SUNSCREEN AND INSECT REPELLENT BULL FROG- spf 50 aerosol, spray Bullfrog Brands, 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 SPF50 Mosquito Coast- Sunscreen+ Inspect Repellent

Active ingredients

Avobenzone 3.0%, Octocrylene 5%, Homosalate 10.0%, Octyl methoxycinnamate 7.5%, Octisalate 5%

Purpose

Sunscreen

Uses

• helps prevent sunburn

Warnings

For external use only

Skin Alert • Limiting sun exposure, wearing protective clothing, and using sunscreen may reduce the risk of skin aging, skin cancer and other harmful effects of the sun

FLAMMABLE:

- do not use near heat, flame or while smoking
- avoid long term storage above 104°F (40°C)
- do not puncture or incinerate
- contents under pressure
- do not store at temperatures above 120°F (49°C).

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 swallowed, 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
- children under 6 months of age: 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), AloeBarbadensis Leaf Oil, C12-15 Alkyl Benzoate, Fragrance, Tocopheryl (Vitamin E) Acetate.

Questions or Comments?

www.bullfrogsunscreen.com or call toll-free 1-800-990-FROG

BullFrog* SPF 50 Mosquito Coast* Sunscreen + Insect Repellent is the perfect combination of trusted broad spectrum sun protection and a proprietary, DEET-free, insect repellent that repels insects for up to 8 hours. This convenient, water-resistant 2-in-1 protection beats the burn and the bite. Made with Aloe & Vitamin E, it soothes & naturally moisturizes the skin. Suitable for the entire family, just spray & go. Perfect for all your outdoor adventures.

Repels mosquitoes that may carry Zika, West Nile, Dengue Fever and Chikungunya viruses.

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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 labe. Spray on pail or his and apply to lace. Amodult muss exply this product be different under 10. For collished profestion from microglubbes, reapply after 8 hours. Do not exceed 7 applications per day for adults, 3 applications per day for children. STORAGE: Store in a cool, dry place. Avoid long term storage above 104°F (40°C). Do not store at temperatures above

DISPOSAL: Do Not Puncture or incinerate! If empty: Nonrefiliable 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 1-900-CLEANUP for disposal

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. Corter's under pessure. Keep away from heat, sperks and open fame. Do not curcture of incherate container. Exposure to temperatures above 1907 may cause bursting. Avoid contact with prasti FIRST AID

f in eyes: Hold eye open and ring contact lesses, if oresent after the first 5 minutes, then confine insists the eye. If Leaf a historic Cortini Center or doctor for treatment advice. or doctor, or going for treatment. You may also contact 1-800-222-1222 for

Letter of could not determine above. Have the product ordainer or bell with you when calling a Potent Control Center or oblist or gring for therein. You may also contral. 1-80-022-1222 for emergency medical treatment information.

(800) 990-FROG DOT-SP 14625



SUNSCREEN+ INSECT REPELLENT

Repels Up to 8 Hours

3-((N-butyl-N-acetyl)amino)propionic acid ethyl ester*
OTHER INGREDIENTS: TOTAL: 10: *IR3535*Insect Repellent U.S. Patent No. 7.037.515

KEEP OUT OF REACH OF CHILDREN

CAUTION

Net Contents 5.5 OZ (156 g)

SUNSCREEN AND INSECT REPELLENT BULL FROG

spf 50 aerosol, spray

Product Information

HUMAN OTC DRUG NDC:77714-003 **Product Type** Item Code (Source)

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Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZ ONE	30 mg in 1 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	50 mg in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 g

Inactive Ingredients		
Ingredient Name	Strength	
ALOE VERA LEAF (UNII: ZY81Z83H0X)		
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)		
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)		

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:77714-003- 15	156 g in 1 CAN; Type 0: Not a Combination Product	01/19/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/19/2022	

Labeler - Bullfrog Brands, LLC (117426500)

Establishment				
Na me	Address	ID/FEI	Business Operations	
Prime Enterprises		101946028	manufacture(77714-003)	

Revised: 1/2022 Bullfrog Brands, LLC