

**BULLFROG SPF50 WATER SPORT- avobenzone, homosalate, octisalate, octocrylene, oxybenzone lotion**

**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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**BF Water Sport SPF50 Lotion**

BullFrog SPF50 Water Sport Lotion

***Active Ingredients***

Avobenzone 2%, Homosalate 10%, Octisalate 5%, Octocrylene 2%, Oxybenzone 5%

***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***

Acrylates Copolymer, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Carbomer, Diisopropyl Adipate, Dimethyl Capramide, Disodium EDTA, Ethylhexylglycerin, Fragrance, Hydroxypropyl Methylcellulose, Macrocystis Pyrifera Extract, Phenoxyethanol, Polyester-8, Polyisobutene, Propylene Glycol, Silica, Sorbitan Oleate, Tocopheryl (Vitamin E) Acetate, Triethanolamine, Water

***Questions or comments?***

[www.bullfrogsunscreen.com](http://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

WATER SPORT

with Water Armor TECH

Lotion

50

BROAD SPECTRUM SPF 50

5 FL OZ (147 mL)



## BULLFROG SPF50 WATER SPORT

avobenzone, homosalate, octisalate, octocrylene, oxybenzone lotion

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70281-324
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2 mg in 100 mg
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 mg in 100 mg
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 mg in 100 mg
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2 mg in 100 mg
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	5 mg in 100 mg

## Inactive Ingredients

Ingredient Name	Strength
BUTYL ACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID COPOLYMER (18000 MW) (UNII: JZ1374NL9E)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
POLYISOBUTYLENE (1300 MW) (UNII: 241BN7J12Y)	
DIISOPROPYL ADIPATE (UNII: P7E6YFV72X)	
DIMETHYL CAPRAMIDE (UNII: O29Y6X2JEZ)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MACROCYSTIS PYRIFERA (UNII: K31S3OG5C4)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENYL CAPPED) (UNII: T9296U138P)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SORBITAN MONOLEATE (UNII: 06XEA2VD56)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0K00R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70281-324-13	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)

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SolSkyn Personal Care LLC