BULL FROG MOSQUITO COAST SPL 50 PUMP- avobenzone, homosalate, octisalate, oxybenzone, octyl methoxycinnamate spray 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.

Bull Frog Mosquito Coast Broad Spectrum Pump Spray SPF 50

Item Number: 31783-700-DM06

NDC Number: 70281-314-12

Product Name: Bull Frog Mosquito Coast SPF 50 Pump

Active Ingredients

Avobenzone 3%, Homosalate 10%, Octisalate 5%, Octocrylene 5%, Octyl Methoxycinnamate 7.5%

Purpose

Sunscreen

Use

• helps prevent sunburn

Warnings

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, not skin cancer or early skin aging.

- 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.

- **Flammable:** do not puncture or incinerate
- Keep out of reach of children.

If 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
- children under 6 months: ask a doctor

Other information

• protect the product in this container from excessive heat and direct sun

Inactive Ingredients

Acrylates/Octylacrylamide Copolymer, SD Alcohol 40 (47% w/w), Aloe Barbadensis Leaf Oil, C12-15 Alkyl Benzoate, Fragrance, Tocopheryl (Vitamin E) Acetate

Questions or comments?

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

INSECT REPELLENT DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Apply liberally and evenly over dry, exposed skin. Do not spray directly on face. Spray on palm of hand and apply to face. An adult must apply this product to children under 10. For continued protection from mosquitoes, re-apply after 8 hours. Do not exceed 7 applications per day for adults, 3 applications per day for children.

PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS: CAUTION: For external use only. Causes moderate eye irritation. Do not get in eyes. Use on children under 6 months of age only with the advice of a physician.

PHYSICAL OR CHEMICAL HAZARDS: Flammable. Keep away from heat and open flame. Contains alcohol. Avoid contact with plastics.

FIRST AID

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing the eye.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-877-800-5553 for emergency medical treatment information.

STORAGE:

Store in a cool, dry place in tightly closed container.

DISPOSAL: Do not Puncture or Incinerate! **If empty: Nonrefillable container. Do not reuse or refill this container.** Place in trash or offer for recycling if available. **If partly filled:** Call your local solid waste agency or 1-800-CLEANUP for disposal instructions.

MAY STAIN SOME FABRICS, PLASTICS AND WOOD SURFACES.

EPA Reg. No.: 11525-78-91874 EPA Est. No.: 54487-GA-001

PRINCIPAL DISPLAY PANEL

Bull Frog Mosquito Coast SPF 50 Sunscreen + Insect Repellent





Drug Facts

Autorizone 7%, Fonosalde 10%, Octobiete 5%, | ourocreen Octobrylene 5%, Octyl Methogolmunate 7,5%

Use . helps prevent suribum . If used as directed with other sun protection measures (see Directional, decreases the risk of skin cancer and early skin aging caused by the sun

For external use only . Do not use . on damaged or broken skin . Stop use and ask a doctor if . rash occurs Flammable . Do not puncture or incinerate

When using this product • keep out of eyes. Rinse with water to remove. Keep out of reach of children. If swellowed, get medical help or contact a Poison Control Center right away

Directions:

- apply liberally 15 minutes before sun exposure
- reapply: 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 a 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-sleeve shirts, parts, hats, and sunglasses
- . children under 6 months: ask a doctor

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STORAGE: Store in a cool, dry place in tightly closed container.

DISPOSAL: If empty: Nonrefillable container. Do not reuse or refill this container. Place in trash or offer for recycling if available. If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

avobenzone, homosalate, octisalate, oxybenzone, octyl methoxycinnamate spray

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70281-314		
Route of Administration	TOPICAL				

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 g		
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 100 g		
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	5 g in 100 g		
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	5 g in 100 g		
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g		

Inactive Ingredients				
Ingredient Name	Strength			
ALCOHOL (UNII: 3K9958V90M)				
ALOE VERA LEAF (UNII: ZY81Z83H0 X)				
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)				
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)				

ı	Packaging						
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date			
ı	1 NDC:70281-314-12	138 g in 1 CAN; Type 0: Not a Combination Product	12/0 1/20 18				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH NOT FINAL	part352	12/0 1/20 18		

Labeler - SolSkyn Personal Care LLC (080010329)

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