

BULLFROG SPF50 LAND SPORT QUIK- avobenzone, homosalate, octisalate, octocrylene, oxybenzone gel

SolSkyn Personal Care 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.

BullFrog Land Sport Quik Gel SPF 50

BullFrog SPF50 Land Sport Quik Gel

Active Ingredients

Avobenzone 3%, Homosalate 15%, Octisalate 5%, Octocrylene 10%, Oxybenzone 6%

Purpose

Sunscreen

Uses

- helps prevent sunburn
- if used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings

- For external use only
- Flammable: keep away from fire or flame.

• Do not use

on damaged or broken skin.

• When using this product

keep out of eyes. Rinse with water to remove.

• Stop use and ask a doctor if rash occurs.

• Keep out of reach of children.

If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply liberally 15 minutes before sun exposure
- re-apply:
 - after 80 minutes of swimming or sweating
 - immediately after towel drying
 - at least every 2 hours

Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with broad spectrum SPF of 15 or higher and other sun protection measures including:

- limit time in the sun, especially from 10 a.m.-2 p.m.
- wear long-sleeved shirts, pants, hats and sunglasses
- children under 6 months: ask a doctor

Other information

- protect this product from excessive heat and direct sun

Inactive Ingredients

Acacia Farnesiana Extract, Acrylates/Octylacrylamide Copolymer, Aloe Barbadensis Leaf Extract, Camellia Oleifera (Green Tea) Leaf Extract, Chamomile Flower Extract, Cyclohexasiloxane, Cyclopentasiloxane, Ethylhexyl Palmitate, Fragrance, Glycerin, Hydroxypropylcellulose, Isopropyl Myristate, Lavender Extract, Phenethyl Benzoate, PPG-12/SMDI Copolymer, Propylene Glycol, Rosemary Leaf Extract, SD Alcohol 40 (50.65% w/w), Tocopheryl (Vitamin E) Acetate

Questions or comments?

www.bullfrogsunscreen.com or call toll-free 1-800-715-3485

MAY STAIN SOME FABRICS, PLASTICS AND WOOD SURFACES.

PRINCIPAL DISPLAY PANEL

Bull
Frog
Sunscreen
Land Sport
Quick Gel
SPF 50



BULLFROG SPF50 LAND SPORT QUIK

avobenzone, homosalate, octisalate, octocrylene, oxybenzone gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:70281-338

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 mg in 100 mg
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	15 mg in 100 mg
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 mg in 100 mg
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 mg in 100 mg
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	6 mg in 100 mg

Inactive Ingredients

Ingredient Name	Strength
VACHELLIA FARNESIANA FLOWER (UNII: 8487B3MG6D)	
.ALPHA-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60)	
CHAMAEMELUM NOBILE FLOWER (UNII: O2T154T6OG)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
CYCLOMETHICONE 5 (UNII: 0TH5PC10R)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
LAVANDULA ANGUSTIFOLIA SUBSP. ANGUSTIFOLIA FLOWER (UNII: 19AH1RAF4M)	
PHENETHYL BENZOATE (UNII: 0C143929GK)	
PPG-12/SMDI COPOLYMER (UNII: 1BK9DDD24E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ROSEMARY (UNII: IJ67X351P9)	
ALCOHOL (UNII: 3K9958V90M)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70281-338-13	147 mg in 1 BOTTLE; Type 0: Not a Combination Product	09/15/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	09/15/2015	

Labeler - SolSkyn Personal Care LLC (080010329)