

BELLAGIO SUNSCREEN SPF 45- homosalate, octinoxate, octisalate, oxybenzone, and zinc oxide lotion

Lifetech Resources, LLC

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.

**BELLAGIO®
SUNSCREEN
LOTION
SPF 45**

DRUG FACTS

ACTIVE INGREDIENTS

Homosalate 14.00%, Octinoxate 6.50%, Octisalate 5.00%, Oxybenzone 5.00%, Zinc Oxide 2.74%

PURPOSE

Sunscreen

USE

Helps prevent sunburn. Higher SPF gives more sunburn protection.

DIRECTIONS FOR USE

Apply evenly and liberally to all exposed areas before sun exposure. Ensure complete coverage. Reapply as needed or after swimming, towel drying, perspiring, or vigorous activity. Ask a doctor before use on children under 6 months of age.

WARNING

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 or irritation develops and lasts.

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

INACTIVE INGREDIENTS

Water, Acrylates Copolymer, Caprylic/Capric Triglyceride, Cyclopentasiloxane, Polysorbate 60, Polysorbate 20, Glycerin, Cetearyl Alcohol, Ceteareth-20, Sorbitan Stearate, Potassium Cetyl Phosphate, Dimethicone, Butyrospermum Parkii (Shea Butter), Squalane, Sodium PCA, Panthenol, Tocopheryl Acetate, Xanthan Gum, Triethoxycaprylylsilane, Disodium EDTA, Sodium Benzoate, Potassium Sorbate, Imidazolidinyl Urea.

PRINCIPAL DISPLAY PANEL - 237 ML Tube Label

BELLAGIO®

SUNSCREEN

LOTION

SPF 45

8 FL OZ / 237 ML



This oil-free, fast absorbing, fragrance-free formula provides broad spectrum UVA/UVB protection and helps nourish skin with antioxidant Vitamin E and Shea Butter.

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Packaged Exclusively for Bellagio Resort
Las Vegas, NV 89109
by Silver Lining Amenities, Inc.
Lake Forest, CA 92630



BELLAGIO®

SUNSCREEN
LOTION

SPF 45

8 FL OZ / 237 ML

BELLAGIO SUNSCREEN SPF 45

homosalate, octinoxate, octisalate, oxybenzone, and zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65643-335
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Homosalate (UNII: V06SV4M95S) (Homosalate - UNII:V06SV4M95S)	Homosalate	143.22 mg in 1 mL
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	66.495 mg in 1 mL
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	51.15 mg in 1 mL
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	51.15 mg in 1 mL
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	28.03 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Medium-Chain Triglycerides (UNII: C9H2L21V7U)	
Cyclomethicone 5 (UNII: 0THT5PC10R)	
Polysorbate 60 (UNII: CAL22UVI4M)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
Polysorbate 20 (UNII: 7T1F30V5YH)	
Sorbitan Monostearate (UNII: NVZ4I0H58X)	
Potassium Cetyl Phosphate (UNII: 03KCY6P7UT)	
Dimethicone (UNII: 92RU3N3Y1O)	
Shea Butter (UNII: K49155WL9Y)	
Squalane (UNII: GW89575KF9)	
Sodium Pyrrolidone Carboxylate (UNII: 469OTG57A2)	
Panthenol (UNII: WV9CM0O67Z)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
Xanthan Gum (UNII: TTV12P4NEE)	
Edetate Disodium (UNII: 7FLD91C86K)	
Sodium Benzoate (UNII: OJ245FE5EU)	
Potassium Sorbate (UNII: 1VPU26JZZ4)	
Imidurea (UNII: M629807ATL)	
OCTYLTRIETHOXYSILANE (UNII: LDC331P08E)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65643-335-18	237 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	01/01/2009	

Labeler - Lifetech Resources, LLC (622559110)

Establishment

Name	Address	ID/FEI	Business Operations
Lifetech Resources, LLC		622559110	MANUFACTURE

Revised: 9/2010

Lifetech Resources, LLC