

**BULLFROG LAND SPORT SPF 50 LIP BALM- avobenzone, octisalate, octocrylene and oxybenzone stick**

**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.*

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**BullFrog Land Sport Lip SPF50**

**BullFrog Land Sport SPF 50 Lip Balm**

***Active Ingredients***

Avobenzone 2%, Octisalate 4%, 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

**• 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
- for use on skin only. Avoid contact with fabric

#### **Inactive Ingredients**

Aloe Barbadensis Leaf Extract, Butylated Hydroxytolulene, Caprylic/Capric Triglyceride, Cetyl Alcohol, Cyclomethicone, Diisobutyl Adipate, Dimethicone, Ethylhexyl Palmitate, Flavor, Glycine Soja (Soybean) Oil, Isostearyl Linoleate, Menthol, Ozokerite, Persea Gratissima (Avocado) Oil, Propylparaben, Saccharin, Simmondsia Chinensis (Jojoba) Seed Oil, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl (Vitamin E) Acetate

#### ***Questions or comments?***

[www.bullfrogsunscreen.com](http://www.bullfrogsunscreen.com) or call 1-800-715-3485 (USA)

#### **PRINCIPAL DISPLAY PANEL**

Bull Frog  
Sunscreen  
LAND SPORT  
Lip Balm  
SPF 50

**Drug Facts**

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 Octocrylene 10%, Oxybenzone 6% } **Purpose**  
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**When using this product** keep out of eyes.  
 Rinse with water to remove.  
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At BullFrog, we believe that life is a participation sport best played in the great outdoors. That's why we make high-performance sunscreens that deliver clinically proven protection. Perfect for all Land Sports. Engineered for Ultimate Performance & Protection.

DISTRIBUTED BY: Selsyn Personal Care LLC, 1725 North Brown Road, Lawrenceville, GA 30043



**BULLFROG LAND SPORT SPF 50 LIP BALM**

avobenzone, octisalate, octocrylene and oxybenzone stick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70281-339
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2 g in 100 g	
OCTISALATE (UNII: 4X49X0596W) (OCTISALATE - UNII:4X49X0596W)	OCTISALATE	4 g	

<b>OCTISALATE</b> (UNII: 4X49 10390 W) (OCTISALATE - UNII:4X49 10390 W)	OCTISALATE	in 100 g
<b>OCTOCRYLENE</b> (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM, OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	10 g in 100 g
<b>OXYBENZONE</b> (UNII: 950OS7VE0 Y) (OXYBENZONE - UNII:950OS7VE0 Y, OXYBENZONE - UNII:950OS7VE0 Y)	OXYBENZONE	6 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>ALOE VERA LEAF</b> (UNII: ZY8 1Z83H0 X)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9 D0 Z171K)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>CYCLOMETHICONE</b> (UNII: NMQ347994Z)	
<b>DIISOBUTYL ADIPATE</b> (UNII: 8OPY05ZY7S)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)	
<b>SOYBEAN OIL</b> (UNII: 241ATL177A)	
<b>ISOSTEARYL LINOLEATE</b> (UNII: 4778M3HR0N)	
<b>MENTHOL</b> (UNII: L7T10EP3A)	
<b>CERESIN</b> (UNII: Q1LS2UJO3A)	
<b>AVOCADO OIL</b> (UNII: 6VNO72PFC1)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>SACCHARIN</b> (UNII: FST467XS7D)	
<b>JOJOBA OIL</b> (UNII: 724GKU717M)	
<b>COCOA BUTTER</b> (UNII: 512OYT1CRR)	
<b>.ALPHA.-TOCOPHEROL SUCCINATE, D-</b> (UNII: LU4B53JYVE)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70281-339-03	4.25 g in 1 CONTAINER; 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)