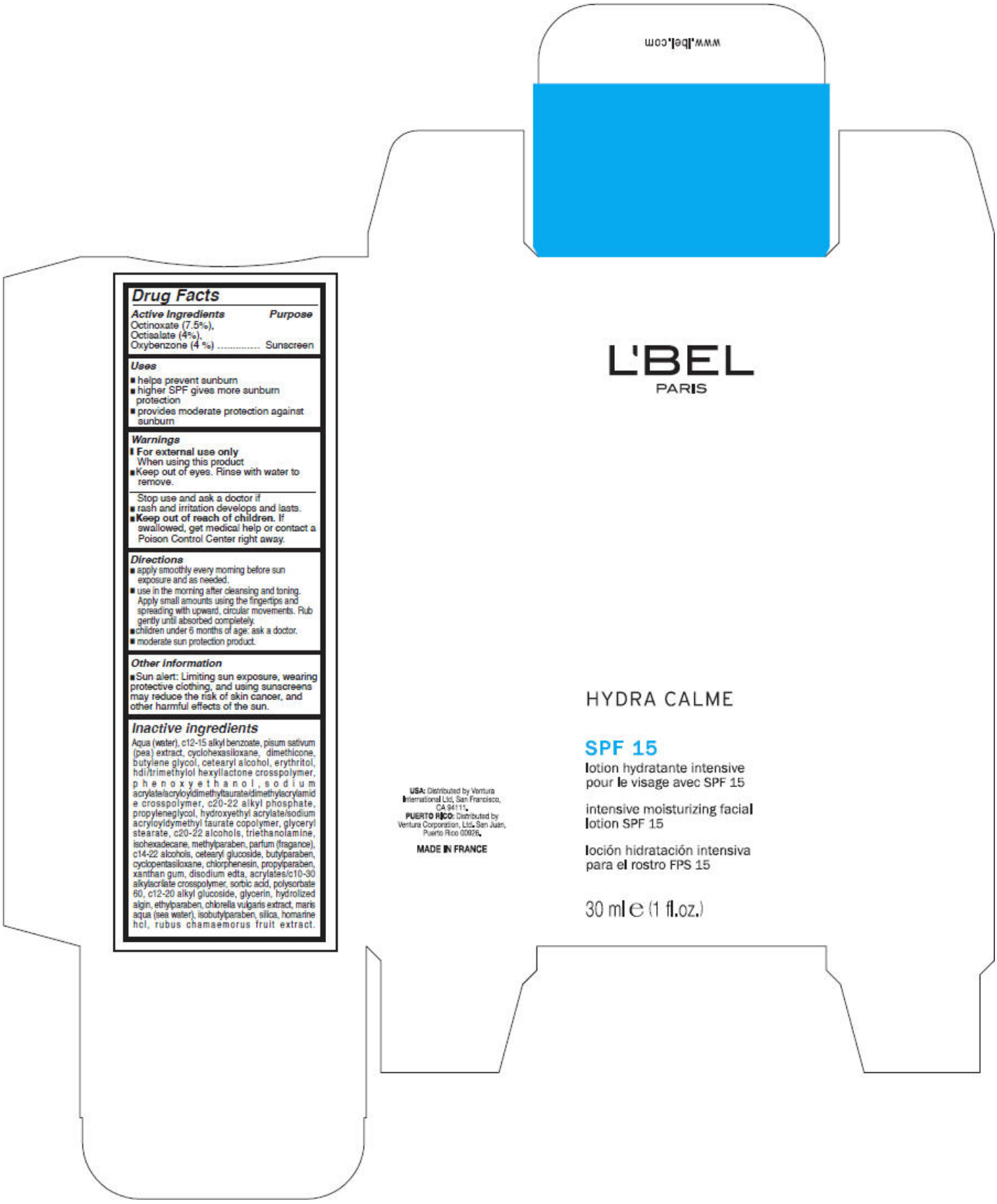
L'BEL
PARIS

HYDRA CALME

SPF 15

intensive moisturizing facial
lotion SPF 15

30 ml e (1 fl.oz.)



LBEL HYDRA CALME

octinoxate, octisalate, and oxybenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:13537-088
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	2.25 mg in 30 mL
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	1.2 mg in 30 mL
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	1.2 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
c12-15 alkyl benzoate (UNII: A9EJ3J61HQ)	
snow pea (UNII: 84SKC33B1I)	
cyclomethicone 6 (UNII: XHK3U310BA)	
dimethicone (UNII: 92RU3N3Y1O)	
butylene glycol (UNII: 3XUS85K0RA)	
cetostearyl alcohol (UNII: 2DMT128M1S)	
erythritol (UNII: RA96B954X6)	
phenoxyethanol (UNII: HIE492ZZ3T)	
propylene glycol (UNII: 6DC9Q167V3)	
glyceryl monostearate (UNII: 230OU9XXE4)	
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)	
glycerin (UNII: PDC6A3C0OX)	
ethylparaben (UNII: 14255EXE39)	
isobutylparaben (UNII: 0QQJ25X58G)	
silicon dioxide (UNII: ETJ7Z6XBU4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-088-63	1 in 1 BOX		
1	NDC:13537-088-62	30 mL in 1 BOTTLE		

Marketing Information

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

LBEL HYDRA CALME

octinoxate, octisalate, and oxybenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:13537-089
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.075 mg in 1 mL
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	0.04 mg in 1 mL
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.04 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
c12-15 alkyl benzoate (UNII: A9EJ3J61HQ)	
snow pea (UNII: 84SKC33B1I)	
cyclomethicone 6 (UNII: XHK3U310BA)	
dimethicone (UNII: 92RU3N3Y1O)	
butylene glycol (UNII: 3XUS85K0RA)	
cetostearyl alcohol (UNII: 2DMT128M1S)	
erythritol (UNII: RA96B954X6)	
phenoxyethanol (UNII: HIE492ZZ3T)	
propylene glycol (UNII: 6DC9Q167V3)	
glyceryl monostearate (UNII: 230OU9XXE4)	
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)	
glycerin (UNII: PDC6A3C0OX)	
ethylparaben (UNII: 14255EXE39)	
isobutylparaben (UNII: 0QQJ25X58G)	
silicon dioxide (UNII: ETJ7Z6XBU4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-089-53	1 in 1 BOX		
1	NDC:13537-089-52	1 mL 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 (602751344)

Revised: 8/2010 Ventura International LTD